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Lower-Limb Prosthetics, Including Microprocessor-Controlled Prosthetics

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For HCSC members residing in the state of Arkansas, § 23-99-417 relating to orthotic devices, orthotic services, prosthetic devices, and prosthetic services, requires coverage for an orthotic device or service, a prosthetic device or service, prosthetic device for athletics or recreation, or a prosthetic device for showering or bathing. "Prosthetic device for athletics or recreation" means a device that provides an individual with the ability or potential for prosthesis ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels including the use of a blade-type foot designed for running and other high activity or high-impact endeavors. A candidate for a recreational prosthesis shall qualify in the Medicare functional level status as a K-3 or K-4 functional level as a user who: 1) Can achieve any high-level activity pursuits; and 2) Exhibits an ability to perform above and beyond normal ambulation. Coverage is not required for a device or service more than once every three [3] years unless medically necessary. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

Coverage

Explanation of Amputee Functional Levels Assessment: Clinical assessment of the amputee's potential rehabilitation should be based on Medicare's classification of functional level (MFL) described in Table 1 below.

Table 1. Medicare's Classification of Functional Levels (Functional K-Levels and Corresponding Definition): (1)

K-Level	Definition of Function
0	Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
1	Has the ability or potential to use a prosthesis for transfers or ambulating on level surfaces at fixed cadence; typical of the limited and unlimited household ambulator.
2	Has the ability or potential for ambulating with the ability to traverse environmental barriers such as curbs, stairs, or uneven surfaces; typical of the limited community ambulator.
3	Has the ability or potential for ambulating 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.
4	Has the ability or potential for prosthetic ambulating that exceeds basic ambulating skills, exhibiting high impact, stress, or energy levels; typical of the prosthetic demands of the child, active adult, or athlete.

Documentation Requirements: Documentation may be required to review requests or claims for lower-limb prosthetics, including microprocessor-controlled prosthetics. Medical records should document the amputee's current functional capabilities and expected functional potential, including an explanation for any difference.

Microprocessor-Controlled, Powered, or Hydraulic Prosthetics

Microprocessor-Controlled and Powered Knees (MPK; MCK; PK)

An MPK **may be considered medically necessary** in amputees who meet **ALL** of the following requirements:

- Has met one (1) of the following MFLs:
  - MFL of 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. The MPK enables fine-tuning and adjustment of the hydraulic mechanism to accommodate the unique motor skills and demands of the functional level K2 ambulator; or
  - MFL of K3: Unlimited community ambulator; or

- MFL of K4: Active adult, athlete who needs to function at a K3 level in daily activities; **AND**

- 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 a faster than normal walking speed; **AND**
- Adequate cognitive ability to master use and care requirements for the technology.

An MPK **is considered not medically necessary** in amputees who do not meet **ALL** of the above criteria, including those amputees who have MFL 0 (defined above in Table 1).

NOTE 1: Physical and Functional Fitting Criteria for New Amputees Seeking an MPK:
- New amputees may be considered if they meet certain criteria as outlined above,
- Pre-morbid and current functional assessment important determinant,
- Requires stable wound and ability to fit the socket,
- Immediate post-operative fit is possible,
- Must have potential to return to an active lifestyle.

NOTE 2: For amputees in whom the potential benefits of the MPKs are uncertain, the amputees may first be fitted with a standard prosthesis to determine their level of function with the standard device. A temporary prosthesis may need to be fitted prior to consideration of the MPK prosthesis. Generally, the temporary prosthesis does not have a cosmetic covering so the prosthetist can adjust the alignment to the knee. Physical therapy and gait training are done with the temporary prosthesis. Once healing has completed (may take 6 weeks or longer), the volume of the residual limb stabilizes (following adjustments), and the amputee has developed a steady level of activity, the amputee can move forward to the permanent/definitive prosthetic. 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 MPKs involve multiple factors including activity levels and the patient's physical and cognitive ability. An amputee'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.

An MPK that has only swing-phase microprocessors **are considered not medically necessary** including, but not limited to, Endolite IP+™, Endolite Smart IP™, Intelligent Knee™, Seattle Power Knee™, and DAW®.

A powered knee **is considered experimental, investigational and/or unproven**, including but not limited to the Power Knee® (Ossur).

The lithium-ion battery for the MPK is included with the knee and is repaired or replaced by the manufacturer when needed. Repair or replacement of the battery is covered under the manufacturer's warranty. When the manufacturer's warranty has expired, necessary repair or replacement of the lithium-ion battery **may be considered medically necessary**.

Spare or extra batteries **are considered not medically necessary**, as they are convenience items.

One (1) lithium-ion battery charger **may be considered medically necessary** for each MPK.

More than one (1) battery charger for each knee system **is considered not medically necessary**.

An osseointegrated/osseoanchored lower limb prosthetic device (e.g., OPRA Implant System) **is considered experimental, investigational or unproven**.

Microprocessor-Controlled and Powered Foot/Ankle Prostheses
Microprocessor-controlled or powered ankle/foot prostheses **are considered experimental, investigational and/or unproven** including, but not limited to, ProPrio Foot® (Ossur), iPED® (Martin Bionics), PowerFoot BiOM® (iWalk), and Êlan® (Endolite).

Hydraulic Hip Prosthetic
A four-axis, hydraulic or pneumatic hip joint (e.g., Helix^{3D}Hip® [OttoBock]) **may be considered medically necessary** when the amputee has a Medicare level K3 or higher.

NOTE 3: The Helix^{3D}Hip may be used in conjunction with the OttoBock C-Leg®.

Conventional or Basic Lower-Limb Prosthetics
General Criteria for Conventional or Basic Lower-Limb Preparatory and Permanent Prostheses
Preparatory (also called initial or temporary) and permanent (also called definitive or non-temporary) lower-limb prostheses **may be considered medically necessary** when the amputee:

- Is at MFL 1-4 (see **NOTE 4** below) **or** can be expected to reach Medicare's functional level 1-4 within a reasonable period of time; **and**
- Meets MFL criteria for prosthetic components (additions, substitutions, and/or replacements) as defined in Tables 1, 2, and/or 3; **and**
- Is motivated to ambulate; **and**
- Has received a physician prescription for the prosthesis, as a result of a recent physician evaluation.

Prosthetic Components (i.e., Additions, Substitutions, Replacements, and/or Modifications) for Conventional or Basic Lower-Limb Prostheses (Refer to Table 2 for component criteria)

Additions, substitutions, replacements, and/or modifications to conventional or basic lower-limb prostheses (***except MPKs***) **may be considered medically necessary** based on the patient's potential functional abilities (see **Table 1** above).

EXCEPTION: Certain additions and substitutions to initial or preparatory prostheses are considered not medically necessary as detailed in Table 3 below, because initial/preparatory prostheses are temporary and include the necessary elements.

Table 2. Additions, Substitutions, Replacements for Permanent (Definitive/Non-Temporary/Final) Conventional or Basic Lower-Limb Prosthesis

Additions, substitutions and/or replacements that **may be considered medically necessary** for permanent/definitive/non-temporary/final conventional or basic lower-limb prosthesis, based on Medicare's functional level:			
Component	**Level 1 or Greater**	**Level 2 or Greater**	**Level 3-4 or Greater**
Knees (except microprocessor knees)	• 4-Bar knee, friction control • Universal multiplex, friction control	• 4-Bar knee, friction control • Universal multiplex, friction control	• Pneumatic and hydraulic knees • 4-Bar knee, friction control • Universal multiplex, friction control
Knee-Shin Systems	• Exoskeletal knee-shin systems • Endoskeletal knee-shin systems	• Exoskeletal knee-shin systems • Endoskeletal knee-shin systems	• Exoskeletal knee-shin systems • Endoskeletal knee-shin systems
Ankles	Axial rotation unit	Axial rotation unit	Axial rotation unit
Foot, Ankle/Foot (except microprocessor ankle/foot)	• External keel SACH (solid ankle-cushion heel) foot • Single-axis ankle/foot	• Flexible-keel foot • Multi-axial ankle/foot • External keel SACH foot • Single-axis ankle/foot	• Flex foot system • Energy-storing foot • Multiaxial ankle/foot, dynamic response • Flex walk system or equal • Shank foot system with vertical loading pylon • Flexible-keel foot • Multi-axial ankle/foot • External keel SACH foot

			• Single-axis ankle/foot
Sockets	**<u>All Levels:</u>** 1. Two (2) test (diagnostic) sockets **may be considered medically necessary** for an individual prosthesis. More than two (2) require documentation of medical necessity. 2. Socket replacements **may be considered medically necessary** with documentation of functional and/or physiological need. Examples include, but are not limited to: • Changes in residual limb, • Functional need changes.		

Table 3. Additions, Substitutions, Replacements for Initial (<u>Preparatory/Temporary</u>) Conventional or Basic Lower-Limb Prosthesis

When these **<u>Temporary</u>** (Initial/Preparatory or Prefabricated Preparatory) **Conventional or Basic Lower-Limb Prostheses** <u>are covered</u>:	Then these additions, substitutions and/or replacements <u>are not covered</u> as they **are considered not medically necessary**:
Below Knee (Initial or Preparatory),	• Acrylic socket; leather socket; wood socket; air, fluid, or gel cushion socket; suction socket; • Protective covering; • Ultra-lightweight exoskeletal system; • Flex foot system.
Below Knee (Prefabricated Preparatory),	• Test socket; acrylic socket; flexible inner socket; air, fluid, or gel cushion socket; • Protective outer covering; • Molded supracondylar suspension (PTS [patellar-tendon-supracondylar] or similar); • Single-axis knee joints.
Above Knee (Initial or Preparatory),	• Acrylic socket; leather socket; wood socket; air, fluid, or gel cushion socket; • Protective outer covering; • Exoskeletal knee-shin system; • Endoskeletal hydra-cadence system; • Ultra-lightweight exoskeletal system; • Flex foot system.
Above Knee (Prefabricated Preparatory),	• Test socket; acrylic socket; air, fluid, or gel cushion socket; flexible inner socket; suction suspension, socket; • Protective outer covering.

NOTE 4: Determination of coverage for selected prostheses and components with respect to potential functional levels represents the usual case. Exceptions will be considered on an individual case basis if additional documentation is provided that justifies the medical necessity.

Custom protective outer surface covers and custom prosthetic covers for permanent prosthetics **are considered not medically necessary.**

Miscellaneous Additional Components, Including Microprocessor-Controlled Knee Prosthetics
Prosthetic socks and harnesses **may be considered medically necessary** when essential to the use of the prosthesis.

When immediate post-surgical or early fitting procedures are provided, test (diagnostic) sockets **are considered not medically necessary** as test sockets cannot be used with these procedures.

Waterproof/water-resistant prosthetic knees, feet, and components **are considered not medically necessary**, including but not limited to the MPK system(s) from OttoBock™ (i.e., 3WR95 Aqua Knee, 3R80, Aqualine System, 1WR95 Aqua Foot, X3).

Fitness foot systems combined with MPK knee systems (i.e., OttoBock™ 3S80 carbon fiber running foot/blade) **are considered not medically necessary**.

Policy Guidelines

Generally, coverage will include supplies necessary for effective use of a covered prosthesis, as well as adjustments, repairs, and replacements that are necessary to make the equipment functional for as long as the equipment continues to be medically necessary.

Shoes (a pair) may be covered when one or both shoes are an integral part of the artificial limb(s). Check the member's contract.

Description

Amputated and/or missing limbs result from accidents, disease, and congenital disorders. A lower-limb prosthetic is a device or artificial substitute designed to replace the function and/or appearance of the absent limb.

Background
More than 100 different prosthetic ankle-foot and knee designs are currently available. The choice of the most appropriate design may depend on the amputee'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.

Individual Selection and Identification

The individual's condition is an important factor to consider in choosing a prosthesis. To be functionally successful with a prosthesis, the patient must demonstrate sufficient trunk control, good upper body strength, static and dynamic balance, and adequate posture. The basic goals with prosthetic use are stability, ease of movement, energy efficiency, and appearance of a natural gait. The prescription for a prosthesis depends on the activity level and specific needs of each individual patient.

Clinical assessment of the amputee's rehabilitation potential should be based on the following functional levels (defined by Centers for Medicare and Medicaid Services [CMS]; known as Medicare Functional Level [MFL]) as shown in Table 1 above. Potential functional ability is based on the reasonable expectations of the prosthetist and treating physician, considering factors including, but not limited to: (1)

a. The patient's past history; and
b. The patient's current condition including the status of the residual limb and the nature of other medical problems; and
c. The patient's desire to ambulate.

Prosthetic Fitting

Generally, the earlier a prosthesis is fitted, the better it is for the amputee. Early ambulation helps keep the patient active, accelerates stump shrinkage, helps prevent flexion contractures, and can reduce phantom limb pain. Immediate postsurgical or early fitting procedures are typically performed in the hospital setting immediately after surgery. These procedures include specific dressings and fittings that are intended to prepare the residual limb for a prosthesis. An initial (preparatory) prosthesis and/or immediate post-operative prosthesis (IPOP) may be used to accelerate the rehabilitation process. It is intended to be temporary for several weeks or months until the stump stabilizes and a permanent (definitive) prosthesis is fitted. The base initial and preparatory prostheses include the necessary elements, and usually additions and/or substitutions are not required. However, many physicians prefer to postpone prosthetic

intervention until the wound is healed. If necessary, a patient can be fitted for a definitive prosthesis without ever having a preparatory prosthesis. In this case, the socket fitting should be delayed until the residual limb is fully mature (usually 3-4 months) or until the patient's weight and stump circumference have stabilized.

There is no precise prescription for lower-limb prostheses as fitting a prosthesis is very individualized to each amputee. A poorly designed or badly fitted prosthesis can be as disabling as the actual amputation. A prosthesis with components that are appropriate for functional level and physical condition helps the patient avoid future medical problems and injury to the residual limb.

Amputation level is a factor to consider in choosing a prosthesis. The following list identifies the base prosthesis for different levels of amputation:

- Partial foot prosthesis (PFP): For absence of the foot and/or toes below the ankle.
- Ankle (Syme's) prosthesis (SP): For absence of the foot and ankle just above the ankle joint.
- Below knee prosthesis (BKP): For absence of the foot and ankle below the knee joint.
- Above knee prosthesis (AKP): For absence of the foot, ankle, shin and thigh above the knee joint.
- Knee disarticulation prosthesis (KDP): For absence of the foot, ankle and shin at the knee joint level.
- Hip disarticulation prosthesis (HDP): For absence of the complete leg including the foot, ankle, shin and thigh at the hip joint level.
- Hemipelvectomy prosthesis (HP): For absence of the complete leg including the foot, ankle, shin, thigh, hip and pelvis.

A lower-limb prosthesis is made up of a base prosthesis combined with the possible addition of any of the following components:

- Socket;
- Prosthetic sock or liner;
- Socket inserts;
- Pylon, or knee-shin system;
- Articulating joint;
- Suspension system;
- Protective outer covering;
- Foot, ankle, or foot-ankle system.

Each additional or "add-on" component requires justification with regard to medical necessity related to Activities of Daily Living (ADLs).

The socket is the basis for the connection between the patient and the prosthesis, and a good fit is extremely important to the success of the prosthesis. The most common socket for the BKP is a patellar-tendon-bearing (PTB) design. With an AKP, the transected femur can support very little weight at its end, so the socket is designed to shift the weight onto the side of the

thigh and the pelvis. The quadrilateral socket has a contoured area called the ischial seat that supports the ischium (part of the hip bone). The ischial containment socket is made of more flexible materials and encapsulates the ischium in a way that provides more stability and control. Sockets can be flexible, expandable, or rigid, and are made of a variety of materials including wood, leather, polyester, acrylic, carbon, plastic, or a combination of these. For example, a rigid carbon frame over a flexible inner socket offers strength and stability with flexibility and comfort.

Prosthetic socks provide comfort with ventilation and help prevent skin abrasion. They should be changed and laundered daily to reduce skin irritation and dermatitis. Prosthetic liners and socket inserts are made of soft material or gel that is molded to the residual limb and acts as an interface between the hard weight-bearing socket and the skin. The suspension system attaches the prosthesis to the residual limb. This system can be a variety of belts, wedges, straps, suction, inserts, or some combination of these.

Knee-shin systems can be exoskeletal (crustacean) or endoskeletal. The exoskeletal knee-shin system is a one-piece design that entails wood or foam enclosed by a hard-plastic finish, usually shaped like a leg, and without interchangeable parts. This type of knee-shin system is very durable and simple. Because it is sturdy and heavy duty, it may be preferred by people who will be in harsh environments, such as farmers or other outdoor workers. Endoskeletal knee-shin systems are more complex and have interchangeable parts under a soft outer cover. Endoskeletal systems are lightweight and have many different component options, such as different knee units that can be introduced as the patient's functional needs change.

Additional Lower-Limb Prostheses Terminology:

- Gait is a term used to describe a walking pattern.
- A complete cycle of gait begins at initial contact of one (1) limb and ends at the repeated initial contact of the same limb, performing all phases of gait (stance and swing) in doing so.
- A step is sometimes incorrectly used to describe this gait cycle. A step however, is different; it is described as the distance of heel strike from one (1) leg to the heel strike of the opposite leg.
- Components/phases of a gait cycle includes the stance phase and the swing phase.
- Normal gait is used to define a pattern which has been generalized from the general public perception, across many variables, including age and sex.
- Stance phase is the time the foot is in contact with the floor, weight acceptance and single leg stance, which makes up 60% of the cycle.
- A stride is the full gait cycle.
- Swing phase is the period of time where the limb is lifted from the floor, limb advancement. This makes up 40% of the cycle.

Microprocessor-Controlled Prostheses

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.

Microprocessor-Controlled Prosthetic Knees (MPK)

The knee joint has three functions: provide support during stance phase of ambulation, produce smooth control during swing phase, and maintain unrestricted motion for sitting and kneeling.

For individuals in whom the potential benefits of the microprocessor knees are uncertain, individuals 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. (2)

A. Contraindications for the use of the MPK should include the following:
   - 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;
   - MFL of K0-no ability or potential to ambulate or transfer;
   - MFL of K1-limited ability to transfer or ambulate on level ground at fixed cadence;
   - MFL of K2-limited community ambulator who 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 (>20^{o});
   - Significant deformity of remaining limb that would impair the 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 the manufacturer;
   - Specific environmental factors-such as excessive moisture or dust, or inability to charge the prosthesis; and
   - Extremely rural conditions where maintenance ability is limited.

B. Indications for the use of the MPK should include the following:
   - 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 the device;

- Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral; lower-extremity amputees are candidates, if they meet functional criteria as listed;
- The individual 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;
- MFL of 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 the patient has cardiovascular reserve, strength, and balance to use the prosthesis. The microprocessor enables fine-tuning and adjustment of the hydraulic mechanism thus accommodating the unique motor skills and demands of the MFL K2 ambulator;
- MFL of K3-unlimited community ambulator;
- MFL of K4-active adult, athlete who needs to function as a K3 level in daily activities;
- Potential to lessen back pain by providing more secure stance control, using less muscle control to keep the knee stable;
- Potential to unload and decrease stress on remaining limb; and
- Potential to return to an active lifestyle.

C. 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 the socket;
- Immediate postoperative fit is possible; and
- Must have potential to return to an active lifestyle.

<u>Additional Prosthetic Knee Options Include</u>:
- Knees with processors for swing-only have a lesser degree of stance control that are considered a clinical option when the patient has a higher activity level combined with a very high residual limb control; examples include the DAW®, Intelligent ™Knee, IP+™, Smart IP™, and Seattle Power™ Knee.
- Manual locking knee is a very stable knee that is locked during gait. The patient releases the lock mechanism manually to sit down. This knee may be used for patients who have very short residual limb and/or poor hip strength and are unable to control the knee.
- Single-axis constant friction knee has a simple hinge and single pivot point. These knees are set to walk at one speed, and do not have stance control.
- Weight-activated stance control knee is a single-axis constant friction knee with a braking mechanism. When the patient puts his weight on the knee during ambulation, a braking mechanism is applied and the knee won't buckle.
- Polycentric knees, also referred to as 4-bar knees, have multiple centers of rotation allowing for stability at all phases of gait. The 4-bar linkage allows the knee to collapse better during

the swing phase and to bend easier for sitting. These can incorporate a hydraulic or pneumatic unit to permit variable walking speeds.
- Pneumatic or hydraulic knees have pistons inside cylinders containing air (pneumatic) or fluid (hydraulic); these units adjust gradually to changes in gait speed, which allows walking at variable speeds and permits a somewhat more natural gait.

Microprocessor-Controlled Ankle-Foot Prostheses

The basic functions of the prosthetic foot are to provide a stable weight bearing and shock absorbing surface, to replace lost muscle function, and to replicate the anatomic joint.

Conventional prosthetic feet can be basic (non-articulated, unmoving), articulated or dynamic-response (energy-storing). Articulated feet have one or more joints. The single-axis foot has one joint that can be used to help keep the knee stable. The multi-axis foot has motion about all three axes of the ankle and is good for walking on uneven surfaces. The multi-axis and dynamic-response feet are energy-storing feet. An energy-storing foot is capable of absorbing energy in a flexible keel (horizontal device in the foot) during the roll-over part of the stance phase of gait. The keel then springs back to provide push-off assistance to get the toe off the ground to start the swing phase. The simplest type of non-articulated the SACH, plus the sole, is able to conform to irregular surfaces, which makes it easier to walk on uneven terrain. The SAFE foot is also called a "flexible keel foot". The SACH and SAFE feet are non-energy-storing feet.

Permanent Prosthetic Covers

There are two general types of protective coverings for a lower limb prosthesis. Both types may start out as an off-the-shelf blank, but they are customized to match the lost limb in size, thickness and coloring.
- Internally supported prostheses (endoskeletal) usually feature an outer protective cover made of closed cell foam and a skin-color finish.
- Externally supported prostheses (exoskeletal) usually feature a hard, synthetic shell, also usually finished to resemble human skin.

Custom shaped protective covers

These types of covers are a complete product for normal daily usage of the prosthetic. They offer protection and weatherproofing. Usually, they are a skin-colored foam cover or stocking that is shaped to the individuals' limb.

Custom protective outer surface covers

These types of covers have a flexible surface that is waterproof and tear resistant. They are designed to be worn over the existing prosthesis. These types of covers are for individuals who need a level of protection beyond what is provided by a custom shaped protective cover. This may include protection for an unusually harsh environmental situation where it's necessary to protect the prosthesis. The need for these types of covers is rare. These are not for everyday usage or convenience reasons.

Regulatory Status

According to the manufacturers, microprocessor-controlled prostheses are considered a class I device by the FDA and are exempt from 510(k) requirements. Manufacturers must register prostheses with the Restorative Devices Branch of the FDA and keep a record of any complaints, but do not have to undergo a full FDA review. This classification does not require submission of clinical data regarding efficacy but only notification of FDA prior to marketing. FDA product codes: ISW, KFX.

Rationale

This policy was created in 2006 and since then updated periodically using the PubMed database and assessments/reviews from the U.S. Veterans Administration (VA). The most recent update was performed through April 11, 2024.

Medical policies 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 (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs 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.

Microprocessor-Controlled Prosthetic Knees for Individuals with Transfemoral Amputation

Clinical Context and Therapy Purpose

The purpose of powered prostheses in individuals who have transfemoral amputation is to improve activity and function.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with transfemoral amputation.

Interventions
The therapy being considered are prostheses with a microprocessor-controlled knee.

Microprocessor-controlled prosthetic knees have been developed, including the Intelligent Prosthesis (Blatchford); the Adaptive (Endolite); the Rheo Knee® (Össur); the C-Leg®, Genium™ Bionic Prosthetic System, and the X2 and X3 prostheses (Otto Bock Orthopedic Industry); and Seattle Power Knees (3 models include Single Axis, 4-bar, and Fusion, from Seattle Systems). These devices are equipped with a sensor that detects when the knee is in full extension and adjusts the swing phase automatically, permitting a more natural walking pattern of varying speeds. The prosthetist can specify several different optimal adjustments that the computer later selects and applies according to the pace of ambulation. Also, these devices (except 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 U.S. 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 (Genium X3) were developed by Otto Bock as part of the Military Amputee Research Program.

Comparators
The relevant comparator is a prosthesis with a conventional knee.

Outcomes
Relevant outcomes are functional outcomes, health status measures, and quality of life. 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.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

In 2000, the Veterans Administration (VA) Technology Assessment Program issued a report on computerized lower-limb prosthesis. (3) This report offered the following observations and conclusions:

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

Systematic Reviews

Thibaut et al. (2022) conducted a systematic review including studies of microprocessor prosthetic knees in patients with lower limb amputation. (4) The authors identified 18 studies (7 RCTs [later determined 5 RCTs were the same study reporting different outcomes], 6 cross-sectional studies, and 5 follow-up studies). All RCTs were cross-over studies. Overall, the authors found better functional status and mobility with microprocessor prosthetic knees, but it remains unclear whether there are differences among various models of microprocessor prosthetic knees.

In a systematic review and meta-analysis of microprocessor prosthetic knees in limited community ambulators, Hahn et al. (2022) identified 13 studies (N=2366; n=704 limited community ambulators). (5) In limited community ambulators, microprocessor prosthetic knees had improved outcomes in terms of falls, fear of falling, risk of falling, and mobility grade when compared with non-microprocessor prosthetic knees.

Nonrandomized Trials

The primary literature consists of small (sample range, 7-50 patients) within-subject comparisons of microprocessor-controlled with non-microprocessor-controlled prostheses in transfemoral amputees. These studies are described in Tables 4 and 5, divided by the Medicare Functional Level (MFL). MFL K2 describes a limited community ambulatory who is able to traverse low barriers such as curbs and walk with a fixed cadence. MFL K3 describes a community ambulatory who 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 MPK (see Table 4). 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 4. Within-Subject Study Characteristics of the Microprocessor Knee

Study	Study Location	Country	N	Partici-pants	MPK	NMPK	Home Monitoring
K2 Ambulators							
Theeven et al. (2011, 2012) (6, 7)	Activity at home and lab-simulated ADLs	Nether-lands	28	Functional level K2	C-Leg® and C-Leg® compact 1-week acclimati on	Own NMPK	1 week for each prosthesis
Burnfield et al. (2012) (8)	Level and ramp walking	United States	10	Functional level K2	C-Leg® compact 3-month acclimati on	Own NMPK	NR
K2 to K3 Ambulators							
VA (2006) (9-11)	Lab and home	United States	8	Functional level K2 to K3	C-Leg®	Hydraulic	1 week
Hafner and Smith (2009) (12)	A-B-A-(A or B) design in lab and	United States	8 - (K2) 9 - (K3)	Functional level K2 to K3	Retest in lab with preferred prosthesi s	Retest in lab with preferred prosthesi s	Prior 4 weeks from 4-, 8-, and 12-

	city sidewalk						month tests
Highsmith et al. (2013) (13)	Ramp	NR	21	Independent community ambulator	C-leg® with 3-month acclimation	Own NMPK	NR
Howard et al. (2018) (14)	4-week laboratory sessions for each phase (A-B-A or B-A-B)	United States	1 - (K2) 6 - (K3)	Functional level K2 or K3	Rheo Knee®	Own NMPK	PROs for 3 weeks prior to use
Hafner et al. (2007) (15)	A-B-A-B design in lab and city sidewalk	United States	17	Proficient community ambulator	NR	Own mechanical	NR
Kaufman et al. (2018) (16)	Free living environment	United States	50 K2	Functional level K2 or K3	One of 4 MPK devices	Own NMPK	Functional measures and PROs 10 weeks
K3 to K4 Ambulators							
Kaufman et al. (2007, 2008) (17, 18)	Lab and home	United States	15	Functional level K3 or K4	MPK acclimation of 10-39 week	Own NMPK	10 days
Johansson (2005) (19)	Laboratory and 0.25-mile indoor track	United States	8	Functional level K3 or K4	10-hour acclimation if not owned	10-hour acclimation if not owned	NR
K2 to K4 Ambulators							
Carse et al. (2021) (20)	Laboratory and 12m indoor walkway	Scotland	5 (K2) 17 (K3) 10 (K4)	Functional level K2, K3, or K4		Own NMPK	

ADLs: activities of daily living; K: knee; MPK: microprocessor-controlled knee; NMPK non-microprocessor-controlled knee; NR: not reported; N: number; PROs: patient-reported outcomes; VA: Veterans Administration.

Results of these studies are described in Table 5 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 MPK did not increase objectively measured activity.
- In studies that included K2 to K3 ambulators, use of a MPK 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 MPK resulted in a more natural gait, and an increase in activity at home. Participants voiced a strong preference for the MPK.
- 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 5. Outcomes with Microprocessor-Controlled Knee Prosthesis versus a Non-Microprocessor-Controlled Knee

Study	Performance	Gait Efficiency	Preference (Self-Report or PEQ)	Activity at Home
K2 Ambulators				
Theeven et al. (2011, 2012) (6, 7)	Improved simulated ADLs for activities requiring balance	NR	• Subjective benefit on PEQ • No preference for C-leg® over C-leg® compact	No difference in objectively measured activity level
Burnfield et al. (2012) (8)	Improved walking on level ground, ramps, and faster TUG (17.7 seconds versus 24.5 seconds)	NR	• PEQ • All wanted to keep the C-Leg® compact	NR
K2 to K3 Ambulators				
VA (2006) (9-11)	NR	Marginally improved	7 of 8 participants preferred the MPK	No difference
Hafner and Smith (2009) (12)	Improved mobility and speed	NR	NR	Decrease in self-reported

				stumbles and falls
Highsmith et al. (2013) (13)	Improved hill descent time (6.0 seconds versus 7.7 seconds) and HAI	NR	NR	NR
Howard et al. (2018) (14)	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	NR
Hafner et al. (2007) (15)	Improved for descent of stairs and hills only	NR	Subjective improvement with MPK	NR
Kaufman et al. (2018) (16)	Reduction in falls			Subjective improvement in PEQ satisfaction with MPK
K3 to K4 Ambulators				
Kaufman et al. (2007, 2008) (17, 18)	More natural gait	No significant difference	Preferred MPK	Increased
Johansson (2005) (19)	More natural gait and decrease in hip work	Oxygen consumption reduced for Rheo Knee® but not C-Leg®	Preferred MPK	NR
K2 to K4 Ambulators				
Carse et al. (2021) (20)		Improved GPS and walking velocity, step length, vertical ground reaction force symmetry index, and center of mass deviation		

ADLs: activities of daily living; AMP: amputee mobility predictor; BBS: Berg Balance Scale; HAI: Hill Assessment Index; K: knee; MPK: microprocessor-controlled knee; NMPK non-microprocessor-controlled

knee; NR: not reported; N: number; PEQ: Prosthesis Evaluation Questionnaire; 6MWT: 6-minute walk test; TUG: Timed Up & Go; VA: Veterans Administration.

A cross-sectional study by Alzeer et al. (2022) identified 38 patients who had been fitted with microprocessor prosthetic knees (Genium) and 38 patients fitted with various non-microprocessor prosthetic knees. (21) Patient-reported outcomes were measured with the Prosthesis Evaluation Questionnaire (PEQ). Total average PEQ scores were higher among patients with microprocessor prostheses (82.14 vs. 73.53; p=.014). Utility (78.41 vs. 68.20; p=.025) and ambulation (75.61 vs. 59.11; p=.003) were also significantly improved. This study indicates improved quality of life outcomes in patients with microprocessor prosthetic knees compared with non-microprocessor varieties but is limited by its small size and observational nature.

Section Summary: Microprocessor-Controlled Knee

The literature consists of systematic reviews and a number of small within-subject comparisons of MPKs with non-microprocessor-controlled knee joints. Studies of prostheses with MPKs in MFL K3 and K4 amputees have shown objective improvements in function on some outcome measures and strong patient preference for the MPKs. The evidence in MFL K2 ambulators suggests that a prosthesis with stance control only can improve activities that require balance and improve walking in this population.

Powered Knee Prostheses for Individuals with Transfemoral Amputation

Clinical Context and Therapy Purpose

The purpose of powered-knee prostheses in individuals who have transfemoral amputation is to improve activity and function.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with transfemoral amputation.

Interventions

The therapies being considered are powered-knee prostheses.

The Power Knee™ (Össur), 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.

Comparators

The relevant comparator is a prosthesis with a conventional knee.

Outcomes

Relevant outcomes are functional outcomes, health status measures, and quality of life. Relevant outcomes 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.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

There was no literature identified on powered knee prostheses.

Section Summary: Powered Knee Prostheses

There is no evidence to inform conclusions about use of powered knee prostheses for transfemur amputations.

Microprocessor-Controlled Prosthetic Ankle-Foot for Individuals with Tibial Amputation

Clinical Context and Therapy Purpose

The purpose of microprocessor-controlled prosthetic ankle-foot in individuals who have a tibial amputation is to improve activity and function.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with tibial amputation.

Interventions

The therapies being considered are microprocessor-controlled ankle-foot protheses.

Microprocessor-controlled ankle-foot prostheses are being developed for transtibial amputees. These include the Proprio Foot® (Össur), the iPED (developed by Martin Bionics and licensed to College Park Industries), Meridium (ottobock), Freedom Kinnex 2.0 (Proteor), and the Elan (Blatchford). 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 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).

Comparators
The relevant comparator is a prosthesis with a conventional ankle/foot.

Outcomes
Relevant outcomes are functional outcomes, health status measures, and quality of life. Relevant outcomes 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.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
A Cochrane review by Hofstad et al. (2004), which evaluated ankle-foot prostheses, concluded that there was insufficient evidence from high-quality comparative studies for an overall superiority of any individual type of prosthetic ankle-foot mechanism. (22) Also, reviewers noted that most clinical studies on human walking have used standardized gait assessment protocols (e.g., treadmills) with limited "ecological validity," and recommended that for future research, functional outcomes be assessed for various aspects of mobility such as making transfers, maintaining balance, level walking, stair climbing, negotiating ramps and obstacles, and changes in walking speed.

ProPrio® Foot
Gait analysis with the ProPrio® Foot was evaluated in 16 transtibial K3-K4 amputees during stair and ramp ascent and descent. (23, 24) Results with the adaptive ankle (allowing 4^{o} 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 increase during 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^{o} in the stair mode is small compared with physiologic ankle angles, and the lack of power generation with this quasi-passive design may

also limit its clinical benefit. For walking up and down a ramp, the adapted mode resulted in a more normal gait during ramp ascent, but not during ramp descent. Some patients reported feeling safer with the plantar flexed ankle (adaptive mode) during ramp descent. Another small within-subject study (2014; 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. (25)

Self-reported and objective performance outcomes for 4 types of prosthetic feet, including the ProPrio® Foot, were evaluated in a randomized within-subject crossover study reported by Gailey et al. (2012). (26) Ten patients with transtibial amputation were initially tested with their prosthesis and tested again following 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 Prosthesis Evaluation Questionnaire and Locomotor Capabilities Index, or for the objective 6-minute walk test (6MWT). Steps per day and hours of daily activity between testing sessions did not differ by type of prosthesis.

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. (27) However, the study found no significant benefit for walking stairs or ramps, for the Timed Up & Go test, or for perceived mobility or walking ability.

Thomas-Pohl et al. (2021) compared 3 different types of ankle-foot prostheses, including the Proprio Foot, in a within-subject crossover study. (28) The primary outcome was to evaluate the ability of these prostheses to adapt to ground inclination. Six patients tested each of the 3 devices; each data acquisition was preceded with a 2-week acclimation period and was followed by a 3-week wash-out period with the patient's energy storing and returning foot. Overall, the study found that microprocessor prostheses allowed for better posture and a reduction of residual knee moment on positive and/or negative slope when compared to the patients' energy storing and returning feet. Patients exhibited the most symmetric balance when they wore the Proprio Foot compared to the other microprocessor feet, but clinical functional tests between microprocessor prostheses and other feet did not differ greatly.

Colas-Ribas et al. (2022) conducted a cross-over study in 45 patients with ankle prosthesis at 2 centers in France. (29) Recruited patients had a prosthetic foot for more than 3 months and were able to walk outdoors. After randomization, each foot (Proprio Foot or non-microprocessor) was worn for a total of 34 days (2 weeks of adaptation/adaptation confirmation and 20 days in everyday life). Energy expenditure was similar between prostheses (19.4 mL/kg/min with Proprio Foot and 19.1 mL/kg/min with other prostheses). Mean Short Form 36 (SF-36) physical scores with the Proprio Foot were significantly better than with other prostheses (68.5 vs. 62.1; p=.005) as were mental scores (72.0 vs. 66.2; p=.006).

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 energy-returning prostheses. Larger, higher quality studies are needed to determine the impact of these devices on health outcomes with greater certainty.

Powered Ankle-Foot Prostheses for Individuals with Tibial Amputation

Clinical Context and Therapy Purpose

The purpose of powered ankle-foot prostheses in individuals who have tibial amputation is to improve activity and function.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with tibial amputation.

Interventions

The therapies being considered are 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. 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.

Comparators

The relevant comparator is a prosthesis with a conventional foot/ankle.

Outcomes

Relevant outcomes are functional outcomes, health status measures, and quality of life. Relevant outcomes 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.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

PowerFoot BiOM®

Au et al. (2008) reported on the design and development of the powered ankle-foot prosthesis (PowerFoot BiOM®); however, clinical evaluation of the prototype was performed in a single patient. (30)

Ferris et al. (2012) reported on a pre-post comparison of the PowerFoot BiOM® with the patient's own energy-storing and energy returning foot in 11 patients with transtibial amputation. Results for both prostheses were also compared with 11 matched controls who had intact limbs. (31) In addition to altering biomechanical measures, the powered ankle-foot increased walking velocity compared with the ESR prosthesis and increased step length compared with the intact limb. There appeared to be an increase in compensatory strategies at proximal joints with the PowerFoot BiOM®; the authors noted that normalization of gait kinematics and kinetics might not be possible with a uniarticular device. Physical performance measures did not differ significantly between the prostheses, and there were no significant differences between conditions on the Prosthesis Evaluation Questionnaire (PEQ). Seven patients preferred the PowerFoot BiOM® and 4 preferred the ESR. Compared with controls with intact limbs, the PowerFoot BiOM® had reduced range of motion but provided greater ankle peak power.

In another similar, small pre-post study (7 amputees, 7 controls), Herr and Grabowski (2012) found gross metabolic cost and preferred walking speed to be more similar to nonamputee controls with the PowerFoot BiOM® than with the patient's own energy-restoring and energy returning prosthesis. (32)

In a conference proceeding, Mancinelli et al. (2011) described a comparison of a passive-elastic foot and the PowerFoot BiOM® in 5 transtibial amputees. (33) The study was supported by the U.S. Department of Defense (DoD), 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).

Empower

Cacciola et al. (2022) conducted a survey of 57 individuals who were current or (n=41) or former (n=16) users of a powered ankle-foot. (34) All survey respondents were male with an average age of 53.5 years and an average of 13.1 years since amputation. Among the current users, numeric rating scale pain scores were significantly improved with Empower compared with a passive foot in terms of sound knee pain (1 vs. 2; p=.001), amputated side knee pain (1 vs. 2; p=.001), and low-back pain (1 vs. 3; p<.001). Although the differences were statistically significant, the small numeric differences between groups is questionably clinically relevant.

Section Summary: Microprocessor-Controlled 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.

Hydraulic Prosthetic Hip
Clinical Context and Therapy Purpose
The purpose of powered hip prostheses in individuals who have a post hip disarticulation is to improve activity and function.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals with post hip disarticulations.

Interventions
The therapies being considered are powered hip prostheses.

Fitting and wearing hip disarticulation prostheses presents several challenges, including poor gait pattern, socket discomfort, instability, loss of mobility, prosthesis weight and energy expenditure. The Canadian hip disarticulation prosthesis was developed by McLaurin more than 50 years ago and is the "standard" hip disarticulation prosthesis. These prostheses move in a single plane and require locking of the knee and hip for walking and unlocking to sit down. A new prosthetic hip joint, the Helix^{3D}Hip® (OttoBock™ Orthopedic Industry), consists of a four-axis mechanism with hydraulic stance and swing-through phase control, which is reported to have the advantages of greater support and stability, and 3D movement similar to the ball joint of the natural hip, and more controlled heel strike. OttoBock™ has produced other modular single axis hydraulic hips available for patient utilization, known within the 7E series, which are still available.

Comparators
The relevant comparator is a prosthesis with a conventional hip.

Outcomes
Relevant outcomes are functional outcomes, health status measures, and quality of life. Relevant outcomes 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.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

The literature primarily consists of a limited number of small within-subject reviews of post-hip disarticulation rehabilitation utilizing prosthetics for patients having had a congenital anomaly, trauma-related, cancer-related, and dysvascular amputations. (35) A retrospective review of 43 patients during a 10-year span found that 18 (43%) of the patients were candidates for a prosthetic fitting following hip disarticulation or hemipelvectomy. (36)

Of the 12 patients retrospectively studied by Ferrapie et al., those who did not die due to the disease causing the initial ambulation, inpatient rehabilitation began at 14 days following amputation surgery. (37) Prosthetic training started on day 13 of admission to the rehab facility. Of those who survived their disease (n=6) and were discharged to home, 2 were able to walk indoors without assistance at discharged. This was followed by 5 wearing their prosthesis all day, 2 participating in a sport, and 4 driving their vehicles. All patients who were active had gone back to work.

Low patient acceptance of a hip disarticulation style prosthetic along with poor gait pattern, socket discomfort, prosthetic weight, mobility loss, instability, and high-energy consumption are contributing factors to patient utilization. A study in 2010 from Ludwig et al. compared 2 prosthetic hip joints, both from OttoBock™ HealthCare, Helix^{3D}Hip® and the 7E7 (Modular Hip Joint Free Mot. Titan). (38) Six amputees were analyzed using 6 charged coupled twice device cameras and 2 force plate sensor systems evaluating kinematics and kinetics. The Helix^{3D} Hip® revealed reduction in pelvic tilt range and slowed stance when compared with the 7E7. However, the Helix^{3D} reduced gait abnormalities. Without either device, the conclusion would be the lack of any ambulation ability by these 6 patients.

Section Summary: Hydraulic Prosthetic Hip

The few studies addressing post hip disarticulation reveal that without a hip prosthetic, patients would lack mobility outside of wheelchairs and crutches. For those active patients, return to improved functionality, such as ambulation, sports participation, or driving, is a critical step in rehabilitation and improve physical fitness. Evidence is sufficient to support an improvement in functional outcomes when patients can utilize a hip prosthesis that is well-fitted, properly trained, low weight and energy impact, and improved stability.

Ongoing and Unpublished Clinical Trials

Some ongoing and unpublished trials that might influence this policy are listed in Table 6.

Table 6. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03204513	Impact of Powered Knee-Ankle Prosthesis Leg on Everyday Community Mobility and Social Interaction	15	Dec 2024
NCT04530457	Safety and Effectiveness of Electronically Controlled Prosthetic Ankle in Patients With Transtibial Amputation	42	Dec 2024
NCT04784429	Assessing Outcomes With Microprocessor Knee Utilization in a K2 Population (ASCENT K2)	107	Dec 2026
NCT05407545	Evaluation of a Motorised Prosthetic Knee	10	Aug 2023
NCT05267639	Clinical Outcomes With Passive MPKs vs. Powered Prosthetic Knees	12	Apr 2024
Unpublished			
NCT04112901	Activity, Mobility, Social Functioning, Mental Health and Quality of Life Outcomes in Limited Mobility Transfemoral and Knee Disarticulation Amputees Using Microprocessor-Controlled Knees or Non-Microprocessor Controlled Knees in the United Kingdom: A Cohort Study	330	May 2020

NCT: National Clinical Trial.

Practice Guidelines and Position Statements

Veteran's Affairs/Department of Defense Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation

In 2019, the Veterans Affairs/Department of Defense Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation made the following recommendations: (39)

"We suggest offering microprocessor knee units over non-microprocessor knee units for ambulation to reduce risk of falls and maximize patient satisfaction. There is insufficient evidence to recommend for or against any particular socket design, prosthetic foot categories, and suspensions and interfaces."

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 within-subject comparisons of microprocessor-controlled knees versus 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 a 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 an improvement in the net health outcome.

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 using a powered knee prosthesis with standard prostheses. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 using microprocessor-controlled ankle-foot prostheses compared with standard prostheses, although quality of life improvements was noted in 1 small study. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a tibial amputation who receive a prosthesis with a powered 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 using powered ankle-foot prostheses compared with standard prostheses. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a post-hip disarticulation followed by prosthetic utilization, the evidence includes limited data to support improvement in functional outcomes with patient use of hip hydraulic prostheses. Key elements to successful patient acceptance of the device is correct prosthetic device selection, in addition to training, fitting, and device features. Relevant outcomes are functional outcomes, health status measures, and quality of life. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	97110, 97112, 97116, 97761, 97762, 97763
HCPCS Codes	L5000, L5010, L5020, L5050, L5060, L5100, L5105, L5150, L5160, L5200, L5210, L5220, L5230, L5250, L5270, L5280, L5301, L5312, L5321, L5331, L5341, L5400, L5410, L5420, L5430, L5450, L5460, L5500, L5505, L5510, L5520, L5530, L5535, L5540, L5560, L5570, L5580, L5585, L5590, L5595, L5600, L5610, L5611, L5613, L5614, L5615, L5616, L5617, L5618, L5620, L5622, L5624, L5626, L5628, L5629, L5630, L5631, L5632, L5634, L5636, L5637, L5638, L5639, L5640, L5642, L5643, L5644, L5645, L5646, L5647, L5648, L5649, L5650, L5651, L5652, L5653, L5654, L5655, L5656, L5658, L5661, L5665, L5666, L5668, L5670, L5671, L5672, L5673, L5676, L5677, L5678, L5679, L5680, L5681, L5682, L5683, L5684, L5685, L5686, L5688, L5690, L5692, L5694, L5695, L5696, L5697, L5698, L5699, L5700, L5701, L5702, L5703, L5704, L5705, L5706, L5707, L5710, L5711, L5712, L5714, L5716, L5718, L5722, L5724, L5726, L5728, L5780, L5781, L5782, L5783, L5785, L5790, L5795, L5810, L5811, L5812, L5814, L5816, L5818, L5822, L5824, L5826, L5828, L5830, L5840, L5841, L5845, L5848, L5850, L5855, L5856, L5857, L5858, L5859, L5910, L5920, L5925, L5926, L5930, L5940, L5950, L5960, L5961, L5962, L5964, L5966, L5968, L5969, L5970, L5971, L5972, L5973, L5974, L5975, L5976, L5978, L5979, L5980, L5981, L5982, L5984, L5985, L5986, L5987, L5988, L5990, L5991, L5999, L7360, L7362, L7367, L7368, L7500, L7510, L7520, L7600, L7700, L8400, L8410, L8415, L8417, L8420, L8430, L8435, L8440, L8460, L8465, L8470, L8480, L8485, L8499, [Deleted 1/2024: K1014, K1022]

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
09/01/2024	Document updated with literature review. The following change was made to coverage: Added a not medically necessary statement for custom protective outer surface covers and custom prosthetic cover for permanent prosthetics. No new references added; some updated.
12/01/2023	Document updated with literature review. Coverage unchanged. References 4, 5, 20, 21, 28, 29 and 34 added; others updated, some removed.
08/15/2022	Reviewed. No changes, other than removal of ALERT info.
12/15/2021	Document updated with literature review. The following change made to the coverage section under Microprocessor-Controlled, Powered, or Hydraulic Prosthetics: An osseointegrated/osseoanchored lower limb prosthetic device (e.g., OPRA Implant System) **is considered experimental, investigational or unproven**. References 14 and 32 added.
10/15/2020	Reviewed. No changes.
12/01/2019	Document updated with literature review. The following changes were made to the coverage section: 1) Added Medicare Functional Table to the Coverage section; 2) Added clarification to the coverage statements for microprocessor-controlled and powered knees; 3) Removed all scoring information for the K-PAVET™ Guide; 4) Removed information addressing cadence scoring; Added NOTE 1 regarding Physical and Functional Fitting Criteria for New Amputees Seeking an Microprocessor-Controlled Knee; 5) Added documentation requirements; 6) Added NOTE 2 regarding generalized information, which includes temporary coverings, physical therapy, qualified professional, daily ambulation, etc.; and 7) Added coverage statements considering waterproof/water-resistant prosthetic knees, feet, and components AND fitness foot systems as not medically necessary. Reference 12 was added; several references removed. Title changed from Lower-Limb Prosthetics, Including Microprocessor Prosthetics.
10/15/2017	Document updated with literature review. Coverage unchanged. The following was added to the beginning of coverage section, “ALERT: Health Care Services Corporation (HCSC) no longer maintains a Hanger Inc. Prosthetics & Orthotics Patient Assessment Validation Evaluation Tool (PAVET™) Evaluation for Microprocessor Knee (K-PAVET™) form on any of our web sites. To utilize the K-PAVET™ form for Microprocessor and Powered Knees, refer to the Hanger Inc., web site at ‘www.hanger.com’.”
04/15/2015	Document updated with literature review. Coverage unchanged. Rationale was substantially revised.
01/01/2015	Reviewed. No changes.
12/15/2013	Document updated with literature review. No changes to Coverage. “Êlan® (Endolite)” was added as an example of a microprocessor-controlled foot/ankle.

12/01/2011	Document updated with literature review. The following was added to Coverage: 1) The Genium™ Bionic Prosthetic System microprocessor knee and a powered knee are considered experimental, investigational and unproven; 2) A four-axis, hydraulic or pneumatic hip joint (e.g., Helix^{3D}Hip® [OttoBock]) may be considered medically necessary when the patient has an overall score of 50 or higher, and cadence score 15 or higher on the PAVET Evaluation, and the Helix^{3D}Hip will be used in conjunction with the OttoBock C-Leg.
01/01/2009	Revised/updated entire document
07/15/2007	CPT/HCPCS code(s) updated
05/15/2007	Revised/updated entire document
06/15/2006	New medical document