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**Preauthorization is not required.**

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: • With transfemoral amputation	Interventions of interest are: • Prosthesis with a microprocessor-controlled knee	Comparators of interest are: • Prosthesis with a conventional knee	Relevant outcomes include: • Functional outcomes • Health status measures • Quality of life
Individuals: • With transfemoral amputation	Interventions of interest are: • Prosthesis with a powered knee	Comparators of interest are: • Prosthesis with a conventional knee	Relevant outcomes include: • Functional outcomes • Health status measures • Quality of life
Individuals: • With tibial amputation	Interventions of interest are: • Prosthesis with a microprocessor-controlled ankle-foot	Comparators of interest are: • Conventional foot-ankle prosthesis	Relevant outcomes include: • Functional outcomes • Health status measures • Quality of life
Individuals: • With tibial amputation	Interventions of interest are: • Prosthesis with a powered ankle-foot	Comparators of interest are: • Prosthesis with a conventional ankle-foot	Relevant outcomes include: • Functional outcomes • Health status measures • Quality of life

### DESCRIPTION

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

### SUMMARY OF EVIDENCE

For individuals who have a transfemoral amputation who receive a prosthesis with a microprocessor-controlled knee, the evidence includes a number of small within-subject comparisons of microprocessor-controlled knees vs. hydraulic knee joints. Relevant outcomes are functional outcomes, health status measures, and quality of life. For K3- and K4-level amputees, studies have shown an objective improvement in function on some outcome measures and a strong patient preference for microprocessor-controlled prosthetic knees. Benefits include a

more normal gait, an increase in stability, a decrease in falls, and a decrease in the cognitive burden associated with monitoring the prosthesis. For these reasons, a microprocessor-controlled knee may provide incremental benefit for these individuals. Those considered most likely to benefit from these prostheses have both the potential and need for frequent ambulation at variable cadence, on uneven terrain, or on stairs. The potential to achieve a high functional level with a microprocessor-controlled knee includes having the appropriate physical and cognitive ability to use the advanced technology. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

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

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

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

## POLICY

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

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

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

A powered knee is considered **investigational**.

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

**POLICY GUIDELINES**

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 two or more of these activities would be needed to show benefit.

**PATIENT SELECTION AND IDENTIFICATION**

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

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

**A. Contraindications for use of the microprocessor knee should include the following:**

- a. Any condition that prevents socket fitting, such as a complicated wound or intractable pain which precludes socket wear.
- b. Inability to tolerate the weight of the prosthesis.
- c. Medicare Level K0—no ability or potential to ambulate or transfer.
- d. Medicare Level K1—limited ability to transfer or ambulate on level ground at fixed cadence.
- e. Medicare Level K2—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.
- f. Inability to use swing and stance features of the knee unit.
- g. Poor balance or ataxia that limits ambulation.
- h. Significant hip flexion contracture (over 20°).
- i. Significant deformity of remaining limb that would impair ability to stride.
- j. Limited cardiovascular and/or pulmonary reserve or profound weakness.
- k. Limited cognitive ability to understand gait sequencing or care requirements.
- l. Long distance or competitive running.
- m. Falls outside of recommended weight or height guidelines of manufacturer.
- n. Specific environmental factors—such as excessive moisture or dust, or inability to charge the prosthesis.
- o. Extremely rural conditions where maintenance ability is limited.

**B. Indications for use of the microprocessor knee should include the following:**

- a. Adequate cardiovascular and pulmonary reserve to ambulate at variable cadence.
- b. Adequate strength and balance in stride to activate the knee unit.
- c. Should not exceed the weight or height restrictions of the device.

- d. Adequate cognitive ability to master technology and gait requirements of device.
  - e. Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral; lower extremity amputees are candidates if they meet functional criteria as listed.
  - f. Patient is an active walker and requires a device that reduces energy consumption to permit longer distances with less fatigue.
  - g. 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.
  - h. Medicare Level K2—limited community ambulator, but only if improved stability in stance permits increased independence, less risk of falls, and potential to advance to a less restrictive walking device, and 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.*
  - i. Medicare Level K3—unlimited community ambulator.
  - j. Medicare Level K4—active adult, athlete, who has the need to function as a K3 level in daily activities.
  - k. Potential to lessen back pain by providing more secure stance control, using less muscle control to keep knee stable.
  - l. Potential to unload and decrease stress on remaining limb.
  - m. Potential to return to an active lifestyle.
- C. Physical and Functional Fitting Criteria for New Amputees:
- a. New amputees may be considered if they meet certain criteria as outlined above.
  - b. Premorbid and current functional assessment important determinant.
  - c. Requires stable wound and ability to fit socket.
  - d. Immediate postoperative fit is possible.
  - e. Must have potential to return to active lifestyle.

### MEDICARE ADVANTAGE

For Medicare Advantage a lower limb prosthesis would only be considered **medically necessary** when the member:

1. Will reach or maintain a defined functional state within a reasonable period of time; and
2. Is motivated to ambulate.

### KNEE

A fluid, pneumatic, or electronic/microprocessor knee may be **medically necessary** for patients whose functional level is three or above (see Medicare Advantage Policy Guidelines).

The powered and programmable flexion/extension assist control addition is **medically necessary** only when the patient meets all of the criteria below:

- Has a microprocessor (swing and stance phase type controlled electronic) knee
- K3 functional level only

- Weight greater than 110 lbs. and less than 275 lbs.
- Has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K3 level function with the use of a microprocessor-controlled knee alone
- Is able to make use of a product that requires daily charging
- Is able to understand and respond to error alerts and alarms indicating problems with the function of the unit

#### FOOT

A microprocessor controlled ankle foot system may be **medically necessary** for patients whose functional level is three or above (see Medicare Advantage Policy Guidelines).

#### MEDICARE ADVANTAGE POLICY GUIDELINES

Potential functional ability is based on the reasonable expectations of the prosthetist, and treating physician, considering factors including, but not limited to:

1. The member's past history (including prior prosthetic use if applicable); and
2. The member's current condition including the status of the residual limb and the nature of other medical problems; and
3. The member's desire to ambulate.

#### REHABILITATION CLASSIFICATION LEVELS

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.

#### BACKGROUND

##### LOWER-EXTREMITY PROSTHETICS

More than 100 different prosthetic ankle-foot and knee designs are currently available. The choice of the most appropriate design may depend on the patient's underlying activity level. For example, the requirements of a prosthetic knee in an elderly, largely homebound individual will differ from those of a younger, active person. Key elements of a prosthetic knee design involve providing stability during both the stance and swing phase of the gait. Prosthetic knees vary in their ability to alter the cadence of the gait, or the ability to walk on rough or uneven surfaces. In contrast to more simple prostheses, which are designed to function optimally at one walking cadence, fluid and hydraulic-controlled devices are designed to allow amputees to vary their walking speed by

matching the movement of the shin portion of the prosthesis to the movement of the upper leg. For example, the rate at which the knee flexes after “toe-off” and then extends before heel strike depends in part on the mechanical characteristics of the prosthetic knee joint. If the resistance to flexion and extension of the joint does not vary with gait speed, the prosthetic knee extends too quickly or too slowly relative to the heel strike if the cadence is altered. When properly controlled, hydraulic or pneumatic swing-phase controls allow the prosthetist to set a pace adjusted to the individual amputee, from very slow to a race-walking pace. Hydraulic prostheses are heavier than other options and require gait training; for these reasons, these prostheses are prescribed for athletic or fit individuals. Other design features include multiple centers of rotation, referred to as “polycentric knees.” The mechanical complexity of these devices allows engineers to optimize selected stance and swing-phase features.

#### Microprocessor-Controlled Prosthetic Knees

Microprocessor-controlled prosthetic knees have been developed, including the Intelligent Prosthesis (Blatchford, England); the Adaptive (Endolite, Basingstoke, Hampshire, UK); the Rheo Knee® (Össur, Iceland); the C-Leg®, Genium™ Bionic Prosthetic System, and the X2 and X3 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN); and Seattle Power Knees (three models include Single Axis, 4-bar, and Fusion, from Seattle Systems). These devices are equipped with a sensor that detects when the knee is in full extension and adjusts the swing phase automatically, permitting a more natural walking pattern of varying speeds. The prosthetist can specify several different optimal adjustments that the computer later selects and applies according to the pace of ambulation. Also, these devices (with the exception of the Intelligent Prosthesis) use microprocessor control in both the swing and stance phases of gait. (The C-Leg Compact provides only stance control.) By improving stance control, such devices may provide increased safety, stability, and function; for example, the sensors are designed to recognize a stumble and stiffen the knee, thus avoiding a fall. Other potential benefits of microprocessor-controlled knee prostheses are improved ability to navigate stairs, slopes, and uneven terrain and reduction in energy expenditure and concentration required for ambulation. In 1999, the C-Leg was cleared for marketing by the Food and Drug Administration (FDA) through the 510(k) process (K991590). Next-generation devices such as the Genium Bionic Prosthetic system and the X2 and X3 prostheses use additional environmental input (e.g., gyroscope and accelerometer) and more sophisticated processing that is intended to create more natural movement. One improvement in function is step-over-step stair and ramp ascent. They also allow the user to walk and run forward and backward. The X3 is a more rugged version of the X2 that can be used in water, sand, and mud. The X2 and X3 were developed by Otto Bock as part of the Military Amputee Research Program.

#### Powered Knee Prostheses

The Power Knee™ (Össur, Iceland), which is designed to replace muscle activity of the quadriceps, uses artificial proprioception with sensors similar to the Proprio Foot to anticipate and respond with the appropriate movement required for the next step. The Power Knee is currently in the initial launch phase in the United States.

#### Microprocessor-Controlled Ankle-Foot Prostheses

Microprocessor-controlled ankle-foot prostheses are being developed for transtibial amputees. These include the Proprio Foot® (Össur), the iPED (developed by Martin Bionics, Oklahoma City, OK, and licensed to College Park Industries, Warren, MI), and the Elan Foot (Endolite). With sensors in the feet that determine the direction and speed of the foot’s movement, a microprocessor controls the flexion angle of the ankle, allowing the foot to lift during the swing phase and potentially adjust to changes in force, speed, and terrain during the step phase. This technology is designed to make ambulation more efficient and prevent falls in patients ranging from the young active amputee to the elderly diabetic patient. The Proprio Foot® and Elan Foot are microprocessor-controlled foot prostheses that are commercially available at this time and are considered class I devices that are exempt from 510(k) marketing clearance. Information on the Össur website indicates the use of the Proprio

Foot® for low- to moderate-impact for transtibial amputees who are classified as level K3 (i.e., community ambulatory, with the ability or potential for ambulation with variable cadence).

#### Powered Ankle-Foot Prostheses

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

#### REGULATORY STATUS

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

#### RELATED PROTOCOLS

Functional Neuromuscular Electrical Stimulation

Myoelectric Prosthetic Components for the Upper Limb

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

#### REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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