Policy

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

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

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 foot is considered **investigational**.

Related Policies

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

Policy Guidelines

Microprocessor-Controlled prosthetic knees are programmable devices 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. (See Table 1.) These lower limb prosthetics will most likely have a prosthetic foot attached that
may or may not be powered or controlled by a microprocessor.

Microprocessor-Controlled prosthetic feet have sensors that control the flexion angle of the ankle. This programmable ankle/foot prosthetic is considered investigational. (See Table 2.) Other conventional types of prosthetic feet do not require review under this medical policy.

An independent qualified professional should evaluate the amputee to help determine the most appropriate prosthetic components and control mechanism. A trial period in a real-life setting may be indicated to evaluate the tolerability and efficacy of the prosthesis during usual activities of daily living.

Decisions about the potential benefits of microprocessor-knees involve multiple factors including activity levels, as well as the patient’s physical and cognitive ability. Typically, daily and frequent participation in 2 or more of the following activities would be needed to show benefit from having the microprocessor-controlled knee:

- Ambulation of at least 400 continuous yards
- Ambulation at variable cadence (i.e. speed of walking changes often)
- Ambulation on uneven terrain (e.g., gravel, grass, curbs)
- Use of ramps and/or stairs (especially stair descent)

Individuals who have a functional level of K3-4 may benefit the most from this specialty prosthetic limb. (See Veterans Health Administration guidelines below for Medicare classification of rehab potential)

When the potential benefits of the microprocessor knee is uncertain, patients may first try a custom fit nonprogrammable prosthesis to determine their level of function with the standard device.

Veterans Health Administration Prosthetic Clinical Management Program
Recommendations
The following are guidelines from the VHA PCMP Clinical Practice Recommendations for Microprocessor Knees(1):

Patient Selection and Identification
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.

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.

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 an active lifestyle.

Orthotics, prosthetics, or prosthetic components added to a conventional prosthesis are not covered when:
- It is considered experimental or investigational or used for experimental or investigational therapy or interventions
- It is used only for recreational, sports or athletic activities
- It is available over-the-counter or off-the-shelf without a prescription from the treating physician or consultation with a prosthetist.

### Table 1. Microprocessor-Controlled knee prosthetics

<table>
<thead>
<tr>
<th>Names of Microprocessor-Controlled Knee Prosthetics (company)</th>
<th>Include but are not limited to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptive (Endolite, Blatchford Inc. United Kingdom)</td>
<td></td>
</tr>
<tr>
<td>C-Leg Compact (Otto Bock Orthopedic Industry, Minneapolis, MN)</td>
<td></td>
</tr>
<tr>
<td>Endolite Intelligent/Smart Prosthesis (Endolite, Blatchford Inc. United Kingdom)</td>
<td></td>
</tr>
<tr>
<td>Genium Bionic Prosthetic system (Otto Bock Orthopedic Industry, Minneapolis, MN)</td>
<td></td>
</tr>
<tr>
<td>Intelligent Prosthesis (IP) (Blatchford, United Kingdom)</td>
<td></td>
</tr>
<tr>
<td>Linx (Endolite, Blatchford Inc. United Kingdom)</td>
<td></td>
</tr>
<tr>
<td>Orion 2 (Endolite, Blatchford Inc. United Kingdom)</td>
<td></td>
</tr>
<tr>
<td>Power Knee™ (Ossur, Iceland)</td>
<td></td>
</tr>
<tr>
<td>RheoKnee® (Ossur, Iceland)</td>
<td></td>
</tr>
<tr>
<td>Seattle Power Knees (Seattle Systems) 3 models include:</td>
<td></td>
</tr>
<tr>
<td>- 4-bar</td>
<td></td>
</tr>
<tr>
<td>- Fusion</td>
<td></td>
</tr>
<tr>
<td>- Single Axis</td>
<td></td>
</tr>
<tr>
<td>X2 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN)</td>
<td></td>
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<tr>
<td>X3 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN)</td>
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</table>

### Table 2. Microprocessor-controlled or powered foot prosthetics

<table>
<thead>
<tr>
<th>Names of Microprocessor-Controlled Foot Prosthetics (company)</th>
<th>Include but are not limited to:</th>
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</thead>
<tbody>
<tr>
<td>élan Foot (Endolite)</td>
<td></td>
</tr>
<tr>
<td>iPED (developed by Martin Bionics LLC and licensed to College Park Industries)</td>
<td></td>
</tr>
<tr>
<td>Proprio Foot® (Ossur, Iceland)</td>
<td></td>
</tr>
<tr>
<td>PowerFoot Biom® (developed at MIT and licensed to iWalk)</td>
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</tr>
</tbody>
</table>

Coding
Background
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 be quite different than a younger, active person. In general, key elements of a prosthetic knee design involve providing stability during both the stance and swing phase of the gait. Prosthetic knees also 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 that is 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 generally 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 (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 are 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 at this time and are 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).

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 (see Related Policies). 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. The Power Knee is currently in the initial launch phase in the United States.

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: ISW, KFX.

Scope

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

Benefit Application

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

New technologies that use microprocessor control are being developed. Based on currently available evidence, no microprocessor-controlled device has been shown to have better outcomes than other (e.g., earlier) models. If more costly, the prosthesis would be considered not medically necessary using the Plan’s definition of medical necessity. Benefit or contract language describing the “least costly alternative” may also be applicable to prostheses.
Rationale

This policy was created in 2003 and since then updated periodically using the MEDLINE database. The most recent update was performed through January 29, 2015.

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/function. In addition, 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 Knee

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

In 2000, the Veterans Administration Technology Assessment Program issued a “short report” on computerized lower-limb prosthesis. (2) 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 decreased 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 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. (3) Eighteen comparative studies were included that used objective/quantifiable outcome measures with the C-leg in one arm of the trial. Due to heterogeneity, meta-analyses were not performed. The 7 papers 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, 1 was considered to be of high methodologic quality, and 5 were considered to be of low quality. Two of the trials reported a statistical improvement in energy efficiency, and 4 reported some improvement in efficiency or speed that failed to reach statistical significance. There were no adverse events, safety concerns, or detrments to energy efficiency reported in association with 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 (VA); e.g., in 2005, 155 veterans were provided with a C-Leg. (4) A series of papers from the VA report results from a within-subject comparison of the C-Leg to a hydraulic Mauch SNS knee. (5-7) 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 8 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. (5) 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. (6) Cognitive performance, assessed by standardized neuropsychologic tests while walking a wide hallway in 5 of the subjects, was not different for semantic or phonemic verbal fluency and not significantly different for working memory when wearing
the microprocessor-controlled prosthesis. (7) Although the study lacked sufficient power, results showed a 50% decrease in errors on the working memory task (1.63 vs 0.88, respectively). 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. (6) The authors noted that without any prompting, all of the 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. (8, 9) 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. 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 were significantly different for the two 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 with 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 was not significantly different (2.3% change). Taken together, the results indicated that amputees in this study spontaneously increased their daily physical activity outside of the laboratory setting when using a microprocessor knee.

Johansson et al. assessed energy efficiency in 8 amputees while using the C-Leg, Össur Rheo, and hydraulic Mauch SNS knee. (10) 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 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. (11) 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 subjects (81%) who completed the study, patient satisfaction was significantly better with the microprocessor-controlled prosthesis, as measured by the Prosthesis Evaluation Questionnaire (PEQ). Fourteen preferred the microprocessor-controlled prosthesis, 2 preferred the mechanical system, and one 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 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 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. (12)

Hafner and Smith evaluated the impact of the microprocessor-controlled prosthesis on function and safety in level K2 and K3 amputees. (13) The K2 ambulators tended to be older (57 vs. 42 years), but this did not achieve statistical significance in this sample (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 (4 additional subjects did not complete the study due to technical, medical, or personal reasons). Similar to 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. (11) Self-reported measures included concentration, multitasking ability, and numbers 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 numbers 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 Veteran’s 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. (1)

**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. (14) Participants first used their own mechanically controlled knee and then with 2 types of microprocessor-controlled knee joints (C-Leg, C-Leg Compact) in a randomized order with 1 week of acclimation. Performance times were significantly improved 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 2 higher functioning subgroups performed significantly faster using microprocessor-controlled knee joints. Perceived performance was improved with the C-Leg for some subscales of the PEQ, but this did not translate to an increase in activity level. (15) With the C-Leg Compact, 2 of 8 subscales on the PEQ 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. (16,17) Seven of the 10 subjects used upper extremity assistive devices (e.g., a 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 and Go (TUG) test (17.7 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 9 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 crossover study with 11 transfemoral amputees. (18) This was a manufacturer-sponsored biomechanical study (e.g., comparison of ground reaction forces, flexion angles, load distribution) that did not evaluate clinical outcomes.

**Rheo Knee**
A small industry-sponsored study 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, TUG, 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. 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 and 9 months. Using a visual analog scale, subjects reported that significantly less effort was required when using the IP prosthesis 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 versus the standard pneumatic leg. Datta and Howitt 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. 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**

The literature consists of a number of small within-subject comparisons of microprocessor-controlled knees versus hydraulic knee joints. Studies on the C-Leg in Medicare level K3 and K4 amputees show objective improvements in function on some outcome measures and a strong patient preference for microprocessor-controlled prosthetic knees. Evidence on the C-Leg Compact in Medicare level K2 ambulators is more limited but suggests a possible benefit. Only one 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.

**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 the overall superiority of any individual type of prosthetic ankle-foot mechanism. (23) In addition, the authors 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. (24,25) Results with the adaptive ankle (allowing 4 degrees 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 be increased in 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 degrees 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 (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. (26)

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. (27) Ten patients with transtibial amputation were tested with their own prosthesis and then after 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 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 TUG test, or for perceived mobility or walking ability.

**PowerFoot BiOM**  
Au et al. reported 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. (29)

In 2012, Ferris et al. reported 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. (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 may not be possible with a uniarticular device. Physical performance measures were not significantly different between the 2 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 non-amputee controls with the PowerFoot BiOM than with the patient’s own ESR. (31)

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. (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).

**Section Summary**  
Several small studies have been reported with micro-processor controlled and powered ankle-foot prostheses for transtibial amputees. 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.

**Ongoing and Unpublished Clinical Trials**  
Some ongoing trials that might influence this policy are listed in Table 3.

**Table 3. 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>
</tr>
<tr>
<td>NCT02382991</td>
<td>Randomized, Cross-over 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>40</td>
<td>Sep 2015</td>
</tr>
<tr>
<td>NCT02240186</td>
<td>Comparative Effectiveness Between Microprocessor Knees and Non-Microprocessor Knees</td>
<td>50</td>
<td>Jun 2016</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.  
* Denotes industry-sponsored or cosponsored trial.

**Clinical Input Received From Physician Specialty Societies and Academic Medical Centers**  
External clinical input was not formally solicited for this policy.
Summary of Evidence
Microprocessor-controlled prostheses use feedback from sensors to adjust joint movement on a real-time as-needed basis. The literature consists of a number of small within-subject comparisons of microprocessor-controlled knees versus hydraulic knee joints. For K3- and K4-level amputees, studies show 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. It is concluded that 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 be able to use the advanced technology.

Evidence is insufficient to permit conclusions regarding the effect of a microprocessor-controlled prosthesis on health outcomes in limited community ambulators. Evidence is also insufficient to permit conclusions regarding the effect of a next-generation microprocessor-controlled prosthesis on health outcomes. Therefore, these are considered investigational.

The limited evidence available to date does not support an improvement in functional outcomes with a microprocessor-controlled or powered ankle-foot prostheses compared with standard prostheses. Therefore, microprocessor-controlled or powered ankle-foot prostheses are considered investigational.

Practice Guidelines and Position Statements
The VA's 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. (1) The New Technology Subgroup of the Pre-Post National Amputation Workgroup met in April 2004 to develop a proposal to define patient selection and identification criteria for microprocessor-prosthetic knees. Their proposal was based on recommendations arising from the May 2003 Microprocessor Prosthetic Knee Forum, hosted at Walter Reed Army Medical Center and sponsored and funded by the American Academy of Orthotists and Prosthetists. The resulting VA Clinical Practice Recommendations for microprocessor knees are listed in Policy Guidelines.

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

Medicare National Coverage
Durable medical equipment regional carriers (DMERC) 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 DMERC document notes 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 patient’s past history, AND
- The patient’s current condition including the status of the residual limb and the nature of other medical problems, AND
- The patient’s desire to ambulate

Table 4. Classification of rehabilitation potential

<table>
<thead>
<tr>
<th>Level</th>
<th>Rehabilitation Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 0.</td>
<td>Does not have the ability or potential to ambulate or transfer safely with or without assistance and prosthesis does not enhance their quality of life or mobility.</td>
</tr>
<tr>
<td>Level 1.</td>
<td>Has the ability or potential to use prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulatory.</td>
</tr>
<tr>
<td>Level 2.</td>
<td>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.</td>
</tr>
<tr>
<td>Level 3.</td>
<td>Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has</td>
</tr>
</tbody>
</table>
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.

References


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**Appendix**

N/A

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**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/10/04</td>
<td>Add to Durable Medical Equipment Section - New Policy PR.1.01.113 replaces BCBSA 1.01.25 (Issue 3:2003).</td>
</tr>
<tr>
<td>09/01/04</td>
<td>Replace Policy - Policy renumbered from PR.1.01.113. No date changes.</td>
</tr>
<tr>
<td>02/08/05</td>
<td>Replace Policy - Policy reviewed with literature search through December 2004; no change to policy statement; references added.</td>
</tr>
<tr>
<td>02/14/06</td>
<td>Replace Policy - Policy reviewed with literature search; no change to policy statement; reference added.</td>
</tr>
<tr>
<td>02/22/06</td>
<td>Codes updated - No other changes, effective date unchanged.</td>
</tr>
<tr>
<td>05/26/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
</tr>
</tbody>
</table>
3/13/07 Replace Policy - Policy updated with literature review; reference added. No change in policy statement.
5/13/08 New BC Policy - Replaces PR.1.01.513, status changed from PR to BC. A microprocessor-controlled knee may be considered medically necessary in amputees who meet the criteria listed. When criteria are not met, it is considered not medically necessary.
5/12/09 Replace Policy - Policy updated with literature search. Policy statements added regarding ankle-foot and powered knee prostheses as investigational. References added.
2/09/10 Code Update - New 2010 codes added.
4/13/10 Replace Policy - Policy updated with literature search; no change to the policy statement. References added.
6/13/11 Replace Policy - Policy updated with literature review through January 2011; reference 21 added; policy number changed from 1.01.25 to 1.04.05 (prosthetics); policy statements unchanged. ICD-10 codes added to policy.
1/27/12 HCPCS code L5312 added.
5/22/12 Replace policy. Policy updated with literature review through December 2011; Rationale revised; references 3, 16, 17, 22 added; some references removed. Policy statements unchanged.
8/24/12 Update Coding Section – ICD-10 codes are now effective 10/01/2014.
5/28/13 Replace policy. Policy updated with literature review through February 1, 2013; Rationale revised; references 12, 15, 17, 23, 26-27 added and references reordered; policy statements unchanged.
8/14/13 Update Related Policies. Change title to policy 1.04.04.
3/21/14 Update Related Policies. 1.04.04 was deleted and replaced with 1.04.502.
8/11/14 Interim Update. Policy Guidelines added with details about when orthotics, prosthetics, or prosthetic components added to a conventional prosthesis are not covered. No new references added. Policy statements unchanged. HCPCS codes L5845 removed from policy; this is not reviewed.
6/17/15 Annual Review. Two tables added to the Policy Guidelines section that list examples of microprocessor-controlled prosthetic knees and feet for the lower limb. Policy Guideline statement added that conventional prosthetic foot is not subject to review under this medical policy. Policy updated with literature review through January 29, 2015. Reference 19 added; others renumbered. Policy statements unchanged. ICD-9 diagnosis codes removed; no utilized in adjudication. HCPCS codes L5312 and L5856 removed; these are not reviewed.
5/10/16 Annual Review. Policy reviewed with literature search; policy statement unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2016 Premera All Rights Reserved.
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  - Qualified interpreters
  - Information written in other languages

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You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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Arabic (Arabic):

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Français (French):

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Avi sila a gen Enfòmasyon Enpòtan ladan. Avi sila a kapab genyen enfòmasyon enpòtan konsénan aplikasyon w la oswa konsénan kouvèti asirans lan atravé Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewva enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

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Hmoob (Hmong):

Ilokano (Illocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalab nga adda ket naglaon iti napateg nga impormasion maijangeeg iti aplikasyonno woyen coverage baben animated Premera Blue Cross. Daytoy ket mabalab dagiti importante a pelsa iit daytoy a pakdaar. Mabalab nga adda rumbeg nga aramidens nga addag sabbay dagiti particulier a naitdung nga adda aldaw tapno mapagtaalneddyo to tyege ti salun-ayto woyen tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukyodo a pagasasa nga awan ti bayadanyo. Turwag ti numero nga 800-722-1471 (TTY: 800-842-5357).

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