Policy Statement

A microprocessor-controlled knee may be considered medically necessary in amputees who meet all of the following requirements:

- One of the following:
  - 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)
  - Demonstrated patient need for regular ambulation on uneven terrain or for regular use on stairs (use of the limb for limited stair climbing in the home or employment environment is not sufficient evidence for prescription of this device over standard prosthetic application)
- Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed
- Adequate cognitive ability to master use and care requirements for the technology

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

A powered knee is considered investigational.

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

Policy Guidelines

Replacement/Repair
Replacement or repair of a microprocessor-controlled knee may be considered medically necessary when both of the following criteria are met:

- The current prosthesis is out of warranty
- The current prosthesis requires repairs and the cost of such repairs would be more than 60% of the cost of a new prosthesis

Prostheses Examples

Any specific products referenced in this Medical Policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Examples of Microprocessor-Controlled Knee Prostheses:
- Endolite Intelligent Prosthesis®
- Ossur RheoKnee®
- Otto Bock C-Leg device®
- Otto Bock Genium™ Bionic Prosthetic System

Examples of Microprocessor Controlled Foot-Ankle Prostheses:
- iWalk PowerFoot BiOM®
- Ossur Proprio Foot®

Prosthetic Evaluation

Amputees should be evaluated by an independent, qualified professional to determine the most appropriate prosthetic components and control mechanism. A trial period may be indicated to evaluate the tolerability and efficacy of the prosthesis in a real-life setting.
Decisions about the potential benefits of microprocessor knees involve multiple factors including activity levels and the patient's physical and cognitive ability. A patient'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, daily and frequent need of two or more of these activities would be needed to show benefit.

**Patient Selection and Identification**

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

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

A. **Contraindications for the use of the microprocessor knee** should include the following:
   - Any condition that prevents socket fitting, such as a complicated wound or intractable pain which precludes socket wear
   - Inability to tolerate the weight of the prosthesis
   - Medicare level K0 - no ability or potential to ambulate or transfer
   - Medicare level K1 - limited ability to transfer or ambulate on level ground at fixed cadence
   - Medicare level K2 - limited community ambulator who does not have the cardiovascular reserve, strength, and balance to improve stability in stance to permit increased independence, less risk of falls, and potential to advance to a less restrictive walking device
   - Inability to use swing and stance features of the knee unit
   - Poor balance or ataxia that limits ambulation
   - Significant hip flexion contracture (over 20°)
   - Significant deformity of remaining limb that would impair the ability to stride
   - Limited cardiovascular and/or pulmonary reserve or profound weakness
   - Limited cognitive ability to understand gait sequencing or care requirements
   - Long distance or competitive running
   - Falls outside of recommended weight or height guidelines of the manufacturer
   - Specific environmental factors - such as excessive moisture or dust, or inability to charge the prosthesis
   - Extremely rural conditions where maintenance ability is limited

B. **Indications for the use of the microprocessor knee** should include the following:
   - Adequate cardiovascular and pulmonary reserve to ambulate at variable cadence
   - Adequate strength and balance in stride to activate the knee unit
   - Should not exceed the weight or height restrictions of the device
   - Adequate cognitive ability to master technology and gait requirements of the device.
   - Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral; lower extremity amputees are candidates if they meet functional criteria as listed.
   - The 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 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 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 K3 - unlimited community ambulator
- Medicare level K4 - active adult, athlete who needs to function as a K3 level in daily activities
- Potential to lessen back pain by providing more secure stance control, using less muscle control to keep the knee stable
- Potential to unload and decrease stress on remaining limb
- Potential to return to an active lifestyle

C. Physical and Functional Fitting Criteria for New Amputees:

- New amputees may be considered if they meet certain criteria as outlined above
- Premorbid and current functional assessment important determinant
- Requires stable wound and ability to fit the socket
- Immediate postoperative fit is possible
- Must have potential to return to an active lifestyle

Coding

There are specific HCPCS codes that describe the microprocessor-controlled knee prosthesis:

- **L5856**: Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
- **L5857**: Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type
- **L5858**: Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type
- **L5859**: Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)

There is a specific HCPCS code for ankle-foot system with a microprocessor control feature:

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

Description

Microprocessor-controlled prostheses use feedback from sensors to adjust joint movement on a real-time as-needed basis. Active joint control is intended to improve safety and function, particularly for patients who can maneuver on uneven terrain and with variable gait.

Related Policies

- Functional Neuromuscular Electrical Stimulation
- Myoelectric Prosthetic Components for the Upper Limb

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.
Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

### Regulatory Status

According to the manufacturers, microprocessor-controlled prostheses are considered a class I device by the U.S. Food and Drug Administration (FDA) and is exempt from 510(k) requirements. This classification does not require submission of clinical data regarding efficacy but only notification of the FDA prior to marketing. FDA product codes: ISW, KFX.

### Rationale

#### Background

**Lower-Extremity Prosthetics**

More than 100 different prosthetic ankle-foot and knee designs are currently available. The choice of the most appropriate design may depend on the patient's underlying activity level. For example, the requirements of a prosthetic knee in an elderly, largely homebound individual will differ from those of a younger, active person. Key elements of 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 upperleg. 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.

**Microprocessor-Controlled Prosthetic Knees**

Microprocessor-controlled prosthetic knees have been developed, including the Intelligent Prosthesis (Blatchford, England); the Adaptive (Endolite, Basingstoke, Hampshire, UK); 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. The prosthetist can specify several different optimal adjustments that the computer later selects and applies according to the pace of ambulation. Also, these devices (with the exception of 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.

**Powered Knee Prostheses**
The Power Knee™ (Össur, Iceland), 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. The Power Knee is currently in the initial launch phase in the United States.

**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, Oklahoma City, OK, and licensed to College Park Industries, Warren, MI), 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).

**Powered Ankle-Foot Prostheses**
In development are lower-limb prostheses that also replace muscle activity to bend and straighten the prosthetic joint. For example, the PowerFoot BiOM® (developed at the Massachusetts Institute of Technology and licensed to iWalk) is a myoelectric prosthesis for transtibial amputees that uses muscle activity from the remaining limb for the control of ankle movement (see Blue Shield of California Medical Policy: Myoelectric Prosthetic Components for the Upper Limb for a description of myoelectric technology). This prosthesis is designed to propel the foot forward as it pushes off the ground during the gait cycle, which in addition to improving efficiency, has the potential to reduce hip and back problems arising from an unnatural gait with use of a passive prosthesis. This technology is limited by the size and the weight required for a motor and batteries in the prosthesis.

**Literature Review**
Assessment of efficacy for therapeutic intervention involves a determination of whether an intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

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

Microprocessor-Controlled Knee

The literature primarily consists of small within-subject comparisons of microprocessor-controlled vs pneumatic prostheses, along with systematic reviews of these studies. The following is a summary of key studies to date.

In 2000, the Veterans Administration Technology Assessment Program issued a report on computerized lower-limb prosthesis. This report offered the following observations and conclusions:

- Energy requirements of ambulation (compared with requirements with conventional prostheses) are decreased at walking speeds slower or faster than the amputee’s customary speed, but are not significantly different 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 deficit in the reintegration of amputees to normal living, particularly those related to decrease recreational opportunities.
- Users’ perceptions of the microprocessor-controlled prosthesis are favorable. Where such decisions are recorded or reported, the vast majority of 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.

C-Leg

A 2010 systematic review evaluated safety and energy efficiency of the C-Leg microprocessor-controlled prosthetic knee in transfemoral amputees. Eighteen comparative studies were included that used objective or quantifiable outcome measures with the C-Leg in 1 arm of the trial. Due to heterogeneity, meta-analyses were not performed. The 7 articles on safety had low methodologic quality and a moderate risk of bias, showing an improvement in some safety or surrogate safety measure. Effect sizes ranged from 0.2 (small) to 1.4 (large). Of the 8 articles identified on energy efficiency, one was considered to be of high methodologic quality, and five were considered to be of low quality. Two of the trials reported a statistical improvement in energy efficiency, and four reported some improvement in efficiency or speed that was not statistically significant. There were no adverse events, safety concerns, or detriments to energy efficiency reported in association with the use of the C-Leg.

A number of lower-limb amputees returning from Operation Iraqi Freedom and Operation Enduring Freedom have received a microprocessor-controlled prosthesis from the Department of Veterans Affairs (e.g., in 2005, 155 veterans were provided with a C-Leg). A series of papers from the Department of Veterans Affairs report resulted from a within-subject comparison of the C-Leg with a hydraulic Mauch SNS knee. Eight (44%) of the 18 functional level 2 to 3 subjects recruited completed the study; most withdrew due to the time commitment of the study or other medical conditions. Of the eight remaining subjects, half showed a substantial decrease in oxygen cost when using the C-Leg, resulting in a marginal improvement in gait efficiency for the group. The improvement in gait efficiency was hypothesized to result in greater ambulation, but a 7-day activity monitoring period in the home/community showed no difference in the number of steps taken per day or the duration of activity. Cognitive performance, assessed in 5 subjects by standardized neuropsychologic tests while walking a wide hallway, did not differ for semantic or phonemic verbal fluency and did not differ significantly different for working memory when wearing the microprocessor-controlled prosthesis. Although the study lacked sufficient power, results showed a 50% decrease in errors on the working memory task (1.63 vs 0.88, respectively). However, due to the lack of power, the effect of this device on objective measures of cognitive
performance cannot be determined from this study. Subjective assessment revealed a perceived reduction in attention to walking while performing the cognitive test (effect size, 0.79) and a reduction in cognitive burden with the microprocessor-controlled prosthesis (effect size, 0.90). Seven of the 8 subjects preferred to keep the microprocessor-controlled prosthesis at the end of the study. The authors noted that without any prompting, all subjects had mentioned that stumble recovery was their favorite feature of the C-Leg.

Kaufman et al published 2 reports (2007, 2008) describing a within-subject objective comparison of mechanical- and microprocessor-controlled knees in 15 transfemoral amputees (12 men, 3 women; mean age, 42 years) with a Medicare Classification Level 3 or 4. Following testing with the subject’s usual mechanical prosthesis, the amputees were given an acclimation period of 10 to 39 weeks (average, 18 weeks) with a microprocessor knee before repeat testing. Patients rated the microprocessor knee as better than the mechanical prosthesis in 8 of 9 categories of the Prosthesis Evaluation Questionnaire (PEQ). Objective gait measurement included knee flexion and the peak extensor moment during stance measured by a computerized video motion analysis system. Both the extensor moment and knee flexion differed significantly for the 2 prostheses, indicating a reduction in active contraction of the hip extensors to “pull back” and force the prosthetic knee into extension and resulting in a more natural gait with the microprocessor knee. Balance was improved by approximately 10% as objectively determined using a computerized dynamic posturography platform. Total daily energy expenditure was assessed over 10 days in free-living conditions. Both daily energy expenditure and the proportion of energy expenditure attributed to physical activity increased. Although the subjects perceived that it was easier to walk with the microprocessor-controlled knee than the mechanical prosthesis, energy efficiency while walking on a treadmill did not differ significantly (2.3% change). Taken together, the results indicated that amputees spontaneously increased their daily physical activity outside of the laboratory setting when using a microprocessor knee.

Johansson et al (2005) assessed energy efficiency in 8 amputees while using the C-Leg, Össur Rheo, and hydraulic Mauch SNS knee. The participants could ambulate at least at a functional classification K3 level and had approximately 10 hours of acclimatization with each prosthesis that was not his or her usual prosthesis (4 C-Leg, 1 Rheo, 1 Endolite, 1 Teh Lin, 1 Mauch). The order in which the knee systems were evaluated was randomized. Oxygen uptake was measured on a quarter mile indoor track, and kinematic and kinetic data were collected in a motion analysis laboratory with subjects walking at self-selected speeds. Compared with the Mauch knee, oxygen consumption was significantly reduced for the Rheo (-5% reduction), but not for the C-Leg (-2%). The Rheo and C-Leg were found to result in an enhanced smoothness of gait, a decrease in hip work production, a lower peak hip flexion moment at terminal stance, and a reduction in peak hip power generation at toe-off.

In a manufacturer-sponsored study from 2007, Hafner et al evaluated function, performance, and preference for the C-Leg in 21 unilateral transfemoral amputees using an A-B-A-B design. Subjects were fully accustomed to a mechanical knee system (various types) and were required to show proficiency in ambulating on level ground, inclines, stairs, and uneven terrain before enrollment. Of the 17 (81%) subjects who completed the study, patient satisfaction was significantly better with the microprocessor-controlled prosthesis, as measured by the PEQ. Fourteen preferred the microprocessor-controlled prosthesis, 2 preferred the mechanical system, and 1 had no preference. Subjects reported fewer falls, lower frustration with falls, and an improvement in concentration. Objective measurements on the various terrains were less robust, showing improvements only for the descent of stairs and hills. Unaffected were stair ascent, step frequency, step length, and walking speed. The subjective improvement in concentration was reflected by a small (nonsignificant) increase in walking speed while performing a complex cognitive task (reversing a series of numbers provided by cell phone while walking on a city sidewalk). A 2013 study by Highsmith et al used a within-subjects pre and post design, first evaluating outcomes with a non-microprocessor-controlled prosthesis followed by the same evaluation after receiving a microprocessor-controlled prosthesis. These researchers reported significantly improved descent times by 23% (6.0 seconds vs 7.7 seconds) and Hill Assessment
Index scores (8.9 vs 7.8) with a C-Leg compared with the subjects’ own non-microprocessor prosthetic knees.

Hafner and Smith (2009) evaluated the impact of the microprocessor-controlled prosthesis on function and safety in level K2 and K3 amputees. The K2 ambulators tended to be older (57 years vs 42 years), but this age difference was not statistically significant (p = 0.05). In this per-protocol analysis, 8 level K2 and 9 level K3 amputees completed testing with their usual mechanical prosthesis, then with the microprocessor-controlled prosthesis, a second time with their passive prosthesis, and then at 4, 8, and 12 months with the prosthesis that they preferred/used most often. Only subjects who completed testing at least twice with each prosthesis were included in the analysis (four additional subjects did not complete the study due to technical, medical, or personal reasons). As with the group’s 2007 report, performance was assessed by questionnaires and functional tasks including hill and stair descent, an attentional demand task, and an obstacle course. Self-reported measures included concentration, multitasking ability, and number of stumbles and falls in the previous 4 weeks. Both level K2 and K3 amputees showed significant improvements in mobility and speed (range, 7%-40%) but little difference in attention with the functional assessments. The self-reported number of stumbles and falls in the prior 4 weeks was found to be lower with the microprocessor-controlled prosthesis. For example, in the level K2 amputees, stumbles decreased from an average of 4.0 to 2.7 per month, semi-controlled falls from 1.6 to 0.6, and uncontrolled (i.e., complete) falls from 0.5 to 0 when using the microprocessor-controlled knee. Reevaluation of each participant’s classification level at the conclusion of the study showed that 50% of the participants originally considered to be K2 ambulators were now functioning at level K3 (about as many K3 ambulators increased as decreased functional level). These results are consistent with the Veterans Health Administration Prosthetic Clinical Management Program clinical practice recommendations for microprocessor knees, which state that use of microprocessor knees may be indicated for Medicare level K2 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 if the patient has cardiovascular reserve, strength, and balance to use the prosthesis.

C-Leg Compact

Two crossover studies evaluated the effect of the C-Leg Compact (stance phase only) on functional performance in Medicare functional level K2 ambulators.

Functional performance with 17 simulated activities of daily living was assessed with the C-Leg Compact in 28 level K2 ambulators. Participants first used their own mechanically controlled knee and then used 2 types of microprocessor-controlled knee joints (C-Leg, C-Leg Compact) in a randomized order with 1 week of acclimation. Performance times improved significantly for the subset of activities that required balance while standing but not for other activities. Stratifying participants into low, intermediate, and high functional mobility level showed that the two higher functioning subgroups performed significantly faster using microprocessor-controlled knee joints. The perceived performance was improved with the C-Leg for some PEQ subscales, but this did not translate to an increase in activity level. With the C-Leg Compact, 2 of 8 PEQ subscales were improved, and only in the subgroup with high functional mobility. There was no change in activity level with the C-Leg or C-Leg Compact when compared with the mechanically controlled knee.

Level walking and ramp walking were assessed in 10 level K2 ambulators with the C-Leg Compact and with the participant’s usual mechanical prosthetic knee joint. Seven of the 10 subjects used upper-extremity assistive devices (e.g., cane or walker) while ambulating. Participants were tested first with their own prosthesis, and then with the C-Leg Compact after a 3-month acclimation period. Use of the C-Leg Compact led to a significant increase in velocity (20%), cadence (9%-10%), stride length (12%-14%), single-limb support (1%), and heel-rise timing (18%) with level walking. Ramp ascent and descent were 28% and 36% faster, respectively, with the C-Leg Compact due to increases in stride length (17%) and cadence (16%) on the ramp. Participants also had significantly faster Timed Up & Go test (17.7 seconds vs 24.5 seconds) and
higher functional scores on the PEQ. At the end of the study, the participants chose which prosthesis to keep; all nine who were offered the opportunity selected the C-Leg Compact.

Genium
The Genium prosthesis was compared with the subject’s own C-Leg in a 2012 crossover study with 11 transfemoral amputees.18 This manufacturer-sponsored biomechanical study (e.g., comparison of ground reaction forces, flexion angles, and load distribution) did not evaluate clinical outcomes.

Rheo Knee
A small industry-sponsored study (2015) compared the Rheo Knee II with the subject’s own non-microprocessor-controlled knee in 10 patients with a functional level of K2 (n=2), K3 (n=5) or K4 (n=3).19 There was little difference in performance between the 2 prostheses as assessed with the PEQ, Activities-specific Balance Confidence scale, Timed Up & Go test, Timed up and down stairs, Hill Assessment Index, Stairs Assessment Index, Standardized Walking Obstacle Course, and One Leg Balance Test. One limitation of this study is that, although participants had an 8-week acclimation period, they did not receive step-over-step training on stairs and ramps before being tested with the microprocessor knee.

Intelligent Prosthesis
Early literature focused on the Intelligent Prosthesis (IP), which is similar to the C-Leg but is not distributed in the United States. Kirker et al (1996) reported on the gait symmetry, energy expenditure, and subjective impression of the IP in 16 patients who had been using a pneumatic prosthesis and were offered a trial of an IP.20 At the beginning of the study, the patients had been using the IP for between 1 month and 9 months. Using a visual analog scale, subjects reported that significantly less effort was required when using the IP walking outdoors or at work at normal or high speeds, but there was no difference for a slow gait. Subjects reported a strong preference for the IP vs the standard pneumatic leg. Datta and Howitt (1998) reported on the results of a questionnaire survey of 22 amputees who were switched from pneumatic swing-phase control prostheses to an IP device.21 All patients, who were otherwise fit and fairly active, reported that the IP was an improvement over the conventional prosthesis. The main subjective benefits were the ability to walk at various speeds, reduction of effort of walking, and patients’ perception of improvement of walking pattern. Datta et al (2005) also reported oxygen consumption at different walking speeds in 10 patients using an IP and a pneumatic swing gait prosthesis.22 The IP was associated with less oxygen consumption at lower walking speeds only.

Section Summary: Microprocessor-Controlled Knee
The literature consists of a number of small within-subject comparisons of microprocessor-controlled knees vs hydraulic knee joints. Studies on the C-Leg in Medicare level K3 and K4 amputees have shown objective improvements in function on some outcome measures and a strong patient preference for microprocessor-controlled prosthetic knees. The evidence on the C-Leg Compact in Medicare level K2 ambulators is more limited but suggests a possible benefit. 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
We did not identify any literature on powered knee prostheses.

Microprocessor-Controlled Ankle-Foot Prostheses
A 2004 Cochrane review of 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.23 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 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.

**Proprio Foot**

Gait analysis with the Proprio Foot was evaluated in 16 transtibial K3-K4 amputees during stair and ramp ascent and descent. 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.

Self-reported and objective performance outcomes for 4 types of prosthetic feet, including the Proprio Foot, were evaluated in a 2012 randomized within-subject crossover study. Ten patients with transtibial amputation were initially tested with their own 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 PEQ 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 between the types of prostheses. Another study (2013) found a lower energy cost of floor walking with the Proprio Foot compared with a dynamic carbon fiber foot in 10 transtibial amputees. 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.

**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 when compared with the same device in the off-mode or compared with 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**

**PowerFoot BiOM**

Au et al (2008) reported on the design and development of the powered ankle-foot prosthesis (PowerFoot BiOM) in 2008; however, clinical evaluation of the prototype was performed in a single patient.

In 2012, Ferris et al reported on a pre-post comparison of the PowerFoot BiOM with the patient’s own energy-storing and -returning (ESR) foot in 11 patients with transtibial amputation. Results for both prostheses were also compared with 11 matched controls who had intact limbs. 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 may 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 PEQ. Seven patients preferred the PowerFoot and 4 preferred the ESR. Compared with controls with intact limbs, the PowerFoot had reduced range of motion, but greater ankle peak power.
Another similar, small pre-post study from 2012 (7 amputees, 7 controls) 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.\(^3\)

In a conference proceeding from 2011, Mancinelli et al describe a comparison of a passive-elastic foot and the PowerFoot BIOM in 5 transtibial amputees.\(^3\) 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).

**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.

**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 small within-subject comparisons of microprocessor-controlled knees vs hydraulic 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 and a strong patient preference for microprocessor-controlled prosthetic knees. Benefits include a more normal gait, an increase in stability, a decrease in falls, and a decrease in the cognitive burden associated with monitoring the prosthesis. For these reasons, a microprocessor-controlled knee may provide incremental benefit for these individuals. Those considered most likely to benefit from these prostheses have both the potential and need for frequent ambulation at variable cadence, on uneven terrain, or on stairs. The potential to achieve a high 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.

Note that the evidence does not permit conclusions on the effect of a microprocessor-controlled prosthesis on health outcomes in limited community ambulators or on the effect of a next-generation microprocessor-controlled prosthesis on health outcomes.

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 with a powered knee 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 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 with 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.
Supplemental Information

Practice Guidelines and Position Statements

The Veteran’s Affairs Prosthetic and Sensory Aids Strategic Healthcare Group established a Prosthetic Clinical Management Program to coordinate the development of clinical practice recommendations for prosthetic prescriptive practices.13 A subgroup of the Pre-Post National Amputation Workgroup met in 2004 to define patient selection and identification criteria for microprocessor-prosthetic knees. Their proposal was based on recommendations arising from the 2003 Microprocessor Prosthetic Knee Forum. The resulting Department of Veterans Affairs clinical practice recommendations for microprocessor knees are listed in the Appendix.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage

Durable Medical Equipment Regional Carriers Are Responsible For Creating Coverage Policies For Medicare Regarding Durable Medical Equipment. There Is No Specific Coverage Policy On Microprocessor-Controlled Knee Prosthesis, In Part Because There Is No Specific HCPCS Code Describing This Prosthesis. However, The Durable Medical Equipment Regional Carriers Document Has Noted That A Determination Of Medical Necessity For Certain Components/Additions To The Prosthesis Is Based On The Patient’s Potential Functional Abilities.33 Potential Functional Ability Is Based On The Reasonable Expectations Of The Prosthetist And Treating Physician, Considering Factors Including, But Not Limited To The Following:

a. The Patient’s Past History, And
b. The Patient’s Current Condition Including The Status Of The Residual Limb And The Nature Of Other Medical Problems, And
c. The Patient’s Desire to Ambulate.

The Document Also Has Provided The Following Classification Of Rehabilitation Potential:

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 ambulatory.

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 ambulatory.

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 demand of the child, active adult, or athlete.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NC02240186</td>
<td>Comparative Effectiveness Between Microprocessor Knees and Non-Microprocessor Knees</td>
<td>50</td>
<td>Oct 2017</td>
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<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCTNo.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>-------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>NCT02382991</td>
<td>Randomized, Crossover Study Comparing the Efficacy of the 3C60 Knee Against Non-microprocessor Controlled Knees on the Risk of Falling and Locomotor Skills of Moderately Active Persons With Leg Amputation Above Knee or Knee Disarticulation</td>
<td>35</td>
<td>Nov 2015 (completed)</td>
</tr>
</tbody>
</table>

NCT: National Clinical Trial.

a Denotes industry-sponsored or cosponsored trial.

References


Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - Date of amputation
  - Physical and cognitive status
  - Current functional K level and level patient is expected to attain and patient’s desire to ambulate
- Prescription for the prosthesis from referring physician (Physiatrist or Orthopedist)
- Name of ordering prosthetist, fax and phone number
- Activities that will require long distance ambulation at variable rates, uneven terrain, or stairs
- All prosthetist’s clinical/office notes including:
  - Current make, model, components in use
  - Describe daily activities and needs related to daily activities
  - Has a prosthesis been previously worn? Has the patient successfully mastered the features of a swing and stance style hydraulic knee unit?
  - Is a prosthesis being currently used?
  - What rehabilitation has patient received?
  - Why is a swing and stance knee unit not appropriate?
- Clearly list all HCPCS codes with descriptions of generic codes

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>HCPCS</td>
<td>L5856</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type</td>
</tr>
<tr>
<td></td>
<td>L5857</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type</td>
</tr>
<tr>
<td></td>
<td>L5858</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type</td>
</tr>
<tr>
<td></td>
<td>L5859</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)</td>
</tr>
<tr>
<td></td>
<td>L5973</td>
<td>Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source</td>
</tr>
<tr>
<td>ICD-10 Procedure</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>
Type | Code | Description
--- | --- | ---
ICD-10 Diagnosis | All Diagnoses |

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/07/2006</td>
<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>01/11/2008</td>
<td>Policy revision with position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>04/02/2010</td>
<td>Policy Revision with title changed from Microprocessor-Controlled Prosthetic Knee</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>02/22/2013</td>
<td>Coding Update</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>09/27/2013</td>
<td>Policy Review</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>07/14/2014</td>
<td>Policy title change from Microprocessor-Controlled Lower Limb Prostheses to Policy revision with position change</td>
<td>Medical Policy Committee</td>
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<tr>
<td>05/29/2015</td>
<td>Coding update</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>10/30/2015</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>04/01/2017</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>12/01/2017</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
</tbody>
</table>

### Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.
Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.