BlueCross BlueShield of Alabama

Name of Policy:
Microprocessor-Controlled Lower Limb Prosthesis

Policy #: 083
Category: DME and Prosthetics

Latest Review Date: May 2018
Policy Grade: C

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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

Lower Extremity Prosthetics

More than 100 different prosthetic ankle-foot and knee designs are currently available. The choice of the most appropriate design may depend on the patient's underlying activity level. For example, the requirements of a prosthetic knee in an elderly, largely homebound individual will be quite different than a younger, active person. In general, key elements of a prosthetic knee design involve providing stability during both the stance and swing phase of the gait. Prosthetic knees also vary in their ability to alter the cadence of the gait, or the ability to walk on rough or uneven surfaces. In contrast to more simple prostheses, which are designed to function optimally at one walking cadence, fluid and hydraulic controlled devices are designed to allow amputees to vary their walking speed by matching the movement of the shin portion of the prosthesis to the movement of the upper leg. For example, the rate at which the knee flexes after "toe-off" and then extends before heel strike depends in part on the mechanical characteristics of the prosthetic knee joint. If the resistance to flexion and extension of the joint does not vary with gait speed, the prosthetic knee extends too quickly or too slowly relative to the heel strike if the cadence is altered. When properly controlled, hydraulic or pneumatic swing-phase controls allows the prosthetist to set a pace that is adjusted to the individual amputee from very slow to a race-walking pace. Hydraulic prostheses are heavier than other options and require gait training; for these reasons, these prostheses are generally prescribed for athletic or fit individuals. Other design features include multiple centers of rotation, referred to as "polycentric knees." The mechanical complexity of these devices allows engineers to optimize selected stance and swing-phase features.

Microprocessor-Controlled Prosthetic Knees

Microprocessor-controlled prosthetic knees have been developed, including the Intelligent Prosthesis (Blatchford, U.K.), the Adaptive (Endolite, England), the Rheo Knee® (Ossur, Iceland) and the C-Leg, Genium Bionic Prosthetic System, and the X2 and X3 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN). These devices are equipped with a sensor that detects when the knee is in full extension and adjusts the swing phase automatically, permitting a more natural walking pattern of varying speeds. For example, the prosthetist can specify several different optimal adjustments that the computer later selects and applies according to the pace of ambulation. In addition, these devices (with the exception of the Intelligent Prosthesis) use microprocessor control in both the swing and stance phases of gait. By improving stance control, they may provide increased safety, stability, and function; for example, the sensors are designed to recognize a stumble and stiffen the knee, thus avoiding a fall. Other potential benefits of microprocessor-controlled knee prostheses are improved ability to navigate stairs, slopes, and uneven terrain, and reduction in energy expenditure and concentration required for ambulation. The C-Leg was cleared for marketing in 1999 through the 510(k) process of the U.S. Food and Drug Administration (FDA, K991590). Next-generation devices such as the Genium Bionic Prosthetic system and the X2 and X3 prostheses utilize additional environmental input (e.g., gyroscope and accelerometer) and more sophisticated processing that are intended to create more

natural movement. One improvement in function is step-over-step stair and ramp ascent. They also allow the user to walk and run forward and backward. The X3 is a more rugged version of the X2 that can be used, for example, in water, sand, and mud. The X2 and X3 were developed by Otto Bock as part of the Military Amputee Research Program.

Powered Knee Prostheses

The Power Knee™ (Ossur), which is designed to replace muscle activity of the quadriceps, uses artificial proprioception with sensors similar to the Proprio Foot in order to anticipate and respond with the appropriate movement required for the next step.

Microprocessor-Controlled Ankle-Foot Prostheses

Microprocessor-controlled ankle-foot prostheses are being developed for transtibial amputees. These include the Proprio Foot® (Ossur) and the iPED (developed by Martin Bionics LLC and licensed to College Park Industries). Sensors in the foot determine the direction and speed of the foot's movement, allowing the foot to lift during the swing phase and adjust to changes in force, speed and terrain during the step phase. The intent of the technology is to make ambulation more efficient and prevent falls in patients ranging from the young active amputee to the elderly diabetic patient. The Proprio Foot® is the only microprocessor-controlled foot prosthesis that is commercially available at this time, and is a Class I device that is exempt from 510(k) marketing clearance. The manufacturer must register the prosthesis with the restorative devices branch of the U.S. Food and Drug Administration (FDA) and keep a record of any complaints, but does not have to undergo a full review. Information on the Ossur website indicates use of the Proprio Foot® for low to moderate impact for transtibial amputees who are classified as level K3.

Powered Ankle-Foot Prostheses

In development are lower-limb prostheses that also replace muscle activity in order to bend and straighten the prosthetic joint. For example, the Power Foot (developed at MIT and licensed to iWalk) is a myoelectric prosthesis for transtibial amputees that use muscle activity from the remaining limb for the control of ankle movement. This prosthesis is designed to propel the foot forward as it pushes off the ground during the gait cycle, which in addition to improving efficiency has the potential to reduce hip and back problems arising from an unnatural gait with use of a passive prosthesis.

Outcome Measures

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

Policy:

Effective for dates of service on or after October 11, 2017:

A high activity knee control frame (L5930) is only covered for patients whose functional level is K4.

Computerized lower limb prosthesis meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage when ordered for persons with above the knee (AKA) amputations and **all** the following indications are met:

- The patient is fit and active with at least a potential Functional Level 3 or 4 (*see Key Points*);
- The patient has the appropriate cognitive abilities to master use and care requirements for the technology;
- The patient does not have additional medical problems that would interfere with maintaining Functional level 3 or 4: i.e., disabling cardiovascular, neuromuscular, peripheral vascular, or musculoskeletal (other than amputation) conditions.

Computerized lower limb prosthesis is contraindicated when:

- Patient is historically non-ambulatory or has a potential Functional Level below 3 (*see Key Points*).
- Patient has demonstrated a lack of proper care for existing equipment.
- Patient is not motivated.
- Patient lives or works in a wet environment.

Blue Cross and Blue Shield of Alabama will cover **one** computerized prostheses per limb **per five years when medically indicated.** Coverage will not be provided if the prosthesis is functioning properly and in good general condition.

A **power knee does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered i**nvestigational**.

A **microprocessor-controlled or powered foot does not meet** Blue Cross and Blue Shield of Alabama's medial criteria for coverage and is considered **investigational**.

A **combination microprocessor-controlled powered foot and microprocessor-controlled knee prosthesis does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

A **combination microprocessor-controlled knee/ankle/foot (i.e. Linx) does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Effective for dates of service prior to October 11, 2017:
A high activity knee control frame (L5930) is only covered for patients whose functional level is K4.

Computerized lower limb prosthesis meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage when ordered for persons with above the knee (AKA) amputations and **all** the following indications are met:

- The patient is fit and active with at least a potential Functional Level 3 or 4 (*see Key Points*);
- The patient has the appropriate cognitive abilities to master use and care requirements for the technology;
- The patient does not have additional medical problems that would interfere with maintaining Functional level 3 or 4: i.e., disabling cardiovascular, neuromuscular, peripheral vascular, or musculoskeletal (other than amputation) conditions.

Computerized lower limb prosthesis is contraindicated when:
- Patient is historically non-ambulatory or has a potential Functional Level below 3 (*see Key Points*).
- Patient has demonstrated a lack of proper care for existing equipment.
- Patient is not motivated.
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Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administer benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This policy is updated periodically using the MEDLINE database. The most recent update was performed through February 05, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Amputees should be evaluated by an independent qualified professional to determine the most appropriate prosthetic components and control mechanism. A trial period may be indicated to evaluate the tolerability and efficacy of the prosthesis in a real-life setting. Decisions about the potential benefits of microprocessor-knees involve multiple factors including activity levels, as well as the patient's physical and cognitive ability. A patient's need for daily ambulation of at least 400 continuous yards, daily and frequent ambulation at variable cadence or on uneven terrain (e.g., gravel, grass, curbs), and daily and frequent use of ramps and/or stairs (especially stair descent) should be considered as part of the decision. Typically, daily and frequent need of 2 or more of these activities would be needed to show benefit.

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

The following are guidelines from the Veterans Health Administration Prosthetic Clinical Management Program Clinical Practice Recommendations for Microprocessor Knees.

Patient Selection and Identification

- Contraindications for use of the microprocessor knee should include
    - Any condition that prevents socket fitting, such as a complicated wound or intractable pain which precludes socket wear.

- Inability to tolerate the weight of the prosthesis.
- Medicare Level K 0—no ability or potential to ambulate or transfer.
- Medicare Level K 1—limited ability to transfer or ambulate on level ground at fixed cadence.
- Medicare Level K 2—limited community ambulator that does not have the cardiovascular reserve, strength, and balance to improve stability in stance to permit increased independence, less risk of falls, and potential to advance to a less-restrictive walking device.
- Inability to use swing and stance features of the knee unit.
- Poor balance or ataxia that limits ambulation.
- Significant hip flexion contracture (over 20 degrees).
- Significant deformity of remaining limb that would impair ability to stride.
- Limited cardiovascular and/or pulmonary reserve or profound weakness.
- Limited cognitive ability to understand gait sequencing or care requirements.
- Long distance or competitive running.
- Falls outside of recommended weight or height guidelines of manufacturer.
- Specific environmental factors—such as excessive moisture or dust, or inability to charge the prosthesis.
- Extremely rural conditions where maintenance ability is limited.

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

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

Microprocessor-Controlled Knee

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

- Energy requirements of ambulation (compared to requirements with conventional prostheses) are decreased at walking speeds slower or faster than the amputee's customary speed, but are not significantly different at customary speeds.
- Results on the potentially improved ability to negotiate uneven terrain, stairs, or inclines are mixed. Such benefits, however, could be particularly important to meeting existing deficit in the reintegration of amputees to normal living, particularly those related to decreased recreational opportunities.
- Users' perceptions of the microprocessor-controlled prosthesis are favorable. Where such decisions are recorded or reported, the vast majority of study participants choose not to return to their conventional prosthesis or to keep these only as back-up to acute problems with the computerized one.
- Users' perceptions may be particularly important for evaluating lower limb prosthesis, given the magnitude of the loss involved, along with the associated difficulty of designing and collecting objective measures of recovery or rehabilitation. However resilient the human organism or psyche, loss of a limb is unlikely to be fully compensated. A difference between prostheses sufficient to be perceived as distinctly positive to the amputee may represent the difference between coping and a level of function recognizably closer to the pre-amputation level.

The primary literature consists of small (sample range, 7-28 patients) within-subject comparisons of microprocessor-controlled with non-microprocessor-controlled prostheses in transfemoral amputees. These studies are described in Tables 1 and 2, divided by the Medicare Functional Level (MFL). MFL K2 describes a limited community ambulatory that is able to traverse low barriers such as curbs and walk with a fixed cadence. MFL K3 describes a community ambulatory that is able to traverse most barriers at variable cadence and may have activities beyond basic locomotion, and MFL K4 exceeds basic ambulation skills and includes activities with high impact or stress that would be performed by a child, athlete, or active adult. The C-Leg compact provides stance control only and has been tested primarily in the more limited MFL K2 amputees. The C-Leg, which provides both stance and swing control, has been tested in MFL K3 and K4 amputees, in addition to MFL K2 amputees.

About half of the studies first tested participants with their own non-microprocessor prosthesis followed by an acclimation period and testing with the microprocessor-controlled knee (see

Table 1). The other studies used an alternating or randomized order, with more than one test session for each type of prosthesis. Most studies compared performance in laboratory activities and about half also included a period of home use.

Table 1. Within-Subject Study Characteristics of the Microprocessor Knee

Study	Study Location	Country	N	Participants	MPK	NMPK	Home Monitoring
K2 ambulators							
Theeven et al (2011, 2012)	Activity at home and lab-simulated ADLs	Netherlands	28	Functional level K2	C-Leg and C-Leg compact 1-wk acclimation	Own NMPK	1 wk for each prosthesis
Burnfield et al (2012)	Level and ramp walking	U.S.	10	Functional level K2	C-Leg compact 3-mo acclimation	Own NMPK	
K2 to K3 ambulators							
VA (2006)	Lab and home	U.S.	8	Functional level K2 to K3	C-Leg	Hydraulic	1 wk
Hafner and Smith (2009)	A-B-A-(A or B) design in lab and city sidewalk	U.S.	• 8 K2 • 9 K3	Functional level K2 to K3	Retest in lab with preferred prosthesis	Retest in lab with preferred prosthesis	Prior 4 wk from 4-, 8-, and 12-mo tests
Highsmith et al (2013)	Ramp		21	Independent community ambulator	C-leg with 3-mo acclimation	Own NMPK	
Howard et al (2018)	4-wk laboratory sessions for each phase (A-B-A or B-A-B)	U.S.	• 1 K2 • 6 K3	Functional level K2 or K3	Rheo Knee	Own NMPK	PROs for 3 wk prior to use
Hafner et al (2007)	A-B-A-B design in lab and city sidewalk	U.S.	17	Proficient community ambulator		Own mechanical	
K3 to K4 ambulators							
Kaufman et al (2007, 2008)	Lab and home	U.S.	15	Functional level K3 or K4	MPK acclimation of 10-39 wk	Own NMPK	10 d
Johansson (2005)	Laboratory and 0.25-mile indoor track	U.S.	8	Functional level K3 or K4	10-h acclimation if not owned	10-h acclimation if not owned	

ADLs: activities of daily living; MPK: microprocessor knee; NMPK non-microprocessor knee; PROs: patient-reported outcomes; VA: Veterans Administration.

Results of these studies are described in Table 2 and summarized below:

- In K2 ambulators, the C-Leg and C-Leg compact improved performance on simulated activities of daily living that required balance, for walking on level ground and ramps, and led to a faster time to stand up from a seated position and move forward (Timed Up & Go test). In the single study that measured activity levels at home, use of a microprocessor-controlled knee did not increase objectively measured activity.

- In studies that included K2 to K3 ambulators, use of a microprocessor-controlled knee increased balance, mobility, speed, and distance compared with performance using the participant's prosthesis. In studies that included independent or proficient community ambulators, the greatest benefit was for the descent of stairs and hills. Normal walking speed was not increased.
- In studies that included K3 to K4 ambulators, use of a prosthesis with a microprocessor-controlled knee resulted in a more natural gait and an increase in activity at home. Participants voiced a strong preference for the microprocessor knee.
- Irrespective of the MFL from K2 to K4, all studies reported that participants preferred the C-Leg or C-Leg compact over their non-microprocessor prosthesis.

Table 2. Outcomes with Microprocessor Knee Prosthesis vs a Non-Microprocessor Knee

Study	Performance	Gait Efficiency	Preference (Self-Report or PEQ)	Activity at Home
K2 ambulators				
Theeven et al (2011, 2012)	Improved simulated ADLs for activities requiring balance		• Subjective benefit on PEQ • No preference for C-leg over C-leg compact	No difference in objectively measured activity level
Burnfield et al (2012)	Improved walking on level ground, ramps, and faster TUG (17.7 s vs 24.5 s)		• PEQ • All wanted to keep the C-Leg compact	
K2 to K3 ambulators				
VA (2006)		Marginally improved	7 of 8 participants preferred the MPK	No difference
Hafner and Smith (2009)	Improved mobility and speed			Decrease in self-reported stumbles and falls
Highsmith et al (2013)	Improved hill descent time (6.0 s vs 7.7 s) and HAI			
Howard et al. (2018)	Improved 6MWT, BBS, and AMP, but inconsistent for normal walking speed and L test	Improved Physiological Cost Index	• Preference for MPK in 6 of 7 participants • PEQ superior in 5 of 7	
Hafner et al (2007)	Improved for descent of stairs and hills only		Subjective improvement with MPK	
K3 to K4 ambulators				
Kaufman et al (2007, 2008)	More natural gait	No significant difference	Preferred MPK	Increased
Johansson (2005)	More natural gait and decrease in hip work	Oxygen consumption reduced for Rheo but not C-Leg	Preferred MPK	

ADL: activity of daily living; AMP: amputee mobility predictor; BBS: Berg Balance Scale; HAI: Hill Assessment Index; MPK: microprocessor knee; NMPK non-microprocessor knee; PEQ: Prosthesis Evaluation Questionnaire; 6MWT: 6-minute walk test; TUG: Timed Up & Go; VA: Veterans Administration.

Section Summary: Microprocessor-Controlled Knee
The literature consists of a number of small within-subject comparisons of microprocessor-controlled knees with non-microprocessor-controlled knee joints. Studies of prostheses with microprocessor knees in Medicare-level K3 and K4 amputees have shown objective improvements in function on some outcome measures and strong patient preference for the microprocessor-controlled prosthetic knees. The evidence in Medicare level K2 ambulators suggests that prosthesis with stance control only can improve activities that require balance and improve walking in this population. Only 1 biomechanical study of the next-generation Genium prosthesis was identified. One small study found little difference in performance between the Rheo Knee II and the user's own non-microprocessor-controlled knee.

Powered Knee Prostheses
We did not identify any literature on powered knee prostheses.

Microprocessor-Controlled Ankle-Foot Prostheses
A 2004 Cochrane review of ankle-foot prostheses concluded that there was insufficient evidence from high-quality comparative studies for the overall superiority of any individual type of prosthetic ankle-foot mechanism. In addition, the authors noted that the vast majority of clinical studies on human walking have used standardized gait assessment protocols (e.g., treadmills) with limited "ecological validity," and recommended that for future research, functional outcomes should be assessed for various aspects of mobility such as making transfers, maintaining balance, level walking, stair climbing, negotiating ramps and obstacles, and changes in walking speed.

Proprio Foot
Gait analysis with the Proprio Foot® was evaluated in 16 transtibial K3-K4 amputees during stair ascent and stair descent. Results with the adaptive ankle (allowing four degrees of dorsiflexion) were compared with tests conducted with the same prosthesis but at a fixed neutral angle (similar to other prostheses) and with results from 16 healthy controls. Adaptive dorsiflexion was found to be increased in the gait analysis; however, this had a modest impact on other measures of gait for either the involved or uninvolved limb, with only a "tendency" to be closer to the controls, and the patient's speed was not improved by the adapted ankle. The authors noted that an adaptation angle of 4 degrees in the stair mode is small compared to physiologic ankle angles, and the lack of power generation with this quasi-passive design may also limit its clinical benefit. For walking up and down a ramp, the adapted mode resulted in a more normal gait during ramp ascent, but not during ramp descent. Some patients reported feeling safer with the plantar flexed ankle (adaptive mode) during ramp descent. Another small within-subject study (n=6) found no benefit of an active Proprio Foot compared with the same prosthesis turned off with level walking or with slope ascent or descent.

Self-reported and objective performance outcomes for four types of prosthetic feet, including the Proprio Foot®, were evaluated in a 2012 randomized within-subject crossover study. Ten patients with transtibial amputation were tested with their own prosthesis and then after training and a 2 week acclimation period with the SACH (solid ankle cushion heel), SAFE (stationary attachment flexible endoskeletal), Talux, and Proprio Foot® in a randomized order. No differences between prostheses were detected by the self-reported PEQ and Locomotor

Capabilities Index, or for the objective 6 minute walk test. Steps per day and hours of daily activity between testing sessions did not differ between the types of prostheses.

Another study by Delussu et al 2013, found a lower energy cost of floor walking with the Proprio Foot compared with a dynamic carbon fiber foot in 10 transtibial amputees. However, the study found no significant benefit for walking stairs or ramps, for the timed up-and-go test, or for perceived mobility or walking ability.

Section Summary: Microprocessor-Controlled Ankle-Foot Prostheses
Several small studies have been reported with microprocessor-controlled prostheses for transtibial amputees. The evidence to date is insufficient to support an improvement in functional outcomes compared with the same device in the off-mode or compared with energy-storing and -returning (ESR) prostheses. Larger, higher quality studies are needed to determine the impact of these devices on health outcomes with greater certainty.

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

In 2012, Ferris et al reported a pre-post comparison of the PowerFoot Biom with the patient's own energy-storing and -returning foot (ESR) in 11 patients with transtibial amputation. Results for both prostheses were also compared with 11 matched controls that had intact limbs. In addition to altering biomechanical measures, the powered ankle-foot increased walking velocity compared to the ESR prosthesis and increased step length compared to the intact limb. There appeared to be an increase in compensatory strategies at proximal joints with the PowerFoot; the authors noted that normalization of gait kinematics and kinetics may not be possible with a uniarticular device. Physical performance measures were not significantly different between the two prostheses, and there were no significant differences between conditions on the PEQ. Seven patients preferred the PowerFoot and four preferred the ESR. Compared to controls with intact limbs, the PowerFoot had reduced range of motion, but greater ankle peak power.

Another similar, small pre- post- study from 2012 (7 amputees and 7 controls) found gross metabolic cost and preferred walking speed to be more similar to non-amputee controls with the PowerFoot Biom than with the patient's own ESR.

In a conference proceeding from 2011, Mancinelli et al described a comparison of a passive-elastic foot and the PowerFoot Biom in 5 transtibial amputees. The study was supported by the U.S. Department of Defense, and, at the time of testing, the powered prosthesis was a prototype and subjects' exposure to the prosthesis was limited to the laboratory. Laboratory assessment of gait biomechanics showed an average increase of 54% in the peak ankle power generation during late stance. Metabolic cost, measured by oxygen consumption while walking on an indoor track, was reduced by an average of 8.4% (p=0.06).

Section Summary: Powered Ankle-Foot Prostheses
Several small studies have been reported with powered ankle-foot prostheses for transtibial amputees. The evidence to date is insufficient to support an improvement in functional outcomes.

Summary of Evidence
For individuals who have a transfemoral amputation who receive prosthesis with a microprocessor-controlled knee, the evidence includes a number of within-subject comparisons of microprocessor-controlled knees vs non-microprocessor-controlled knee joints. Relevant outcomes are functional outcomes, health status measures, and quality of life. For K3- and K4-level amputees, studies have shown an objective improvement in function on some outcome measures, particularly for hill and ramp descent, and strong patient preference for microprocessor-controlled prosthetic knees. Benefits include a more normal gait, an increase in stability, and a decrease in falls. The evidence in Medicare level K2 ambulators suggests that prosthesis with stance control only can improve activities that require balance and improve walking in this population. For these reasons, a microprocessor-controlled knee may provide incremental benefit for these individuals. The potential to achieve a higher functional level with a microprocessor-controlled knee includes having the appropriate physical and cognitive ability to use the advanced technology. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a transfemoral amputation who receive prosthesis with a powered knee, the evidence includes limited data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The limited evidence available to date does not support an improvement in functional outcomes with a powered knee prostheses compared with standard prostheses. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have a tibial amputation who receive a prosthesis with a microprocessor-controlled ankle-foot, the evidence includes limited data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The limited evidence available to date does not support an improvement in functional outcomes with microprocessor-controlled ankle-foot prostheses compared with standard prostheses. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have a tibial amputation who receive a prosthesis with a powered ankle-foot, the evidence includes no data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
The Veteran's Affairs Prosthetic and Sensory Aids Strategic Healthcare Group established a Prosthetic Clinical Management Program to coordinate the development of clinical practice recommendations for prosthetic prescriptive practices. A subgroup of the Pre-Post National Amputation Workgroup met in 2004 to define the patient selection and identification criteria for microprocessor prosthetic knees. Their proposal was based on recommendations arising from the

2003 Microprocessor Prosthetic Knee Forum. The resulting Department of Veterans Affairs clinical practice recommendations for microprocessor knees are listed in the Appendix.

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

Key Words:

C-leg, microprocessor control prostheses, computerized leg, computerized lower limb prosthesis, bionic leg, Proprio Foot®, Power Foot, microprocessor-controlled foot, power knee, powered foot, iPED, Intelligent Prosthesis, Symbionic® Leg, PowerFoot Biom, Genium, Otto Bock®, Rheo Knee, Linx system (endolite), knee/ankle/foot/prosthesis system

Approved by Governing Bodies:

According to the manufacturers, microprocessor-controlled prostheses are considered a class I device by the FDA and are exempt from 510(k) requirements. This classification does not require submission of clinical data regarding efficacy but only notification of FDA prior to marketing.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: Special benefit considerations may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

HCPCS codes:

L5828	Addition, endoskeletal, knee-shin system, single axis, fluid swing and stance phase control
L5845	Stance extension, damping, adjustable
L5848	Addition to endoskeletal knee-shin system, fluid stance extension, dampening feature, with or without adjustability
L5850	Addition, endoskeletal system above knee or hip disarticulation, knee extension assist
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)
L5930	Addition, endoskeletal system, high activity knee control frame
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control

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Policy History:

Medical Policy Group, September 2002
Medical Policy Group, November 2002 **(2)**
Medical Policy Administration Committee May 2003
Available for comment May 23-July 7, 2003
Medical Policy Group, April 2004
Medical Policy Group, November 2005 **(2)**
Medical Policy Group, May 2007 **(1)**
Medical Policy Group, August 2007 **(1)**
Medical Policy Administration Committee, August 2007
Available for comment August 13-September 27, 2007
Medical Policy Group, February 2009 **(2)**
Medical Policy Administration Committee, March 2009
Available for comment March 4-April 17, 2009
Medical Policy Group, February 2010 **(2)**
Medical Policy Administration Committee February 2010
Medical Policy Group, November 2012: Added new 2013 Code L5859 effective 1/1/13; Deleted Code K0670 which deleted 1/1/06.
Medical Policy Panel, March 2013
Medical Policy Group, August 2013 **(2):** Policy updated with literature review through July 2013. Added an investigational statement for combination microprocessor knee and power foot prostheses. Description, Key Words, Key Points, Codes, and References updated.
Medical Policy Administration Committee, September 2013.
Available for comment September 19 through November 2, 2013
Medical Policy Group, December 2013 **(5):** 2014 Coding Update – added new code L5969 to current coding effective 01/01/2014
Medical Policy Group, February 2014 **(5):** Update to Policy statement to only cover code L5930 for functional level of K4. Key Points and References also updated.
Medical Policy Administration Committee, February 2014
Available for comment February 5 through March 21, 2014
Medical policy Group, June 2014 **(5):** Updated description, Key Points and References; Policy statements unchanged.
Medical Policy Group, February 2015 **(6)**: Updated References; no change to policy statement.
Medical Policy Panel, April 2015
Medical Policy Group, April 2015 **(6):** Updates to Description, Key Points, Key Words and References; no change to policy statement.
Medical Policy Group, November 2016 **(6)**: Updates to coding section:L5848: Addition to endoskeletal knee-shin system, fluid stance extension, dampening feature, with or without adjustability.
Medical Policy Panel, November 2017
Medical Policy Group, November 2017 **(6):** Removed old policy statement. Added "A combination microprocessor-controlled knee/ankle/foot (i.e. Linx) does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered investigational." to policy statement from existing investigational listing. Updates to Key Points, Governing Bodies, Key Words and References.

Medical Policy Panel, April 2018
Medical Policy Group, May 2018 **(6)**: Updates to Description, Key Points, Practice Guidelines and References.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case by case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.