Healthy Blue

Medical Policy

Subject:	Microprocessor Controlled Lower Limb Prosthesis		
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Description/Scope

This document addresses the use of microprocessor controlled lower limb prostheses including, but not limited to, knee prostheses (such as the Otto-Bock C-Leg® device, the Genium™ Bionic Prosthetic System, the Genium™ X2® and X_3® devices, the Ossur Rheo Knee®, and the Endolite Intelligent Prosthesis®) and foot-ankle prostheses (such as the Proprio Foot®, the PowerFoot BiOM, and the Endolite élan foot).

Note: For additional information regarding lower limb prosthesis, please see:

- CG-DME-13 Lower Limb Prosthesis

Position Statement

Medically Necessary:

The use of a microprocessor controlled lower limb prosthesis (for example, Otto-Bock C-Leg device, Otto-Bock Genium Bionic Prosthetic System, the Ossur Rheo Knee or the Endolite Intelligent Prosthesis) is considered **medically necessary** for transfemoral (above knee) and knee disarticulation amputees when *all* of the criteria set forth in (A) and (B) below have been met:

A. Selection criteria:
   1. Individual has adequate cardiovascular reserve and cognitive learning ability to master the higher level technology; **and**
   2. Individual has a functional K-Level 3 or above (this is usually demonstrated through the use of a preparatory lower limb prosthesis); **and**
   3. Individual has demonstrated better mobility or stability using a temporary device, or when unable to complete such a trial, the provider documents or attests that there is a reasonable likelihood of improved mobility or stability; **and**
   4. Either of the following:
      a. Individual has a documented need for daily long distance ambulation (generally 400 yards or greater) at variable rates (for example, ambulation in the community for work or school or stay at home parenting); **or**
      b. Individual has a demonstrated need for regular ambulation on uneven terrain or regular use on stairs (use for limited stair climbing in the home or place of employment is generally not sufficient).

B. Documentation and performance criteria:

1. Complete multidisciplinary assessment of individual including an evaluation by a trained prosthetic clinician. The assessment must objectively document that all of the above selection criteria have been evaluated and met.

Not Medically Necessary:

The use of a microprocessor controlled lower limb prosthesis is considered **not medically necessary** in all other cases, including when the criteria above have not been met, including for individuals with a functional K-Level 2 or below.

Investigational and Not Medically Necessary:

The use of a microprocessor controlled foot-ankle prosthesis (for example, Proprio Foot or the PowerFoot BiOM) is considered **investigational and not medically necessary** for all indications.

Rationale

At this time, the available peer-reviewed published literature addressing the clinical benefit of a microprocessor controlled lower limb prostheses is mostly limited to nonrandomized controlled clinical trials, and case series of limited size. Additionally, the majority of these studies have involved highly selected subjects who were otherwise in good health.

Microprocessor Controlled Knee Prosthesis

Hafner and others (2007) reported the findings of a small, nonrandomized, cross-over controlled design study in which each subject was exposed to two different prosthetic limb conditions (mechanical and microprocessor controlled C-Leg) twice during the trial. This study included 21 subjects, each of whom used both a standard mechanical knee and lower limb prosthesis and the C-Leg microprocessor controlled prosthesis. Subjects were recruited for participation from a local amputee population. Seventeen subjects completed the study. Subjects were told at the time of enrollment that they would be allowed to keep the test prosthesis whether or not they completed the trial. The subjects began the trial with a 2-month period using their standard prosthesis followed by an activity assessment and functional, performance and subjective perception evaluation. Next, all subjects used the microprocessor controlled prosthesis until acclimation was demonstrated. This was then followed by a 2-month acclimation period with the microprocessor controlled prosthesis, ending with an activity assessment and functional, performance and subjective perception evaluation. Subjects were then reverted back to the standard prosthesis for 2 weeks and again an activity assessment and functional, performance and subjective perception evaluation was done. In the final stage of the trial, participants were allowed to use either one or both prosthetic devices over a 4-month period. Daily use and activity levels were measured for each device. The study concluded with a final activity assessment and functional performance and subjective perception evaluation with the microprocessor controlled device. A variety of objective and subjective outcome measures were reported. The authors reported no significant differences between the two prosthetic devices in terms of daily activity as measured by mean daily step frequency and mean estimated step distance, in performance on level or varied surfaces, or in

cognitive demand during use of the devices. They did note a significant improvement with the C-Leg prosthesis in subjects' Stair Assessment Index (SAI) scores, time to descend scores, and a surveyed preference for the microprocessor controlled C-Leg as compared with a mechanical prosthetic knee. There was no difference noted in ascending stairs, but self-reported frequency of stumbles and falls was lower for the C-Leg prosthesis. Limitations of this study include its small size, lack of outcome comparisons to a group randomized to continued use of a standard prosthesis, and lack of control of the type of mechanical prosthesis used. In addition, the period of time allowed for the subject to revert back to a standard prosthesis (2 weeks) for a functional assessment prior to the 4-month combined use measures was quite limited.

An article by Williams and colleagues (2006) describes a randomized two-group cross-over design study of C-Leg versus a standard hydraulic knee prosthesis (Mauch SNS® knee). Subjects were given a 3-month acclimation period for each device prior to testing. This study was not blinded and was hampered by a significant drop-out rate (56%) that left only 8 participants in the evaluable study population. The findings concluded that in non-demanding walking conditions with experienced amputees, participants reported the C-Leg required less cognitive attention than the non-computerized knee. However, this subjective experience did not translate into improved performance on neuropsychologic screening instruments or walking speed.

In another report of the same trial (Orendurf, 2006), the authors report that they found no significant difference between the groups in either oxygen efficiency or gait efficiency. It is noted in the discussion section of this article that the programming of each C-Leg requires a high degree of tailoring to meet the needs of the user. The authors commented that the parameters used by each of the study participants varied widely, with some preferring their C-Leg to operate in a manner not too dissimilar to that of a standard non-computerized limb, and others preferring significantly different functional parameters. With this degree of variation, even within such a small study population, it would indicate that a much larger study population should be used in further studies of the C-Leg in order to control for this potential source of bias.

A nonrandomized cross-over study conducted by Kaufman and colleagues (2007) compared the C-Leg to the standard hydraulic prosthesis in gait and balance parameters. The study included 15 participants, who were allowed an average of 4.5 months of acclimation time with each device. The authors indicate that there was a significant ($p<0.01$) improvement in objective, standardized measures of both gait (knee flexor movement) and balance (Sensory Organization Test) with the computerized prosthesis. The investigators point out that the study included a select group of healthy, highly effective ambulators with no additional musculoskeletal conditions. It is unclear what impact the use of computerized prosthetic knee devices may have on individuals with lower functional classifications.

Seymour and colleagues published a study comparing energy expenditure, obstacle course negotiation and quality of life (QOL) measures in 10 highly effective healthy ambulators who use both a C-Leg and a non-computerized prosthesis (2007). This study had a 23% drop-out rate. A subset of participants (10 of 13) in this study underwent an 8-minute energy consumption test on a treadmill using one of their prostheses, and then again using the other device after a 10-minute rest. They were then asked to undergo a walking obstacle course 8 times, 4 holding a laundry basket containing a 10 lb. weight, and 4 times unencumbered. Finally, they were asked to complete a standardized quality of life questionnaire (SF-36v2). The authors report a statistically significant lower energy

consumption rate for participants when wearing their C-Leg devices at both typical and fast paces. On the obstacle course, statistical differences were noted in the number of steps taken, elapsed time, and the number of times participants stepped out of bounds during the unencumbered portion of the trial. During the encumbered trial, the elapsed time (11.5 sec vs. 15.5 sec) was shorter for the C-Leg prosthesis group (p=0.007). No stumbles or falls were reported in either group. The results of the QOL questionnaire associated with wearing the C-Leg indicated that the participants were at or above the normative data available for the general population.

A study by Kahle and colleagues (2008) investigated the impact of the C-Leg on several functional parameters, including stumbles, falls, performance in walking and stair descent and QOL. The study involved 21 (9 K-2 and 8 K-3) subjects, with 19 completing the study, and utilized a simple pre-test/post-test design. Participants in the study had a wide variation in physical status and health, but were all community ambulators. Some participants utilized assistive devices for ambulation. This is the first published study to include a mixed population. The authors report significant improvement in the number of stumbles (p=0.006), but no significant improvement in the number of falls. No statistical analysis was provided for either walking or stair descent performance. Finally, there was a significant improvement (20%, p=0.007) in QOL scores with the C-Leg prosthesis.

In 2009, Hafner and colleagues reported the results of a nonrandomized crossover study involving 17 subjects with unilateral transfemoral amputations. Subjects were classified as either Medicare Functional Classification Level-2 (MFCL-2, also known as K-2, n=8) or MFCL-3 (also known as K-3, n=9) and were microprocessor controlled prosthesis naive. The investigators began the study with all subjects using their standard prosthesis and underwent functional evaluations at 2 months, after which they underwent fitting, training, a 2-month acclimation period and another round of functional evaluations with the C-Leg prosthesis. Subjects were then transitioned back to their standard prosthesis for 2 weeks before another round of assessments was given. Once the assessments were completed, all subjects were sent home with both prostheses and told to use them as they desired, and return for additional assessments at 4, 8, and 12 months, using the prosthesis most used or preferred during the previous 4-month period. For both K-2 and K-3 subjects, significant performance benefits were reported for most assessments, including stair mobility (K-2, p=0.008; K-3 p=0.004), Hill mobility (K-2, p=0.008; K-3, p=0.09), Hill speed (K-2, p=0.002; K-3, p=0.017), obstacle course speed (K-2, p=0.02; K-3, p=0.007), and attention speeds (K-2, p=0.02; K-3, p=0.22). The reported relative increase in functional outcomes was reported to be greater in K-2 vs. K-3 subjects. When data for both groups were combined, significant improvements were noted for all assessments noted above ($p<0.05$). With regard to self-reported measures, only the K-3 subjects had significant improvements in satisfaction (p=0.002) and in a utility Prosthesis Evaluation Questionnaire [PEQ] (p=0.01). Self-reported relative frequency of stumbles was significantly better in both groups (p=0.05 and p=0.03, respectively), however, this was not mirrored in a significant decrease in reported stumbles. No significant differences in frequency of number of semi-controlled falls was reported for either group. Only the K-2 subjects experienced a significant improvement in the frequency (p=0.01 vs. p=0.1, respectively) and number of uncontrolled falls (p=0.01 vs. 0.28). At the completion of the study, reassessment of K-levels found that 50% of the K-2 subjects were reclassified as K-3 and 33.3% of K-3 subjects were reclassified as K-4. However, 2 K-3 subjects were reclassified as K-2. The authors concluded that the results suggest the C-leg improves function and reduces the frequency of adverse events in a population that is at risk for falls and may allow persons with amputation to expand their functional abilities.

Theeven and others (2011) conducted a small randomized controlled cross-over trial that was significantly different from the previously discussed studies in two respects. First, instead of including only highly selected healthy amputee subjects, their study only included K-2 subjects, which represents an intermediate capacity for physical functioning, commonly termed as "limited community ambulatory." Second, this study not only compared standard mechanical prosthetic devices to microprocessor controlled devices, but also compared two microprocessor controlled devices with one another. The study design called for each participant to wear a different prosthesis for sequential week-long periods, with testing at the end of each week. All participants wore their standard mechanical prosthesis for the first week, followed by the two microprocessor controlled prosthetic devices (either the Otto-Bock C-leg, or the Otto-Bock C-Leg Compact). A total of 41 subjects were randomized, but only 28 subjects (68%) completed the trial.

The authors further stratified study subjects into three groups ("High", "Intermediate", or "Low") based on expert opinion regarding functional levels within the MFCL category. Subject performance on the ADAPT testing circuit was further stratified by specific sections of the test. The ADAPT test circuit presents three separate sets of physical challenges, each addressing discrete subsets of skills or abilities that become increasingly challenging. Activity Subset 1 (AS1) focuses on activities that require adequate balance, Activity Subset 2 (AS2) focuses on actions that challenge muscle strength and weight distribution, and Activity Subset 3 (AS3) focuses on actions dependent upon prosthesis-related and cognitive skills. The authors reported a large variation in the functional performance level seen within the study's K-2 population, as well as between prosthetic devices. The Low functional level subjects demonstrated no benefit from a microprocessor controlled prosthesis at any level of the test. Both Intermediate and High group subjects were reported to have significant improvements in performance of AS2 activities, with the High group performing significantly better than the Intermediate group. For AS3 activities, only the High group demonstrated any benefit. Inter-device comparison found that the High group performed significantly better with both computerized prostheses in AS1, but none in AS2. In AS3, the High group had significantly better times only when subjects wore the C-Leg Compact Device, but not the standard C-Leg. In contrast, the intermediate group only had significant improvements in AS2 with the standard C-Leg, but not with the more advanced C-Leg compact device.

The authors conclude that there is a wide disparity in functional levels within the K-2 classification. They also note that despite the overall data showing benefit by functional levels, performance at the individual level was significantly variable across functional levels. Additionally, there was a significant variation in achieved benefit depending upon device type. In this study, the data are limited by the small study sample. Also, the authors note that the choice of break-in period may have a significant impact on the results, and longer acclimation times may significantly change the results. This is the first study looking at the use of microprocessor controlled knee prostheses in lower functioning subjects in a rigorous manner. The results showed significant variation in performance between individuals and unexpected results with regard to outcomes between device types. It highlights that there are still many questions left to address with regard to the benefits derived from these devices. Further research is warranted.

This group published another study involving 30 K-2 subjects using a randomized cross-over design (Theeven, 2012). Full datasets were available for only 19 subjects at the completion of the study, but all 30 were included in the intent-to-treat analysis. Subjects underwent three separate trial periods using three different knee joint

prostheses, including one mechanical knee joint and two microprocessor controlled joints. The latter two prosthetic joints included one with microprocessor controlled stance and swing phase and another with only a microprocessor controlled stance phase. Subjects were assessed using each prosthesis for a 1-week period in the home and community setting. The perceived performance and satisfaction were measured using the PEQ. Subject activity levels were monitored via uniaxial accelerometer. The results indicated that the subjects' perceptions regarding ambulation, residual limb health, utility, and satisfaction were significantly higher when subjects used the microprocessor controlled devices vs. the mechanical knee devices. There were no significant differences between groups with regard to activity level. The authors conclude that K-2 amputees report benefitting in terms of their performance from using an MPK; this is not reflected in their actual daily activity level after 1 week of using an MPK.

Another group published the results of testing in a group of K-2 subjects (Burnfield, 2012). This study investigated the sequential use of standard mechanical prostheses followed by the C-Leg device in 10 K-2 subjects who were asked to complete a series of tasks while measurements were taken on gait, stride, motion analysis, timed functional assessments along with questionnaires and EMG. The authors noted significantly better performance with the C-Leg with regard to ramp ascent and descent and intact limb function. Intact limb function improvements were used as a proxy measure for stability and user confidence since longer stride and a more regular gait are indicative of prosthetic confidence and comfort. EMG data was not of sufficient quality to allow proper analysis. The Timed Up and Go (TUG) test, which measures physical function during a specified series of tasks, showed significant improvement in the C-Leg group. The results of the Prosthetic Evaluation Questionnaire (PEQ), Activities-specific Balance Confidence Scale (ABC) and the Houghton Scale were mixed, with the PEQ and ABC demonstrating significant benefits with the C-Leg, but not on the Houghton Scale. This study supports some of the positive findings mentioned earlier in the Theeven trial, but further study is needed to fully understand the impact of microprocessor controlled knee prostheses in the K-2 population.

As discussed earlier in the Theeven study, the authors noted significant differences between specific microprocessor controlled knee prostheses. This question was further investigated by Bellmann and colleagues (2012), who compared performance parameters of the C-Leg vs. the Genium device. This study enrolled 11 K-3-4 C-Leg users who were put through a battery of tests while using their own C-Leg device. Subjects were then introduced to the Genium device, which was attached to their own socket and foot prosthesis. They were then given approximately 24 hours to accommodate to the new prosthesis before being given a battery of tests. The authors reported significant benefits of the Genium device over the C-Leg in many measures, including foot loading, sway, step symmetry, and knee flexion during a variety of activities. However, the very short acclimation time and very small sample size of this study do not allow the results to be generalized to a wider population.

A small, nonrandomized controlled trial involving 15 K-3-4 ambulatory subjects was published by Highsmith in 2014. Each participant was subjected to a series of six balance tests with both a standard knee prosthesis and then with the C-Leg. The trials involved the use of the Sensory Organization Test (SOT) to assess sensory dependence. The six different tests involved evaluations under pre-specified conditions with varying balance challenges with their standard prosthesis, followed by an accommodation period with the C-leg and repeat testing. A significant 3% increase in reliance on somatosensory system input (p=0.047) was reported while using the C-Leg vs. a standard prosthesis. There was a statistically significant (33%) reduction in the number of falls when using the C-Leg

(p=0.03). Standard prosthesis use resulted in 21 falls among 7 subjects (average, 1.4 ± 2.3 falls per person) compared with 14 falls among 4 subjects (average 0.9 ± 2.1 falls per person) while utilizing the C-Leg. No data representing real-life use of the prosthesis was reported.

Eberly (2014) reported on another nonrandomized controlled trial involving 10 K-2 ambulatory subjects with a mean age of 62 years. Investigators evaluated each subject for stride characteristics, kinematics, kinetics, and electromyographic activity on a 10 meter walkway with both their standard prosthesis and then with the C-Leg Compact, the latter after a 3-month acclimation period. Subjects were required to walk the 10 meter walkway at a self-selected customary comfortable walking pace and then at a self-selected customary fast walking pace. The results indicated approximately 20% improvement in walking speed with the C-leg vs. the control prosthesis in both the free walking phase (p=0.002) and the fast walking phase (p=0.000). This was attributed to increases in both stride length (12%-14%; p=0.003) and cadence (9%-10%; p=0.001). The peak external ankle dorsiflexion moment in late stance increased by more than 20% while walking with the C-Leg vs. the standard prosthesis during both free (p=0.001) and fast (p=0.008) walking. Walking with the C-Leg produced modestly higher tibialis anterior activity in the intact limb (6%-8% maximal voluntary contraction [MCV] increase) and moderately more intense lower gluteus maximus activity (19% MVC increase) in the prosthetic limb in both free and fast walking compared to walking with the standard prosthesis ($p<0.05$). There were no significant differences between the prostheses in mean EMG activity of the remaining muscles during free or fast walking.

Theeven and colleagues (2013) published a systematic review of the available literature addressing microprocessor controlled prosthetic knee joints. A total of 37 studies and 72 outcome measures were identified and included in the study. They reported that a majority (67%) of the outcome measures addressed the body functions component of the International Classification of Functioning, Disability and Health (ICF), which measures and describes the anatomy and physiology/psychology of the human body. This component is commonly used to quantify the level of impairment present. Measurement of how microprocessor controlled prosthetic knee joints affect an individual's actual performance in daily life was reported in only 31% of studies. Also noted was that the available research primarily focused on young, fit and active persons. Their findings conclude with the comment that scientifically valid evidence regarding the performance of persons with a microprocessor controlled prosthetic knee joint in everyday life is limited.

In 2015, Prinsen and others published the results of a randomized controlled cross-over study involving 10 subjects (n=2 K-2, 5 K-3, and 3 K-4) assigned to begin the study with either a standard knee prosthesis or the Rheo Knee II device. Following an 8-week acclimation period to their assigned device, subjects were given a battery of tests including the TUG test, Timed Up and Down Stairs Test, and Standardized Walking Obstacle Course. Following these measurements, subjects were crossed over to use the other device, acclimated for another 8 weeks, and then retested. The authors reported that significantly higher scores were found for the Rheo Knee group on the Residual Limb Health subscale of the Prosthesis Evaluation Questionnaire when compared to the standard device group (p=0.047). Interestingly, Rheo Knee subjects needed significantly more steps to complete an obstacle course compared to the non-microprocessor controlled prosthetic knee (p=0.041). On other outcome measures, no significant differences were found. The authors concluded that transition towards the Rheo Knee had little effect on the studied outcome measures.

Another study from 2015 by Wong involved 8 subjects over 40 years of age with peripheral arterial disease-related amputations. There were 2 K-1 subjects, 2 K-2 subjects, and 4 K-3 subjects. Unilateral amputations were noted in 6 subjects and 2 were bilateral amputations. All subjects were asked to undergo a battery of tests including the Berg Balance Scale and the TUG test with their standard prosthetic device and then, after an 8-week acclimation period, with either the C-Leg (n=5) or the C-Leg Compact (n=3) devices. After acclimation using the microprocessor controlled prosthesis, subjects demonstrated improvements in fear of falling, balance confidence, TUG time, and rate of falls ($p<0.05$ for all). Decreases in the number of falls correlated with faster TUG speed ($p=0.76$) and greater balance confidence ($p=0.83$). The authors concluded that individuals with peripheral artery disease and transfemoral amputations had fewer falls and improved balance confidence and walking performance when using a microprocessor controlled prosthesis.

Bell (2016) investigated the impact of the Otto Bock Genium X2 microprocessor controlled prosthetic knee in 21 K4 ambulators with transfemoral amputation and experience with prosthesis use on descending sloped surfaces. The X2 device is similar to the commercially available Genium prosthetic device but has been specifically designed for injured U.S. military service members, with updated control software and sensor hardware to improve biomimetic timing. Participating subjects went through a trial of slope walking with their usual leg, (n=13 with C-Leg, 8 with the Mauch device), and then acclimated to the X2 devices prior to retrial. The trial involved the evaluation of descent technique and biomechanics as subjects descended an instrumented 10° slope at a self-selected walking velocity. The authors reported that the use of the X2 device in the subjects who usually used the Mauch device resulted in greater hill assessment scores ($p=0.026$). They attributed this finding primarily to decreased reliance on handrail use. The use of the X2 device in the C-Leg group increased prosthetic knee flexion to a median of 6.4° at initial contact ($p=0.002$) and 73.7° in swing ($p=0.005$). This contributed to longer prosthetic limb steps ($p=0.024$) and increased self-selected velocity ($p=0.041$). Additionally, the use of the X2 in the C-Leg group increased prosthetic limb impact peaks ($p=0.004$) and improved impact peak symmetry ($p=0.004$). The conclusion was that the decreased reliance on handrail use as Mauch device users descended in the X2 device indicates improved function and perhaps greater confidence in the device. The authors suggested that additional biomechanical improvements for existing C-Leg users suggest potential longer-term benefits with regard to intact limb health and overuse injuries. Further investigation is warranted into these aspects of X2 device use.

Prinsen and colleagues (2017) conducted a randomized crossover study comparing microprocessor controlled knee prosthesis (Rheo Knee II) to non-microprocessor controlled prosthetic knees (NMPK) across different walking speeds, in 9 subjects with a transfemoral amputation or knee disarticulation (n=2 K-2, 5 K-3, and 3 K-4). The authors compared knee kinematics, such as intact ankle vaulting and vertical acceleration of the pelvis, across groups. Measurements were performed at three walking speeds: preferred walking speed, 70% preferred walking speed and 115% preferred walking speed. The results indicated no differences between groups with regard to peak prosthetic knee flexion during swing or in peak vertical acceleration of the pelvis during initial and mid-swing of the prosthetic leg. At 70% preferred walking speed, they found that vaulting, described as premature ankle plantar flexion of the intact leg during mid-stance, was significantly decreased while walking with the Rheo Knee II compared to the NMPK ($p=0.028$). They concluded that there were limited differences in gait parameters while walking with the Rheo Knee II vs. NMPK across different walking speeds.

Hasenoehrl (2017) reported on a small sample of 5 elderly, low-active (K-2) transfemoral amputees. All subjects were fitted with a microprocessor controlled device specifically designed for older and low-active transfemoral amputees (Genium with Cenior-Leg ruleset microprocessor-controlled knee prosthesis) and re-evaluated after 4 to 6 weeks of familiarization. A third evaluation with only questionnaires was conducted after participants were refitted to their standard device another 4 weeks later. No specific training was provided to subjects. The authors reported that the questionnaires and functional tests showed an increase in the perception of safety. Moreover, gait analysis revealed more physiologic knee and hip extension/flexion patterns when using the microprocessor controlled device. They concluded that although the microprocessor device might help to improve several safety-related outcomes as well as gait biomechanics, the results of this study were hampered by lack of training and a sufficient acclimation period. Moreover, this study was limited by the small sample size, lack of blinding, and other methodological flaws.

In 2018, Kaufman described a prospective non-randomized cross-over trial involving 50 subjects assessed at K-2 (n=48) and K-3 (n=2) levels who were current users of a non-microprocessor controlled prosthesis. Subjects were randomly assigned to one of four different microprocessor controlled prostheses (OttoBock Compact, Ossur Rheo 3, Endplate Orion 2, or Freedom Innovation Plié 3). The study began with all subjects being tested with their usual prosthesis, followed by a 3-month acclimation process with their assigned microprocessor controlled prosthesis and then tested. Afterwards, they were tested again with their usual prosthetic device. Testing included activity monitoring and subjective satisfaction and safety questionnaires. Self-reported data demonstrated a significant reduction in falls, with a median of 2 falls per person per month with the non-powered knee at baseline vs. 0 falls per person per month with the microprocessor controlled prosthesis ($p=0.01$). The number of falls rebounded to 3 falls per person per month after subjects were retested with their usual device. Time spent sitting decreased from 61% with the usual device to 52% with the microprocessor controlled prosthesis ($p=0.01$). As with falls, this increased when subjects returned to their usual device (64%). There was a significant increase in activity with the microprocessor controlled prosthesis as measured by the percentage of the day using the control prosthesis vs the microprocessor controlled prosthesis (16% vs 20%, $p=0.02$).

Although the evidence continues to evolve, it is reasonable to consider microprocessor controlled lower limb prostheses appropriate for a select group of individuals meeting strict criteria for fitness, health and daily utilization expectations. However, these devices may not be appropriate for all potential users. The currently available scientific evidence demonstrates some limited benefits for individuals with a K-3 or K-4 functional level. Such individuals are capable of performing physical tasks requiring significant strength, coordination, aerobic fitness, and cognitive capacity. These tasks include ambulation at variable cadences and for extended distances or time periods (for example, 400 yards or more), or the ability to traverse challenging environmental barriers (for example, several flights of stairs). They may also be capable of participating in athletic activities involving high impact or aerobic needs. As such, the use of microprocessor controlled lower limb prostheses may be appropriate for users who have the physical capacity for such activities on a regular basis. Alternatively, the data does not show significant benefits of microprocessor controlled lower limb prostheses for individuals who do not have high-level physical needs, such as those with K-1 or K-2 functional levels, or those who do not have a demand for extensive physical activity. The benefits of the marginal improvements in functional capacity provided by microprocessor controlled lower limb devices, such as reduced oxygen consumption, improving walking speed, and safety when ambulating in more challenging environments, are not clear for individuals at lower function levels. Given lack of

clear data, it is reasonable to consider the use of these devices not medically necessary in those individuals. Furthermore, for those individuals who do have K-3 or K-4 functional levels, but do not encounter a regular need to ambulate for long distances over significant environmental challenges, beyond what may be encountered in the average home or workplace, there is little benefit provided from the use of microprocessor controlled lower limb devices. In addition, these devices require substantial training to allow for faster than normal walking speed. A user should have adequate cognitive learning ability to master the higher level technology. The criteria set forth above assist in the identification of potential users for whom the device may provide an improvement in functional capacity.

The assessment of K-levels is usually conducted early in an individual's care and it is common for an individual to use a non-microprocessor controlled device during the functional assessment process. Additionally, when assessing whether or not an individual will benefit from a microprocessor controlled device, such as assessing potential benefit in mobility and stability, a temporary microprocessor controlled device may be used during those evaluations. When that is not possible, the judgement of the treating provider should be documented in the clinical record.

There is substantial uncertainty with regard to what clinically important factors may predict an individual's capability to utilize the functional benefits provided by an advanced hydraulic, microprocessor controlled knee device. To address this issue, Hahn and others (2016) conducted a retrospective cross-sectional cohort analysis involving routine trial fitting data from 899 subjects with above knee amputations using the C-Leg device. The outcomes involved prosthetist-rated performance indicators addressing the functional benefits of advanced maneuvering capabilities of the devices. Additionally, subjects were asked to rate their perceptions as well. The authors reported that the ability to vary gait speed, perform toileting, and ascend stairs were identified as the most sensitive performance predictors of successful microprocessor controlled knee device use. Subjects with prior C-Leg experience demonstrated benefits during advanced maneuvering. While the data reported that the variables indicated plausible and meaningful effects, they could not be demonstrated to have predictive power. Mobility grade showed the largest effect, but also failed to be predictive, and other clinical parameters such as reason for amputation, age, and mobility grade, were shown to have no predictive potential. Finally, they did note that daily walking distance may pose a threshold value. As such, they suggested that it be considered as part of any proposed predictive instrument.

Microprocessor Controlled Foot and Ankle Prosthesis

There are currently several different models of microprocessor controlled foot-ankle prostheses, including the Proprio Foot, the PowerFoot BiOM, and the Endolite élan foot.

Published peer-reviewed evidence addressing the use of a microprocessor controlled foot-ankle prosthesis is limited. One small study involved 12 subjects and measured socket pressures in individuals undergoing gait analysis during various locomotion tasks using the Proprio Foot (Ossur) for five walking conditions with and without the device's ankle adaptation mode (Wolf, 2009). The study concluded that the adaptive ankle-foot prostheses favorably altered joint kinetics and stump pressures on stairs and ramps.

A second study involved 32 subjects, 16 healthy controls and 16 transtibial amputees using the Proprio Foot (Alimusaj, 2009). The subjects underwent three-dimensional (3D) gait analysis on stairs. Kinematics and kinetics of the lower limbs were compared during stair ascent and descent with the prosthetic foot set to a neutral ankle angle and then with an adapted dorsi-flexion ankle angle of 4 degrees. Comparisons were also made between experimental group subjects and control subjects. The study concluded that for both stair ascent and descent, the prosthesis resulted in an improvement in kinematic and kinetic measures of the knee with an increase of knee flexion and increase of the knee stability during stance.

Fradet and colleagues (2010) describe a nonrandomized controlled study involving 16 transtibial amputee subjects using the Proprio Foot and 16 healthy controls. All participants underwent conventional 3D gait analysis while walking up and down a ramp. The authors reported that subjects, when using the foot ankle prosthesis in adaptive mode, exhibited more physiologic kinematics and kinetics of the lower limbs during ramp ascent but not during ramp descent. Additionally, subjects using the prosthesis in adaptive mode reported subjective feelings of being safer during ramp descent.

Herr and colleagues (2011) conducted a small study investigating the metabolic energy costs, preferred velocities, and biomechanical patterns in 7 unilateral transtibial amputees and 7 non-amputee controls. The experimental group was tested using both a bionic prosthesis (PowerFoot BiOM) and their own passive-elastic prosthesis. The authors reported that compared with the passive-elastic prosthesis, the bionic prosthesis decreased metabolic cost by 8%, increased trailing prosthetic leg mechanical work by 57% and decreased the leading biological leg mechanical work by 10%, on average, across walking velocities of 0.75-1.75 m s^{-1}. Use of the bionic prosthesis also increased preferred walking velocity by 23%. They concluded that the bionic prosthesis resulted in metabolic energy costs, preferred walking velocities and biomechanical patterns that were not significantly different from people without an amputation. However, due to the small study size it is unclear whether or not these results would be seen in the general population.

In 2012, Gailey and colleagues published the results of a study involving 10 subjects with transtibial amputation. All subjects were tested at baseline and after receiving training with their existing prosthesis and with the study socket and four different prosthetic feet, including SACH (solid ankle cushion heel), SAFE (stationary attachment flexible endoskeletal), Talux, and Proprio Foot over 8 to 10 weeks. The authors reported that no differences were detected by the PEQ-13, Locomotor Capabilities Index (LCI), 6-minute walk test (6MWT), or step activity monitor. On the Amputee Mobility Predictor with a prosthesis (AMPPRO) tool, they did note a significant difference between the baseline measures with the subject's existing prosthesis and the Proprio Foot ($p<0.05$). Additionally, only the Proprio Foot demonstrated signifncantly greater 6MWT in the subgroup of subjects without peripheral vascular disease (PVD, $p<0.05$).

Delussu (2013) described a study involving 10 subjects with transtibial amputation and K-2 and above functional levels who underwent trials with either a Proprio Foot or a dynamic carbon fiber foot. The objective of the study was to assess the energy cost of walking (ECW). Subjects were asked to walk at a self-selected speed on a regular floor surface and on a treadmill with -5%, 0% and 12% slopes while instrumented for various physical measures. The authors reported that ECW with the Proprio-Foot obtained in the final floor-walking test was significantly

lower than ECW with the control foot (p=0.002). The authors reported no significant improvements in walking speed, Hill assessment index, timed up and go test, LCI-5, objective perceived mobility or walking ability.

Agrawal (2013) published a study involving 10 K-2 level and above subjects with transtibial amputation. Subjects were evaluated while wearing each of the following prostheses: SACH, SAFE, Talux, and the Proprio Foot in a random fashion. All subjects wore a custom-fit socket with each prosthesis. Following a 10- to 14-day accommodation and training period with each foot, subjects were asked to ascend and descend a set of stairs to assess movement proficiency and symmetry, ground reaction force and center of mass. Subjects were stratified by K-level (n=5 per group). The Proprio Foot demonstrated a significantly greater interlimb symmetry during ascent than the SACH and SAFE prostheses. The authors commented that the swing-phase dorsiflexion appeared to promote greater interlimb symmetry because it facilitated forward motion of the body, resulting in a heel-to-toe center of pressure trajectory.

In 2014, Darter reported the results of a small nonrandomized study involving 6 subjects who performed treadmill walking tests using their customary prosthesis, the Proprio Foot in its "on" setting (Pon), and lastly, the Proprio Foot in the "off" setting (Poff). Through the study, the slope of the treadmill was changed to three different slopes, -5°, 0°, and +5°. The results included the observation that metabolic energy expenditure, energy cost for walking, and rating of walking difficulty were not statistically different between the Pon and Poff settings for all tested slopes. However, for slope descent, energy expenditure and energy cost for walking improved significantly by an average of 10%-14% for both the Pon and Poff compared to the customary limb. Walking difficulty also improved with slope descent for both the Pon and Poff compared to the customary device. An improvement with slope ascent was found for Pon compared to the customary limb only. The authors concluded that adaptive ankle motion provided no meaningful physiological benefit during slope walking but was less demanding than the customary device for slope descent.

Rosenblatt and others (2014) reported the results of a small study of 8 subjects using both a standard non-powered foot prosthesis and the Proprio Foot. All subjects underwent a treadmill-based evaluation using a motion capture system, first with their standard foot and then with the Proprio Foot. The goal of this study was to evaluate minimum toe clearance and calculate likelihood of tripping. The authors reported that there was a 70% increase in minimum toe clearance with the Proprio Foot device. Regression analysis found significant differences in average hip, knee, and ankle angles at time of minimum toe clearance between the two device types ($p<0.05$ for all). The authors concluded that the Proprio Foot device contributes significantly to an increased minimum toe clearance measurement which may provide a significant contribution to decreased likelihood of tripping. However, no actual real-life use results were reported regarding fall occurrence.

Agrawal (2015) published the results of a controlled study involving 10 K-2 to K-4 Level subjects who underwent six testing sessions with four different prostheses: (1) SACH foot, (2) SAFE foot, (3) Talux foot, and (4) the Proprio Foot. The initial testing session was conducted with all subjects using their usual foot prosthesis. This was followed by a 2-week period of training and acclimation to a new standardized socket which was used in combination with their usual prosthesis, followed by another testing session. This process was then repeated with each of the four study prostheses. For the ramp ascent test, no significant differences were reported between prosthesis groups. For the stair descent test, the data indicated that there was a significant benefit in energy

expenditure between the Proprio Foot and the basic SACH foot prosthesis ($p<0.05$). No significant differences were reported between the Talux foot and the Proprio Foot. This study seems to indicate little benefit to the use of the Proprio Foot compared to the non-microprocessor controlled Talux foot prosthesis.

At this time, further study is needed to establish a meaningful clinical outcome benefit of the Proprio Foot over the conventional ankle-foot prosthesis.

Currently, there is no peer-reviewed published evidence addressing the clinical efficacy of the PowerFoot BiOM or the Endolite élan microprocessor controlled foot-ankle prostheses. Such information is necessary to properly evaluate the impact of this device.

Background/Overview

Prostheses are devices that are used to replace or compensate for the absence of a body part. Such absence may be present at birth or due to amputation as the result of illness or trauma. Prosthetic devices have been used to replace body parts from individual fingers to entire limbs. Additionally, prostheses may include replacements for other body parts including breasts, eyes, and teeth. There are a wide variety of prostheses for the replacement of limbs made from various materials using a wide range of technologies.

The functional ability level of individuals with missing lower limbs is commonly rated via the use of the Medicare Functional Classification Level (MFCL), also known as K-Levels or Functional Levels (Centers for Medicare & Medicaid Services, 2017). The system is used to stratify individuals based on their ability to ambulate and function in various conditions. Additionally, K-Levels are commonly used to guide the appropriateness of specific types of lower limb prostheses. Provided below are definitions of these levels. Please note that within the functional classification hierarchy, bilateral amputees often cannot be strictly bound by functional level classifications.

Level 0: 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.
Level 1: 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 ambulator.
Level 2: Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
Level 3: Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

For prostheses used to replace lower limbs where the leg is missing from the knee or above, there is a need for a device to replace the normal function of the knee. In people with intact legs, the knee naturally and automatically

adjusts its action to the speed and stride of the person. Conventional prosthetic legs use a pneumatic or hydraulic return mechanism to mimic the natural pendulum action of the knee. This mechanism is usually set by a prosthetist to work at the individual's normal walking speed and does not allow any room for variation in speed. Changes in an individual's walking speed require the individual to compensate for any delay in knee action through a variety of means including altering stride length and body position, among others. Such maneuvers lead to an abnormal gait and require extra effort and concentration for what is normally an unconscious act.

Microprocessor controlled lower limb prostheses for the transfemoral amputee use computer-controlled mechanisms to detect step time and alter prosthetic function such as knee extension level to suit walking speed or angle of the terrain. More advanced models, such as the Otto-Bock C-Leg, have multiple sensors that gather and calculate data on various parameters such as the amount of vertical load, ankle movement, and knee joint movement in an attempt to mimic more natural leg function to provide stability and gait fluidity as needed on uneven terrains and/or during sports activities. The claimed advantages of a computerized leg prosthesis include a decreased level of effort in walking, improved symmetry of movement between legs leading to more natural movement, and the avoidance of falls.

For individuals who have lost a limb below the knee, there is a need for a device to replace the function of the ankle and foot. Stair ambulation is limited in the transtibial amputee due to the neutral and fixed ankle position which exists in traditional prosthetic ankles. Under study are newer prosthetic ankles which adjust the foot-ankle angle during the swing phase using sensor and microprocessor technologies to identify sloping gradients and the ascent or descent of stairs after the first step. Users can place the foot fully on a step when climbing or descending stairs and it will automatically adapt the ankle position to enable the next step. On ramp ascent and descent, adaptation begins on the second step and the device makes small adjustments until it reaches the degree of slope of the ramp. The Proprio Foot is one such "quasi-passive" device. The device is passive since no power is generated through the ankle in stance. The device is also said to be designed to dorsiflex, or bring the toes closer to the shin, during the swing phase to improve ground clearance, improve gait symmetry and reduce the likelihood of falls. Other claims include the device's ability to assist in standing from a seated position and plantar (bottom of the foot) flexion when kneeling, sitting and lying down. Early pilot studies suggest that both during stair ascent and descent, the Proprio Foot improves knee flexion kinematics. The weight of the Proprio Foot device is more than twice the weight of a conventional ankle-foot prosthetic such as the LP Vari-Flex (995g versus 405g). Concern has been raised that because of its weight, the Proprio Foot might not benefit amputees with limited endurance and knee musculature.

Also under study are active prosthetic ankle prostheses which do generate power during the ankle stance. Early results are said to be promising, but these devices are bulky and of considerable weight due to the motor and batteries needed to generate power.

Another type of microprocessor controlled foot-ankle prosthetic device, the PowerFoot BiOM, is proposed to simulate the natural function of the foot by simulating the action of the ankle, Achilles tendon and calf muscles to move the individual forward when they step. These devices utilize various sensors in the ankle and foot to detect foot position, direction, and force of movement. This data is analyzed by several microcomputers that translate it into instructions for a motor-activated spring device in the sole of the prosthesis. The loaded spring device is released as the sensor detects that the user is taking a step forward, forcing the ball of the foot downwards and

propelling the foot forward. The spring mechanism reloads itself in-between steps. This device uses batteries to operate this system and requires daily recharging.

The FDA classified the Proprio Foot as a Class I device and the PowerFoot as a class II device, both exempt from requirements for pre-market notification by submission and FDA review of a 510(k) clearance. This is based on the level of active assistance provided and the perceived risk associated with these devices.

Definitions

Computerized leg prosthesis: A prosthetic device for individuals with some degree of leg amputation which uses a computer microprocessor to adapt prosthetic function to environmental conditions that impact locomotion.

Kinematics: A study of motion without regard to the forces present; mathematical methods to describe motion.

Prosthesis: For the purposes of this document, a device used to replace or compensate for the absence of a limb. Prostheses may be artificial replacements for a wide variety of body parts.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

When services may be Medically Necessary when criteria are met:

HCPCS	
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)
ICD-10 Diagnosis	
	All diagnoses, including, but not limited to, the following:
S78.111D, S78.111S	Complete traumatic amputation at level between right hip and knee, subsequent encounter or sequela
S78.112D, S78.112S	Complete traumatic amputation at level between left hip and knee, subsequent encounter or sequela

S78.119D, S78.119S	Complete traumatic amputation at level between hip and knee, unspecified side, subsequent encounter or sequela
S88.011D, S88.011S	Complete traumatic amputation at right knee level, subsequent encounter or sequela
S88.012D, S88.012S	Complete traumatic amputation at left knee level, subsequent encounter or sequela
S88.019D, S88.019S	Complete traumatic amputation at knee level, unspecified side, subsequent encounter or sequela
Z89.611	Acquired absence of right leg above knee
Z89.612	Acquired absence of left leg above knee
Z89.619	Acquired absence of unspecified leg above knee

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met, or when the code(s) describes a procedure indicated in the Position Statement section as not medically necessary.

When services are Investigational and Not Medically Necessary:

HCPCS

L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s) [when specified as addition to microprocessor controlled ankle-foot system]
L5973	Endoskeletal ankle-foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source

ICD-10 Diagnosis

All diagnoses

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Index

The use of specific product names is illustrative 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.

Document History

Status	Date	Action
Revised	01/24/2019	Medical Policy & Technology Assessment Committee (MPTAC) review. MN criteria related to mobility and stability benefit, ambulation (including distance and on uneven terrain or stairs) were clarified. NMN statement clarified. Updated Rationale and References sections.
	06/21/2018	Revised Rationale section for Herr, 2011 study to identify device used.
Reviewed	05/03/2018	MPTAC review. Updated Rationale and References sections.

Revised	03/22/2018	MPTAC review. Added functional K-Levels to clinical indications section. Updated Background, Rationale, References, and Index sections.
Reviewed	01/25/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale and References sections.
Revised	02/02/2017	MPTAC review. Clarified MN statement criteria regarding demonstrating ability to ambulate faster than baseline rate. Updated Description, Rationale, References and Index sections.
Reviewed	11/03/2016	MPTAC review. Updated Rationale and References sections.
Reviewed	11/05/2015	MPTAC review. Updated Rationale and Reference sections. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated Rationale and Reference sections.
Reviewed	11/14/2013	MPTAC review. Updated Coding section with 01/01/2014 HCPCS changes.
Reviewed	11/08/2012	MPTAC review. Updated Rationale, Reference and Index sections. Updated Coding section with 01/01/2013 HCPCS changes.
Reviewed	11/17/2011	MPTAC review. Added the Genium Bionic Prosthetic System to existing medically necessary statement addressing microprocessor controlled lower limb prosthesis. Added PowerFoot BiOM device to existing investigational and not medically necessary statement addressing microprocessor controlled foot-ankle prosthesis. Updated Rationale, Background, and Reference and Index sections.
Reviewed	02/17/2011	MPTAC review. Updated Index section.
Revised	02/25/2010	MPTAC review. Added microprocessor controlled foot-ankle prosthesis (e.g., Proprio Foot) as investigational and not medically necessary for all indications. Updated Coding, Rationale and Reference sections.
Revised	02/26/2009	MPTAC review. Added medically necessary position and criteria for microprocessor controlled lower limbs. Updated Rationale, Coding and Reference sections.
Revised	08/28/2008	MPTAC review. Changed position statement from Investigational and Not Medically Necessary to Not Medically Necessary. Updated Rationale, Coding and Reference sections.
Reviewed	05/15/2008	MPTAC review. Updated Rationale and Reference sections
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	05/17/2007	MPTAC review. Updated Rationale and Reference sections. Coding updated; removed HCPCS L5846 and L5847 deleted 12/31/2004, and K0670 deleted 12/31/2005.
Reviewed	06/08/2006	MPTAC review.
	01/01/2006	Updated Coding section with 01/01/2006 CPT/HCPCS changes
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	09/19/2003	OR-PR.00003	Computerized Limbs
WellPoint Health Networks, Inc.	06/24/2004	9.01.07	Microprocessor Controlled Lower Limb Prosthesis (Above Knee Prosthetics)