Anthem

Clinical UM Guideline

Subject: Microprocessor Controlled Lower Limb Prosthesis
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Description

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

Clinical Indications

Medically Necessary:

I. Microprocessor controlled lower limb prostheses (for example, Otto-Bock C-Leg device, Otto-Bock Genium Bionic Prosthetic System, the Ossur Rheo Knee or the Endolite Intelligent Prosthesis) are considered **medically necessary** for individuals with transfemoral (above knee) and knee disarticulation amputations 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; **and**
      3. The provider has documented that there is a reasonable likelihood of better mobility or stability with the device instead of a mechanical knee prosthesis; **and**
      4. There is documented need for ambulation in situations where the device will provide benefit (for example, regular need to ascend/descend stairs, traverse uneven surfaces or ambulate for long distances [generally 400 yards or greater cumulatively])
      and
   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.

II. Microprocessor controlled foot or ankle systems (such as the Propio Foot or Endolite élan foot) are considered **medically necessary** for individuals with transtibial amputation 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; **and**
      3. The provider has documented that there is a reasonable likelihood of better mobility or stability with the device instead of a mechanical foot or ankle prosthesis; **and**
      4. There is documented need for ambulation in situations where the device will provide benefit (for example, regular need to ascend/descend stairs, traverse uneven surfaces or ambulate for long distances [generally 400 yards or greater cumulatively]);
      and
   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.

Use of both a microprocessor controlled knee prosthesis and microprocessor controlled foot-ankle prosthesis simultaneously for the same individual, either for the same limb or for different limbs, is considered **medically necessary** when the applicable criteria for knee prosthesis and foot-ankle prosthesis above have both been met.

Repairs and replacements of a myoelectric lower extremity prosthetic devices are considered medically necessary when:

A. Needed for normal wear or accidental damage; **or**
B. The changes in the individual's condition warrant additional or different equipment, based on clinical documentation.

Not Medically Necessary:

Microprocessor controlled lower limb (knee/foot/ankle) prostheses are 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.

Repairs and replacements of a myoelectric lower extremity prosthetic devices are considered **not medically necessary** when the criteria above have not been met

Microprocessor controlled foot-ankle prostheses with power assistance, which includes any type of motor, (for example, the PowerFoot BiOM) are considered **not medically necessary** for all indications.

Coding

The following codes for treatments and procedures applicable to this guideline 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.

Knee prostheses
When services may be Medically Necessary when criteria are met:

HCPCS	
L5615	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
L5857	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 for a situation indicated in the Clinical Indications section as not medically necessary.

Ankle/Foot prostheses
When services may be Medically Necessary when criteria are met:

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

ICD-10 Diagnosis	
	All diagnoses, including, but not limited to, the following:
S88.111D, S88.111S	Complete traumatic amputation at level between knee and ankle, right lower leg, subsequent encounter or sequela
S88.112D, S88.112S	Complete traumatic amputation at level between knee and ankle, left lower leg, subsequent encounter or sequela
S88.119D, S88.119S	Complete traumatic amputation at level between knee and ankle, unspecified lower leg, subsequent encounter or sequela
Z89.511	Acquired absence of right leg below knee
Z89.512	Acquired absence of left leg below knee
Z89.519	Acquired absence of unspecified leg below knee

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met, or for a situation indicated in the Clinical Indications section as not medically necessary.

When services are also 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]

ICD-10 Diagnosis	
	All diagnoses

Repair
When services may be Medically Necessary when criteria are met:

HCPCS	
L7510	Repair of prosthetic device, repair or replace minor parts
L7520	Repair prosthetic device, labor component, per 15 minutes

ICD-10 Diagnosis	
	All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met.

Discussion/General Information

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, individuals with bilateral amputations 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 individuals with transfemoral amputations 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 individuals with transtibial amputations 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 individuals with amputations 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 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.

Microprocessor Controlled Knee Prosthesis

Microprocessor controlled knee prosthesis have been clinically available and widely used for some time. While the studies addressing these devices are often relatively underpowered and may not be randomized, the clinical benefits of the devices have been well established. Hafner (2007) reported the findings of a underpowered, nonrandomized, cross-over controlled design study in which each participant was exposed to two different prosthetic limb conditions (mechanical and microprocessor controlled C-Leg) twice during the trial. This study included 21 participants, each of whom used both a standard mechanical knee and lower limb prosthesis and the C-Leg microprocessor controlled prosthesis. While 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 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. In addition, the self-reported frequency of stumbles and falls was lower for the C-Leg

prosthesis.

Williams (2006) described a randomized two-group cross-over design study of C-Leg compared to a standard hydraulic knee prosthesis (Mauch SNS® knee). The report concluded that, in non-demanding walking conditions with experienced individuals with amputations, participants reported the C-Leg required less cognitive attention than the non-computerized knee. Kaufman (2007) compared the C-Leg to a standard hydraulic prosthesis in gait and balance parameters in 15 participants and found 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. Seymour (2007) compared energy expenditure, obstacle course negotiation and quality of life (QOL) measures in 10 individuals who used C-Leg and a non-computerized prosthesis. This study found a statistically significant lower energy consumption rate for participants when wearing their C-Leg devices at both typical and fast paces, an increase in the number of steps taken, reduced elapsed time, and a reduction in the number of times out of bounds through an obstacle course.

Hafner (2009) reported the results of a nonrandomized crossover study involving 17 participants with unilateral transfemoral amputations. Participants 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. All participants began the study using their standard prosthesis and underwent functional evaluations at 2 months. Participants then underwent fitting, training, a 2-month acclimation period, and another round of functional evaluations with the C-Leg prosthesis. Participants were then transitioned back to their standard prosthesis for 2 weeks before another round of assessments was given. Once the assessments were completed, all participants were sent home with both prostheses and told to use them as they desired. Additional assessments were conducted 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 participants, 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 for K-2 than for K-3 participants. 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 participants 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 participants 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 participants were reclassified as K-3 and 33.3% of K-3 participants were reclassified as K-4. However, 2 K-3 participants 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 (2011) conducted a 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 individuals with amputations as participants, their study only included K-2 participants, 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 participants were randomized, but only 28 participants (68%) completed the trial. The authors further stratified study participants into three groups (“High”, “Intermediate", or “Low”) based on expert opinion regarding functional levels within the MFCL category. Participant 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 participants demonstrated no benefit from a microprocessor controlled prosthesis at any level of the test. Both Intermediate and High group participants 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 participants 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 participants 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, particularly in K-2 ambulators.

Theeven (2012) published on 30 K-2 participants using a randomized cross-over design. Full datasets were available for only 19 participants at the completion of the study, but all 30 were included in the intent-to-treat analysis. Participants 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. Participants 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. Participant activity levels were monitored via uniaxial accelerometer. The results indicated that the participants' perceptions regarding ambulation, residual limb health, utility, and satisfaction were significantly higher when participants 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 individuals with amputations report benefitting in terms of their performance from using a microprocessor-controlled prosthetic knee (MPK); this is not reflected in their actual daily activity level after 1 week of using an MPK.

Burnfield (2012) investigated the sequential use of standard mechanical prostheses followed by the C-Leg device in 10 K-2 participants 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.

Bellmann (2012) compared performance parameters of the C-Leg vs. the Genium device in 11 K-3-4 C-Leg users. 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 brief acclimation time and very small sample size of this study do not allow the results to be generalized to a wider population.

Theeven (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. The researchers concluded that "scientifically valid evidence regarding the performance of persons with an MPK in everyday life is limited. Future research should specifically focus on activities and participation to increase the understanding of the possible functional added value of MPKs."

Highsmith (2014) studied 15 K-3-4 ambulators on 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 participants (average, 1.4 ± 2.3 falls per person) compared with 14 falls among 4 participants (average 0.9 ± 2.1 falls per person) while utilizing the C-Leg.

Eberly (2014) reported on stride characteristics, kinematics, kinetics, and electromyographic activity on a 10 meter walkway with both their standard prosthesis and then with the C-Leg Compact in 10 K-2 ambulatory participants at self-selected comfortable and fast walking paces. 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.

Prinsen (2015) published the results of a randomized controlled cross-over study involving 10 participants (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, participants were given a battery of tests including the TUG test, Timed Up and Down Stairs Test, and Standardized Walking Obstacle Course. Following these measurements, participants 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 participants 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.

Wong (2015) published on 8 participants over 40 years of age with peripheral arterial disease-related amputations. There were 2 K-1 participants, 2 K-2 participants, and 4 K-3 participants. Unilateral amputations were noted in 6 participants and 2 were bilateral amputations. All participants 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, participants 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 participants 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 participants descended an instrumented 10° slope at a self-selected walking velocity. The authors reported that the use of the X2 device in the participants 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.

Hahn (2016) conducted a retrospective cross-sectional cohort analysis involving routine trial fitting data from 899 participants 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, participants 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. Participants with prior C-Leg experience demonstrated benefits during advanced maneuvering. 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.

Prinsen (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 participants 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 (2018) reported on a sample of 5 elderly, low-active (K-2) individuals with transfemoral amputations. All participants were fitted with a microprocessor controlled device specifically designed for older and low-active individuals with transfemoral amputations (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 participants. 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.

According to the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation (2017), it is suggested that a microprocessor-controlled knee unit should be offered over a non-microprocessor knee unit for ambulation to reduce risk of falls and to maximize the satisfaction of the individual. The guideline also stated the following:

> Access to early weight-bearing prostheses has expanded through the introduction of several different prefabricated systems that are commercially available. More research is required to further delineate the risks and benefits associated with this intervention as well as to further determine the differences between articulated and non-articulated devices.

Kaufman (2018) published a prospective non-randomized cross-over trial involving 50 participants assessed at K-2 (n=48) and K-3 (n=2) levels who were current users of a non-microprocessor controlled prosthesis. Participants were randomly assigned to one of four different microprocessor controlled prostheses (OttoBock Compact, Ossur Rheo Knee 3, Endplate Orion 2, or Freedom Innovation Plié 3). The study began with all participants 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 participant 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 participants 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 participants 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).

Wurdeman (2018) reported the results of a retrospective study of a convenience sample of 450 participants with either below the knee amputation (n=150) or above the knee amputation who used a standard knee prosthesis (n=150) or a microprocessor controlled knee prosthesis (n=150). Participants were matched for age and Functional Comorbidities Index (FCI) results, but not for height or weight. The results from the PLUS-M survey tool indicated that while participants in the microprocessor knee group had significantly greater mobility than the standard knee prosthesis group (p<0.001), both groups had poorer mobility than the below the knee amputation group (p=0.003). The authors concluded that on the basis of the PLUS-M survey tool, the use of a microprocessor controlled knee prosthesis provided improved functional mobility to individuals with above the knee amputations.

Bellmann (2018) published the results of a crossover comparative trial involving 6 K3-4 participants undergoing repeat trials comparing the Otto-Bock C-Leg 4 or the Ossur Rheo Knee XC on a 12 m instrumented walkway, on stairs, and up and down and 10^{o} slope. A tripping simulation was also conducted. The authors concluded that when walking down stairs, on slopes or while recovering from a stumble, the C-Leg demonstrated a reliable prosthetic side load-bearing capacity resulting in reduced loading on the residual body. The Rheo Knee XC, in contrast, required increased compensatory movements of the remaining locomotor system in order to compensate for reduced load-bearing and safety reserves.

Thiele (2019) reported the results of a crossover study involving 4 K3 participants with above the knee amputations who underwent a series of 8 to 10 trials involving walking at self-selected and fast speeds down a 12 m instrumented walkway with each of three microprocessor controlled knee devices: 1) the Otto-Bock C-Leg 4, 2) the Freedom Plié, 3) the Ossur Rheo Knee 3. The authors reported significant differences between devices with regard to both self-selected and fast speed (p=0.03) and conscious stance phase flexion (p<0.001). The slope of the linear correlation between the maximum knee flexion angle and gait velocity was similar between the three devices (R^2=0.02). Mean slope of the swing flexion behavior of the prosthetic leg, when compared to the contralateral side showed decreasing correlation when evaluating at the Plié device (R^2=0.9), the Rheo Knee (R^2=0.52), and the C-Leg (R^2=0.26). No stumbles were reported in any group. The authors concluded that the biomechanical results showed that only if a knee joint adapts flexion and extension resistances by the microprocessor can all known advantages of MPKs become apparent, but not all users may benefit from the examined functions.

Jayaraman and colleagues (2021) conducted a randomized crossover longitudinal clinical trial to investigate the benefits of using an MPK C-Leg in a group of individuals with transfemoral amputation due to dysvascular or diabetic conditions. The study included 10 individuals, 4 males and 6 females, who were randomized to one of two groups, either an intervention with the MPK with a standardized 1M10 foot or the NMPK with a standardized 1M10 foot. The mean age of the participants was 63 ± 9 years and they had a mean time of 5.8 ± 8.1 years since their amputation. Each intervention lasted for 6 months which included 3 months of acclimation and 3 months of take-home trial to monitor home use. At the end of each intervention, clinical and self-reported outcomes were collected to compare with their baseline. Clinical performance-based measures consisted of the 10-minute walk test (10MWT), 6-minute walk test (6MWT), BERG balance test, Four Square Step Test (FSST), and the TUG. These performance measures were used to assess the balance and gait capabilities. Participants were allowed to use assistive devices during the acclimation sessions and during the outcomes testing. In comparison to baseline gait speed, 66% of the participants improved their gait speed above K3 gait speed when using the MPK C-Leg + 1M10, while only 33% of the participants using the NMPK and 1M10 feet improved their gait speed above K3 level gait speed. In regard to balance, participant balance scores improved to values within the range of scores achieved by individuals with K3 functional level (BERG ≥ 50.5/56) when using the MPK C-Leg combination. The researchers concluded statistically significant and clinically meaningful improvements were observed in gait performance, safety, and self-reported

measures (PEQ-A) when using the MPK C-Leg + 1M10 foot combination in comparison to their baseline condition.

Thibaut and colleagues (2021) conducted a systematic review of 18 articles that included 7 RCTS, 6 cross-sectional and 5 follow-up studies to evaluate the impact of the use of all types of MPKs on an individual's functional status and quality of life. One of the clinical trials tested the effect of a C-Leg versus the Genium prosthesis in 20 individuals. The prosthesis was used for a period varying from 2 weeks to 3 months depending on the individual's ability. Overall, the Genium induced stronger improvement on different gait parameters and functional outcomes compared to the C-Leg, except for the stepping rate which was found to be better in the C-Leg compared to the Genium. One prospective clinical trial evaluated a group of 75 previously fitted individuals and a group of 25 non-previously fitted individuals with amputations after 6 months of use of a C-Leg. The results of the study suggested that active individuals with transfemoral amputations with a prescribed C-Leg may show improved locomotor ability, satisfaction and physical component of quality of life as compared with the experience with a previous mechanical device. A large sample (n=602) retrospective trial compared different types of MPKs. The participant's functional mobility and satisfaction were similar among the four groups, as well as for the number of falls. However, a better quality of life was identified for the group using the C-Leg compared to the Plie®. There was no other difference found for any of the other variables. The authors wanted to note that many studies comparing different kinds of MPKs were carried out with a small number of participants and therefore, were not reported in their systematic review as they only included trials with at least 20 participants in order to have a representative sample. The authors also noted that the functionalities of the C-Leg have improved over time and the current available C-Leg MPK devices are more advanced compared to those of 5 or 10 years ago. The authors concluded that although it was clear that MPKs outperform NMPKs both for functional status and quality of life, additional benefits of one MPK over another is less clear and that future studies are required to clarify these aspects.

Palumbo (2022) evaluated the impact of knee prosthesis type on falls in a retrospective study involving data from 815 prosthesis-naive participants with new unilateral transfemoral amputation or knee disarticulation undergoing inpatient rehabilitation. Participants used one of 4 types of prostheses: 1) locked knees (17.4% of participants), 2) articulating mechanical knees (AMKs, 7.8%), 3) fluid-controlled knees (34.5%), and 4) microprocessor controlled knees (40.4%). The data analyzed involved 1486 hospitalizations. Males accounted for 91% of the participant pool. One-hundred nine (109) falls occurred in 88 participants during 32,213 inpatient-days. This was calculated to be 3.35 falls per 1000 patient-days, as estimated by the mixed-effect Poisson model. Data for what prosthesis was used during 16 falls was unavailable, resulting in 93 falls available for analyses. Most falls (73.1%, 68 falls) occurred while the participant was wearing a prosthesis. Prosthesis type was significantly associated with falls (p=0.001). In particular, fluid-controlled knees expose participants to a higher fall rate than both locked knees (p=0.013) and microprocessor controlled knees (p=0.009). The authors concluded that fluid-controlled prosthetic knees expose inpatients with transfemoral amputation to higher incidence of falling than microprocessor controlled knees during rehabilitation training.

Stevens and Wurdeman (2019) published recommendations for the selection of individuals with unilateral transfemoral amputations. In this document they proposed the following recommendations:

> Recommendation 1. Fluid knee benefits and indications: Knees with hydraulic or pneumatic swing resistance are indicated for active walkers, permitting increased walking comfort, speed, and symmetry.
> Recommendation 2. Microprocessor knee benefits: Compared with nonmicroprocessor knees: a) With respect to self-report indices and measures, microprocessor knees are indicated to reduce stumbles, falls, and associated frustrations as well as the cognitive demands of ambulation. b) With respect to self-report indices and measures, microprocessor knees are indicated to increase confidence while walking, self-reported mobility, satisfaction, well-being, and quality of life. c) With respect to physical performance indices and measures, microprocessor knees are indicated to increase self-selected walking speed, walking speed on uneven terrain, and metabolic efficiency during gait.
> Recommendation 3. Microprocessor knee equivalence: Given the comparable values observed with the use of microprocessor and nonmicroprocessor knees with regard to daily step counts, temporal and spatial gait symmetry, self-reported general health, and total costs of prosthetic rehabilitation, these parameters may not be primary indications in prosthetic knee joint selection.
> Recommendation 4. Microprocessor knees for limited community ambulators: Among limited community ambulators, microprocessor knees are indicated to enable increases in level ground walking speed and walking speed on uneven terrain while substantially reducing uncontrolled falls and increasing both measured and perceived balance.

Microprocessor controlled lower limb prostheses are appropriate for individuals who meet criteria for fitness, health and daily utilization expectations. The currently available scientific evidence demonstrates 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, 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. 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 evidence-based literature reviewed for the microprocessor controlled lower limb prosthesis evaluated actual and functional outcomes. The evidence includes a number of participant comparisons of the microprocessor controlled knee versus non-microprocessor controlled knee joints. Many of the studies reflect an objective improvement in function in regard to some outcome measures when the microprocessor controlled knee is used as compared to a more traditional non-microprocessor controlled knee. In addition, some of the literature reviewed revealed the microprocessor controlled knee prosthesis demonstrated a significant improvement with individuals in such areas of SAI scores, time to descend scores and improvement in function. Improvement of the individual's performance within these areas can potentially reduce adverse events. The choice of the most appropriate prosthetic design will be impacted by the individual's underlying activity level, improved functional mobility and other factors that would improve walking performance.

Microprocessor Controlled Foot and Ankle Prosthesis

Microprocessor controlled foot and ankle prosthesis are devices that involve the use of microprocessors to control the position and action of the prosthetic ankle joint to mimic natural joint resistance and motion. This process has been proposed to result in more

natural joint stability while standing and walking. Currently, two types of microprocessor-controlled foot-ankle prosthetic devices are discussed in the peer-reviewed literature, those without powered propulsion push-off at the end of the Stance Phase of the gait cycle and those with powered propulsion push-off at the end of the Stance Phase of the gait cycle. Examples of the former are the Proprio Foot and Endolite élan foot devices, while the latter includes the PowerFoot BiOM and emPOWER Ankle devices.

The VA/DOD Clinical Practice Guideline for Rehabilitation of individuals with Lower Limb Amputation (2017) suggest there are inconclusive studies regarding differences in socket design, prosthetic foot categories as well as advantages and disadvantages of various types of suspensions and interfaces. The guideline reports that each component of a prosthetic prescription should be carefully selected based on the capabilities and anticipated compliance of the user as well as the integrity and shape of the residual limb. The individual's desired outcome, goals, and the compatibility of the entire prosthetic system should also be a consideration when prescribing prosthetic components.

Microprocessor Controlled Foot-Ankle Prosthesis Without Powered Propulsion

These types of prostheses do not use electric power to augment push-off at the end of the Stance Phase of the gait cycle. It uses an inter-step accommodation strategy which mean that it only makes adjustments to the ankle when the foot is in the Swing Phase of the gait cycle. Furthermore, it does not make these adjustments on each step but instead requires multiple steps to adjust, depending on the terrain.

Wolf (2009) published a study of 12 participants using the Proprio Foot (Ossur) which measured socket pressures in individuals undergoing gait analysis during various locomotion tasks for five walking conditions with and without the device's ankle adaptation mode. The study concluded that the adaptive ankle-foot prostheses favorably altered joint kinetics and stump pressures on stairs and ramps.

Alimusaj (2009) published a study of three-dimensional (3D) gait analysis on stairs of 16 healthy controls and 16 individuals with transtibial amputations using the Proprio Foot. 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. 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 (2010) described a nonrandomized controlled study involving 16 individuals with transtibial amputations participants 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 participants, 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, participants using the prosthesis in adaptive mode reported participant feelings of being safer during ramp descent.

Gailey (2012) published the results of a study involving 10 participants with transtibial amputation. All participants 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 participant's existing prosthesis and the Proprio Foot ($p<0.05$). Additionally, only the Proprio Foot demonstrated signifncantly greater 6MWT in the subgroup of participants without peripheral vascular disease (PVD, $p<0.05$).

Delussu (2013) described a study involving 10 participants 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). Participants 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 participants with transtibial amputation. Participants were evaluated while wearing each of the following prostheses: SACH, SAFE, Talux, and the Proprio Foot in a random fashion. All participants wore a custom-fit socket with each prosthesis. Following a 10- to 14-day accommodation and training period with each foot, participants were asked to ascend and descend a set of stairs to assess movement proficiency and symmetry, ground reaction force and center of mass. Participants 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.

Darter (2014) reported the results of a nonrandomized study involving 6 participants 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 $+5^{\circ}$. 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 (2014) reported the results of a study of 8 participants using both a standard non-powered foot prosthesis and the Proprio Foot. All participants 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 participants 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 participants 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.

Colas-Ribas (2022) reported the results of a unblinded, randomized, controlled, cross-over study involving 45 participants with unilateral transtibial amputations. Participants underwent evaluation with both their prescribed unpowered device and the Proprio Foot. The study was conducted in 2 periods with 2 sequences of 34 days each using each device, with the selection of which device used first chosen at random. At the end of the 34-day period, participants underwent treadmill testing with 4 different speeds and inclines. The primary outcome was oxygen uptake (VO2), and secondary outcomes were postural balance and QOL. The authors reported no significant difference between groups with regard to energy expenditure at the highest performed activity ($p=0.93$). In static stabilometry evaluations, center or pressure was found to significantly reduced on an inclined ramp for the Proprio Foot vs. control prosthesis ($p<0.01$). QOL, as measured by SF-36, was reported to be significant improved after the use of the Proprio Foot vs. controls, both on the physical mental scores ($p<0.01$ for both). The authors concluded that use of the Proprio Foot improved balance, quality of life, and patient satisfaction despite no reduction or increase in energy expenditure.

Combined Microprocessor Controlled Knee And Microprocessor Controlled Foot-Ankle Prosthesis

The use of both microprocessor-controlled knee prosthesis and microprocessor-controlled foot-ankle prosthesis at the same time for the same limb has been proposed for certain individuals who may benefit from the use of both devices simultaneously. Such prosthesis may consist of two separate devices combined into one system by a provider or may come from the manufacturer as a single unit (e.g., Ossur Symbionic® Leg 3, Blatchford LiNX® Limb System). Use of such combined devices is rare and usually limited to high functioning individuals who are able to manage the weight of such devices.

Foot-Ankle Prosthesis with Powered Propulsion

These types of prosthetic devices offer powered propulsion of the foot by emulating the function and power of missing muscles and tendons of the ankle and foot. In addition, these devices automatically adjusts foot stiffness in the heel strike portion of the Stance Phase which has been proposed to optimize shock absorption and foot loading.

In 2007, the VA Office of Research and Development collaborated with researchers at MIT and Brown University to introduce a powered ankle-foot prosthesis that uses tendon-like springs and an electric motor to move users forward. According to the VA, studies have shown that individuals using the powered ankle-foot expend less energy while walking, have better balance, and walk 15 percent faster. The device originally sold as the BiOM Ankle and is now marketed as the emPOWER Ankle.

Herr (2011) conducted a study investigating the metabolic energy costs, preferred velocities, and biomechanical patterns in 7 individuals with unilateral transtibial amputations and 7 control individuals without amputations. The experimental group was tested using a 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.

Ferris (2012) reported on the results of a prospective study involving 11 participants with transtibial amputations and 11 healthy controls. All participants participated in a battery of tests including a 10-meter forward run, a 5-meter side-shuffle to right, a 10-meter side shuffle to left, a 5-meter side-shuffle to right, a 10-meter backward run, a Four Square Step Test, and hill and stair assessments. Participants in the amputation group conducted the tests first with an energy-storing and returning (ESR) prosthesis and then with the BiOM prosthesis. The authors reported that the BiOM prosthesis ankle range of motion was significantly larger (approximately 30%) than that of the ESR limb. However, both devices demonstrated significantly less ankle range of motion than the intact limbs. The BiOM prosthesis was reported to have generated significantly greater peak ankle power than control (35%) and ESR (approximately 125%) limbs, resulting in the BiOM limb absorbing twice the peak knee power observed in the control and intact limbs. The BiOM's limb peak hip power generation was approximately 45% greater at preswing than that of the intact limb. No significant differences were reported in walking velocity between the ESR and BiOM groups. The authors concluded that use of the BiOM appeared to increase compensatory strategies at proximal joints. The clinical impact of these benefits is unclear.

Gates (2013) reported a controlled study involving 11 participants with transtibial amputation who were asked to participate in two data collection trials involving different walking speeds across a loose rock surface using their standard ESR prosthesis and then the BiOM device. Participants using the BiOM had a 10% faster self-selected walking speed compared to when using the ESR device (1.16 m/s vs. 1.05 m/s; $p=0.031$). Ankle plantarflexion was also increased on their prosthetic limb throughout the gait cycle when wearing BiOM vs ESR devices, especially during push-off ($p<0.001$). A small (< 3°), but statistically significant decrease in knee flexion during early stance was noted with the BiOM device ($p=0.045$). No significant differences in kinematics of the knee and hip were reported, but participants had decreased medial–lateral motion of their center of mass when wearing the BiOM prosthesis ($p=0.020$). The authors concluded that use of the BiOM did not significantly alter their proximal joint kinematics when used on an irregular surface.

Grabowski (2013) reported the results of a controlled trial involving 14 participants, 7 with transtibial amputations and 7 healthy controls, subject to level ground walking trials at 0.75, 1.00, 1.25, 1.50, and 1.75 m/s. The amputation participants conducted their walking trials with their standard prosthesis and then with the BiOM prosthesis. The investigators were interested in how physical performance measures of the intact limb of the amputation group participants were impacted by the use of the BiOM prosthesis compared to the standard device and healthy controls. They reported that the use of the BiOM significantly decreased intact limb peak resultant forces and first peak knee external adduction moments. Loading rates were not significantly different between prosthetic feet. They concluded that use of the BiOM prosthesis could reduce the risk of comorbidities such as knee osteoarthritis. However, no long term data have yet been published addressing that proposition.

Gardinier (2018) reported the results of a controlled trial involving 10 participants with transtibial amputations and 10 healthy participants. Testing included an 8-meter walk test at self-selected speeds and an 8-minute treadmill test. Walking speed was measured during the former and metabolic rate during the latter. Amputation group participants were randomly assigned to undergo testing first with either the BiOM or their standard prosthetic device. The authors reported no significant differences between either of the prosthetic groups with regard to walking speeds or metabolic costs. This study did not demonstrate significant benefits with the use of the BiOM.

Kim (2021) reported the results of a unblinded, randomized, controlled, cross-over study involving 12 participants with unilateral transtibial amputations assigned to undergo a battery of tests with both their prescribed, unpowered prosthesis and the BiOM device. The BiOM was used first in the trial by 7 participants and the unpowered device by 5 participants, before crossover. Participants used the devices for 2 weeks while wearing activity monitors and laboratory testing was conducted to evaluate metabolism and QOL. Ten

participants completed the study, 9 whom were K3 ambulators and the tenth was a K4 ambulator. No differences between groups were reported with regard to fixed treadmill speed and self-selected walking speeds with the unpowered device (p=0.435) or BiOM (p=0.794), self-selected walking speed in the lab (p=0.452) or in daily life (p=0.226), metabolic cost of transport (p=0.585), or daily step count away from home (p=0.452). Results on the Prosthesis Evaluation Questionnaire indicated significantly less social burden with the BiOM (p=0.043). On SF-36 results, no significant differences were reported on the physical or mental components (p=0.48 and p=0.37, respectively). The results of this study indicate no significant overall benefits to the use of the BiOM device.

Evidence in the published peer-reviewed literature for the use of a microprocessor controlled foot or ankle prosthesis is comprised of underpowered non-randomized studies, which do not fully address functional or quality of life benefits for individuals with a functional K-3 level or above. However, consideration of clinical input and other relevant factors supports that use of these devices without powered propulsion in individuals with functional K-3 level or above is consistent with generally accepted standards of medical practice. Additional evidence is needed to better evaluate devices with a power propulsion to fully evaluate whether there are clinical presentations where that functionality improves outcomes over other 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.

Foot-Ankle Prosthesis Without Powered Propulsion: A prosthetic device that does not use electric power to augment push-off at the end of the Stance Phase of the gait cycle.

Foot-Ankle Prosthesis with Powered Propulsion: A prosthetic device that offers a powered push-off feature by emulating the function and power of lost muscles and tendons. The device automatically adjusts its foot stiffness in the heel strike portion of the Stance Phase which ensures optimum shock absorption and foot loading.

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

Multidisciplinary assessment: An evaluation process that may involve professionals from multiple medical specialties, including any of physiatrists, physical or occupational therapists, internal medicine, cardiologists, behavioral health, and others.

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.

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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.

History

Status	Date	Action
	12/28/2023	Updated Coding section with 01/01/2024 HCPCS changes, added L5615 replacing K1014 deleted as of 01/01/2024.
	10/25/2023	Corrected typo in MN and NMN repairs and replacement statements.
New	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development. Moved content of OR-PR.00003 to clinical utilization management guideline document with the same title.