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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 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.

EXCEPTION: For members residing in the state of Maine, 24-A s 4315 requires a carrier shall provide coverage for prosthetic devices in all health plans that, at a minimum equals the coverage and payment

for prosthetic devices provided under federal laws and regulations for the aged and disabled pursuant to 42 United States Code, Sections 1395k, 1395l and 1395m and 42 Code of Federal Regulations, Sections 414.202, 414.210, 414.228 and 410.100. Covered benefits must be provided for: (1) A prosthetic device determined by the enrollee's provider to be the most appropriate model that adequately meets the medical needs of the enrollee; and (2) With respect to an enrollee under 18 years of age, in addition to coverage of a prosthetic device required by paragraph (2), a prosthetic device determined by the enrollee's provider to be the most appropriate model that meets the medical needs of the enrollee for recreational purposes, as applicable, to maximize the enrollee's ability to ambulate, run, bike and swim and to maximize upper limb function. A carrier may require prior authorization for prosthetic devices in the same manner as prior authorization is required for any other covered benefit. Coverage under this section must also be provided for repair or replacement of a prosthetic device if repair or replacement is determined appropriate by the enrollee's provider. For an enrollee under 18 years of age, coverage is not required pursuant to this section for a prosthetic device that is designed exclusively for an athletic purpose. "Prosthetic device" means an artificial device to replace, in whole or in part, an arm or a leg. This applies to Fully Insured Small Group, Mid-Market, Large Group, Student PPO, HMO, POS, EPO.

EXCEPTION: Illinois: 215 ILCS 5/356z.18 Prosthetic and Customized Orthotic Devices (SB 2195) requires that with respect to any an enrollee at any age, in addition to coverage of a prosthetic or custom orthotic device, benefits shall be provided for a prosthetic or custom orthotic device determined by the enrollee's provider to be the most appropriate model that is medically necessary for the enrollee to perform physical activities, as applicable, such as running, biking, swimming, and lifting weights, and to maximize the enrollee's whole body health and strengthen the lower and upper limb function. Repairs and replacements of prosthetic and orthotic devices are also covered, subject to the co-payments and deductibles, unless necessitated by misuse or loss. For the purposes of this section, customized orthotic device means a supportive device for the body or a part of the body, the head, neck, or extremities, and includes the replacement or repair of the device based on the patient's physical condition as medically necessary, excluding foot orthotics defined as an in-shoe device designed to support the structural components of the foot during weight-bearing activities. Licensed provider means a prosthetist, orthotist, or pedorthist licensed to practice in this State. Prosthetic device means an artificial device to replace, in whole or in part, an arm or leg and includes accessories essential to the effective use of the device and the replacement or repair of the device based on the patient's physical condition as medically necessary. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

Coverage

A determination of the medical necessity for certain components/additions to a prosthesis is based on the individual's potential functional abilities. Potential functional ability is based on the reasonable expectations of the treating practitioner and prosthetist, considering factors including, but not limited to:

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

Documentation Requirements: The medical records must document the individual's current functional and physical capabilities and their expected functional potential, including an explanation for the difference, if that is the case. It is recognized, within the functional classification hierarchy, that bilateral amputees often cannot be strictly bound by functional level classifications. Refer to Policy Guidelines for classification of functional levels.

Prostheses **is considered not medically necessary** if the individual's potential functional level is 0.

If a prosthesis **is considered not medically necessary**, related additions will also be considered **not medically necessary**.

General:

- When an initial below knee prosthesis (L5500) or a preparatory below knee prosthesis (L5510, L5520, L5530, L5540) is provided, prosthetic substitutions and/or additions of procedures and components **may be considered medical necessary** when in accordance with the functional level assessment except for codes L5629, L5638, L5639, L5646, L5647, L5704, L5785, L5962, and L5980 which **will be considered not medically necessary**.
- When a below knee preparatory prefabricated prosthesis (L5535) is provided, prosthetic substitutions and/or additions of procedures **may be considered medical necessary** when in accordance with the functional level assessment except for codes L5620, L5629, L5645, L5646, L5670, L5676, L5704, and L5962 which **will be considered not medically necessary**.
- When an above knee initial prosthesis (L5505) or an above knee preparatory (L5560, L5570, L5580, L5590, L5595, L5600) prosthesis is provided, prosthetic substitution and/or additions of procedures and components **may be considered medical necessary** when in accordance with the functional level assessment except for codes L5610, L5631, L5640, L5642, L5644, L5648, L5705, L5706, L5964, L5980, and L5710, L5711, L5712, L5714, L5716, L5718, L5722, L5724, L5726, L5728, L5780, L5790, L5795 which **are considered not medically necessary**.
- When an above knee preparatory prefabricated prosthesis (L5585) is provided, prosthetic substitution and/or additions of procedures and components **may be considered medical necessary** when in accordance with the functional level assessment except for codes L5624, L5631, L5648, L5651, L5652, L5705, L5706, L5964, and L5966 which **will be considered not medically necessary**.

The determination of coverage for selected prostheses and components with respect to potential functional levels represents the usual case. Exceptions will be considered in an individual case if additional documentation is included which justifies the medical necessity.

Feet:

A determination of the type of foot for the prosthesis will be made by the treating practitioner and/or the prosthetist based upon the functional needs of the individual. Basic lower extremity prostheses include a solid ankle cushioned heel (SACH) foot. Other prosthetic feet may be considered for coverage based upon functional classification.

An external keel SACH foot (L5970) or single axis ankle/foot (L5974) **may be considered medically necessary** for individuals whose functional level is 1 or above.

A flexible-keel foot (L5972) or multiaxial ankle/foot (L5978) **may be considered medically necessary** for individuals whose functional level is 2 or above.

A microprocessor-controlled ankle foot system (L5973), energy storing foot (L5976), dynamic response foot with multi-axial ankle (L5979), flex foot system (L5980), flex-walk system or equal (L5981), or shank foot system with vertical loading pylon (L5987) **may be considered medical necessary** when **one** of the following criteria is met:

1. The individual's functional level is 3 or above; or
2. The individual 's functional level is 2; and
 - a. Meets the functional level 2 coverage criteria for a fluid, pneumatic, or electronic/microprocessor control addition for a prosthetic knee; and
 - b. A higher-level (i.e., functional level 3) foot is required for the safe and proper use of the prescribed knee system.

The microprocessor foot or ankle system addition with power assist (e.g., ProPrio Foot® (Ossur), iPED® (Martin Bionics), PowerFoot BiOM® (iWalk), and Êlan® (Endolite). which includes any type motor (L5969) **is considered not medically necessary**.

Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of foot. This information must be retained in the treating practitioner's or prosthetist's files.

A user-adjustable heel height feature (L5990) **is considered not medically necessary**.

Knees:

A determination of the type of knee for the prosthesis will be made by the treating practitioner and/or the prosthetist based upon the functional needs of the individual. Basic lower extremity prostheses include a single axis, constant friction knee. Other prosthetic knees **may be considered medically necessary** for coverage based upon functional classification, 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.

A high activity knee control frame (L5930) **may be considered medically necessary** for individuals whose functional level is 4.

A fluid or pneumatic knee unit (L5610, L5613, L5614, L5615, L5722, L5724, L5726, L5728, L5780, L5814, L5822, L5824, L5826, L5828, L5830, L5840, and L5841), or control addition, fluid (L5848), or electronic/microprocessor (L5856, L5857, L5858) **may be considered medically necessary** for individuals whose functional level is 3 or above.

A fluid or pneumatic knee unit (L5610, L5613, L5614, L5615, L5722, L5724, L5726, L5728, L5780, L5814, L5822, L5824, L5826, L5828, L5830, L5840, and L5841), or control addition, fluid (L5848), or electronic/microprocessor (L5856, L5857, L5858) **may be considered medically necessary** under limited circumstances for individuals whose functional level is 2, when **ALL** of the following criteria (1-3) are met:

1. The individual has had a clinical evaluation to determine their functional level (see FUNCTIONAL LEVELS in Policy Guidelines); and,
2. Supporting documentation in the medical record outlines, in the context of the individual's overall medical health, the rationale for selection of a fluid, pneumatic, or electronic/microprocessor-controlled knee, including (at minimum) how the selected knee will:
 - a. Improve the individual's functional health outcomes (e.g., fall reduction, injury prevention, lower energy expenditure); and,
 - b. Help the individual accomplish their activities of daily living (ADLs); and,
3. Lower-level knee systems (e.g., knee systems which exclude use of fluid, pneumatic, or microprocessor) have been considered and ruled out based on the individual's specific functional and medical needs.

In addition, for coverage of an electronic/microprocessor-controlled knee system (L5856, L5857, or L5858 plus associated components) for individuals whose functional level is 2, **ALL** of the following criteria (1-4) must also be met:

1. The electronic/microprocessor knee is indicated for functional level 2; and,
2. The electronic/microprocessor knee has integrated technology that allows the knee to detect when the user trips or stumbles and can automatically adjust to stabilize the knee unit (e.g., stumble recovery); and,
3. The individual is able to make use of a product that requires daily charging; and,
4. The individual is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

L5859 (ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, POWERED AND PROGRAMMABLE FLEXION/EXTENSION ASSIST CONTROL, INCLUDES ANY TYPE MOTOR[S]) **may be considered medically necessary** when the individual meets **ALL** of the criteria below:

1. Has a microprocessor (swing and stance phase type [L5856]) controlled (electronic) knee; and
2. K3 functional level only; and
3. 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; and
4. Is able to make use of a product that requires daily charging; and
5. Is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

If these coverage criteria for the knee components are not met, L5859 will be considered **not medically necessary**.

Other knee systems (L5611, L5616, L5710, L5711, L5712, L5714, L5716, L5718, L5810, L5811, L5812, L5816, L5818) **may be considered medically necessary** for individuals whose functional level is 1 or above.

Coverage **may be considered medically necessary** and extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of knee. This information must be retained in the treating practitioner's or prosthetist's files.

When an initial below knee prosthesis (L5500) or a preparatory below knee prosthesis (L5510, L5520, L5530, L5540) is provided, prosthetic substitutions and/or additions of procedures and components are covered in accordance with the functional level assessment.

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

ANKLE AND LOWER EXTREMITY MOTION UNITS

Codes L5968, L5982, L5984, L5985, L5986 and L5988 describe separate products which provide either a single motion or a combination of motions generally attributed to functional movement of the lower limb during ambulation. The use of these codes can be used to fully describe additional features or functions not found in the prosthetic foot system (L5969, L5970, L5971, L5972, L5973, L5974, L5975, L5976, L5978, L5979 L5980, L5981 and L5987).

L5968 describes a product that is used as an addition to L-code foot systems for lower limb prosthesis construction. The product provides multiaxial motion in the coronal and sagittal plane from articulating components. At transition of stance phase to swing phase, the product will increase the ankle's dorsiflexion angle and maintain it throughout swing phase. The product provides an accommodation of changing heel heights without the user's input. The predicate product is the Rincoe R-Hab Ankle manufactured by R.G. Rincoe & Associates, Inc.

L5982 describes an exoskeletal device that allows adjustable amount of vertical twisting motion between the foot and pelvis during ambulation. Motion of this product is separate from any similar incidental prosthetic foot/ankle motions.

L5984 describes an endoskeletal device that allows an adjustable, or non-adjustable, amount of vertical twisting motion between the foot and pelvis during ambulation. Motion of this product is separate from any similar incidental prosthetic foot/ankle motions.

L5985 describes an endoskeletal pylon device that provides simulated multiaxial ankle motion through a dynamic vertical shank separate from any similar incidental prosthetic foot motions. The predicate product is The Seattle Ankle manufactured by Seattle Medical Systems Group.

L5986 describes a product that is used as an addition to L-code foot systems for lower limb prosthesis construction. The product provides multiaxial motion in all three planes of motion, sagittal, coronal, and transverse. This code does not describe the multiaxial motion achieved from the inherent flexibility of the prosthetic keel or a split keel/heel prosthetic foot design. The predicate product is a device that was manufactured by Medical Center Prosthetic, which is represented in the coding narrative by "MCP."

Use of L5968, L5982, L5984 or L5986 is based on the beneficiary's K-level modifier (K0-K4), as referenced in the LCD.

L5988 describes an endoskeletal pylon device that allows vertical shock reduction between the foot and pelvis during ambulation. The vertical shock reducing pylon feature of L5988 is a separate function from other products which use a piston/telescoping mechanism such as products described by L5781 or L5782. The predicate product is the Total Shock that was manufactured by Century XXII International, Inc.

Hips:

A pneumatic or hydraulic polycentric hip joint (L5961) (e.g., Helix^{3D}Hip® [OttoBock]) **may be considered medically necessary** for individuals whose functional level is 3 or above.

NOTE 1: The Helix^{3D}Hip may be used in conjunction with the OttoBock C-Leg®.

Sockets:

More than 2 test (diagnostic) sockets (L5618, L5620, L5622, L5624, L5626, L5628) for an individual prosthesis **is considered not medically necessary** unless there is documentation in the medical record which justifies the need. Exception: A test socket **may be considered medically necessary** for an immediate prosthesis (L5400, L5410, L5420, L5430, L5450, L5460).

No more than two of the same socket inserts (L5654, L5655, L5656, L5658, L5661, L5665, L5673, L5679, L5681, L5683) are allowed per individual prosthesis at the same time.

Socket replacements **may be considered medically necessary** if there is adequate documentation of functional and/or physiological need. It is recognized that there are situations where the explanation includes but is not limited to: changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to excessive individual weight or prosthetic demands of very active amputees.

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**.

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 built exclusively for water activities (e.g., showering, swimming) **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.

Functional Level Characteristics

Not all traits listed for K levels must be realized by the patient in order to receive a K level assignment, but generally, documentation should demonstrate that equivalent activities can be achieved by the prosthetic user.

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

Level 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.

- a. The individual does not have sufficient cognitive ability to safely use a prosthesis with or without assistance.
- b. The individual requires assistance from equipment or a caregiver in order to transfer and use of a prosthesis does not improve mobility or independence with transfers.
- c. The individual is wheelchair dependent for mobility and use of a prosthesis does not improve transfer abilities.
- d. The individual is bedridden and has no need or capacity to ambulate or transfer.

Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence, typical of the limited and unlimited household ambulator.

- a. The individual has sufficient cognitive ability to safely use a prosthesis with or without an assistive device and/or the assistance/supervision of one person.
- b. The individual is capable of safe but limited ambulation within the home or on a similar flat surface like a home, with or without an assistive device and/or with or without the assistance/supervision of one person.
- c. The individual requires the use of a wheelchair for most activities outside of their residence.
- d. The individual is not capable of most of the functional activities designated in Level 2.

Level 2: Has the ability or potential for ambulation with the ability to transverse low level environmental barriers such as curbs, stairs or uneven surfaces. This level is typical of the limited community ambulator.

- a. The individual can, with or without an assistive device (which may include one or two handrails) and/or with or without the assistance/supervision of one person:
 - i. Perform the Level 1 tasks designated above;
 - ii. Ambulate on a flat, smooth surface (e.g., concrete, asphalt) such as might be found outside the home. (e.g., porch, deck, patio garage, driveway)
 - iii. Negotiate a curb;
 - iv. Access public or private transportation;
 - v. Negotiate 1-2 stairs;
 - vi. Negotiate a ramp built to ADA specifications.
- b. The individual may require a wheelchair for distances that are beyond the perimeters of the yard/driveway, apartment building, etc.
- c. The individual is only able to increase their generally observed speed of walking for short distances or with great effort.
- d. The individual is generally not capable of accomplishing most of the tasks at Level 3 (or does so infrequently with great effort).

Level 3: Has the ability or potential for ambulation with variable cadence, typical of the community ambulator who has the ability to transverse most environmental barriers and may

have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

- a. With or without an assistive device (which may include one or two handrails), the individual is independently capable (i.e. requires no personal assistance or supervision) of performing the Level 2 tasks above and can:
 - i. Walk on terrain that varies in texture and level (e.g., grass, gravel, uneven concrete);
 - ii. Negotiate 3-7 consecutive stairs;
 - iii. Walk up/down ramps built to ADA specifications;
 - iv. Open and close doors;
 - v. Ambulate through a crowded area (e.g., grocery store, big box store, restaurant);
 - vi. Cross a controlled intersection within their community within the time limit provided (varies by location);
 - vii. Access public or private transportation;
 - viii. Perform dual ambulation tasks (e.g. carry an item or meaningfully converse while ambulating).
- b. The individual does not perform the activities of Level 4.

Level 4: Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress or energy levels typical of the prosthetic demands of the child, active adult, or athlete.

With or without an assistive device (which may include one or two handrails), this individual is independently capable (i.e., requires no personal assistance or supervision) of performing high impact domestic, vocational or recreational activities such as:

- a. Running;
- b. Repetitive stair climbing;
- c. Climbing of steep hills;
- d. Being a caregiver for another individual; and
- e. Home maintenance (e.g. repairs, cleaning).

Individual Selection and Identification

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. (36)

- A. Contraindications for the use of the microprocessor knee 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
 - Medicare level K0-no ability or potential to ambulate or transfer

- Medicare level K1-limited ability to transfer or ambulate on level ground at fixed cadence
 - Medicare level 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 ($>20^{\circ}$)
 - 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
 - Extremely rural conditions where maintenance ability is limited.
- B. Indications for the use of the microprocessor knee 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
 - 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 the individual has the cardiovascular reserve, strength, and balance to use the prosthesis. The microprocessor enables fine-tuning and adjustment of the hydraulic mechanism to accommodate the unique motor skills and demands of the functional level K2 ambulator.
 - Medicare level K3-unlimited community ambulator
 - Medicare level 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
 - 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
- Must have potential to return to an active lifestyle

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

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 Policy Guidelines 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°);
 - 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.

Additional Prosthetic Knee Options Include:

- 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

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.

This policy is supported in part by Centers for Medicare and Medicaid Services (CMS) guidelines. Additional information that was taken into consideration is outlined below.

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. (5) 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). (6) 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.

Randomized Controlled Trials

Morgan et al. (2025) conducted an RCT evaluation of the effects of MPKs compared to NMPKs in patients with recent transfemoral amputation. (4) Patients (N=18) were randomized to either MPKs (n=10) or NMPKs (n=8) as their first prosthesis; 15 patients completed the 3 month trial after receiving their prosthesis. Performance based outcomes (i.e., 6 minute walk test, amputee mobility predictor score, timed-up and go speeds, average daily step count, and mean stride velocity) were not statistically significant between groups ($p>.05$ for all outcomes). Participants with MPKs demonstrated significantly better self-reported outcomes including mobility, balance confidence, and return to normal living scores compared to those with NMPKs. Specifically, participants with an MPK had significantly higher Prosthetic Limb Users Survey of Mobility (Hedges' g: 1.70; 95% CI, 0.38 to 2.96; $p=.01$), Activity-specific Balance Confidence (Hedges' g: 1.75; 95% CI, 0.51 to 2.94; $p=.01$), and Return to Normal Living Index (Hedges' g: 0.54; 95% CI, 0.44 to 1.50; $p=.05$) scores.

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 1 and 2, 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 1). The other studies used an alternating or randomized order, with more than one test session for each type of prosthesis. Most studies compared performance in laboratory activities and about half also included a period of home use.

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

Study	Study Location	Country	N	Participants	MPK	NMPK	Home Monitoring
<i>K2 Ambulators</i>							
Theeven et al. (2011, 2012) (7, 8)	Activity at home and lab-simulated ADLs	Netherlands	28	Functional level K2	C-Leg® and C-Leg® compact 1-week acclimation	Own NMPK	1 week for each prosthesis
Burnfield et al. (2012) (9)	Level and ramp walking	United States	10	Functional level K2	C-Leg® compact 3-month acclimation	Own NMPK	NR
<i>K2 to K3 Ambulators</i>							
VA (2006) (10-12)	Lab and home	United States	8	Functional level K2 to K3	C-Leg®	Hydraulic	1 week
Hafner and Smith (2009) (13)	A-B-A-(A or B) design in lab and city sidewalk	United States	8 - (K2) 9 - (K3)	Functional level K2 to K3	Retest in lab with preferred prostheses	Retest in lab with preferred prostheses	Prior 4 weeks from 4-, 8-, and 12-month tests
Highsmith et al. (2013) (14)	Ramp	NR	21	Independent community ambulator	C-leg® with 3-month acclimation	Own NMPK	NR
Howard et al. (2018) (15)	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) (16)	A-B-A-B design in lab and city sidewalk	United States	17	Proficient community ambulator	NR	Own mechanical	NR

Kaufman et al. (2018) (17)	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) (18, 19)	Lab and home	United States	15	Functional level K3 or K4	MPK acclimation of 10-39 week	Own NMPK	10 days
Johansson (2005) (20)	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) (21)	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 2 and summarized below:

- In K2 ambulators, the C-Leg® and C-Leg® compact improved performance on simulated activities of daily living that required balance, for walking on level ground and ramps, and led to a faster time to stand up from a seated position and move forward (Timed Up & Go test). In the single study that measured activity levels at home, use of a 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 a study that primarily included K2 ambulatory, there was a reduction in falls demonstrated by the change from baseline while using a microprocessor knee and an increase in falls with reversion to a non-microprocessor knee.
- 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 2. Outcomes with Microprocessor-Controlled Knee Prosthesis versus a Non-Microprocessor-Controlled Knee

Study	Performance	Gait Efficiency	Preference (Self-Report or PEQ)	Activity at Home
<i>K2 Ambulators</i>				
Theeven et al. (2011, 2012) (7, 8)	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) (9)	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
<i>K2 to K3 Ambulators</i>				
VA (2006) (10-12)	NR	Marginally improved	7 of 8 participants preferred the MPK	No difference
Hafner and Smith (2009) (13)	Improved mobility and speed	NR	NR	Decrease in self-reported stumbles and falls
Highsmith et al. (2013) (14)	Improved hill descent time (6.0 seconds versus 7.7 seconds) and HAI	NR	NR	NR
Howard et al. (2018) (15)	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) (16)	Improved for descent of stairs and hills only	NR	Subjective improvement with MPK	NR
Kaufman et al. (2018) (17)	Reduction in falls	NR	NR	Subjective improvement in PEQ satisfaction with MPK
K3 to K4 Ambulators				
Kaufman et al. (2007, 2008) (18, 19)	More natural gait	No significant difference	Preferred MPK	Increased
Johansson (2005) (20)	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) (21)	NR	Improved GPS and walking velocity, step length, vertical ground reaction force symmetry index, and center of mass deviation	NR	NR

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. (22) 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 transfemoral 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 prostheses.

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. (23) 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. (24, 25) Results with the adaptive ankle (allowing 4° 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° 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. (26)

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). (27) 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. (28) 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. (29) 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. (30) 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. Empower (Ottobock) is a commercially available powered ankle-foot 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. (31)

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. (32) 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. (33)

In a conference proceeding, Mancinelli et al. (2011) described a comparison of a passive-elastic foot and the PowerFoot BiOM® in 5 transtibial amputees. (34) 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. (35) 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.

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 and systematic reviews of these studies. 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 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 no data. Relevant outcomes are functional outcomes, health status measures, and quality of life. 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 although quality of life improvements were noted in 1 small study. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

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

In 2024, the updated Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation made the following recommendations (Table 4) (36).

Table 4. VA/DoD Clinical Practice Recommendations for Lower Limb Amputation

Recommendation	Strength
For prosthetic ambulators, we suggest prescribing microprocessor knee units over non-microprocessor knee units for reducing falls, optimizing functional mobility, and improving patient satisfaction.	Weak for
For prosthetic ambulators, there is insufficient evidence to prescribe any specific energy storing and return (ESAR) or microprocessor foot and ankle component over another.	Neither for nor against
For prosthetic ambulators, we suggest energy storing and return (ESAR) or microprocessor-controlled foot and ankle components over solid ankle cushioned heel (SACH) feet to improve ambulation and patient satisfaction	Weak for

Ongoing and Unpublished Clinical Trials

Some ongoing and unpublished trials that might influence this policy are listed in Table 3.

Table 3. 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
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
NCT05267639	Clinical Outcomes With Passive MPKs vs. Powered Prosthetic Knees	13	Aug 2024

NCT: National Clinical Trial.

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	L2221, 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, L5827, 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, L5992, 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]
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*Current Procedural Terminology (CPT®) ©2024 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
01/01/2026	Document updated. Coverage section extensively revised. Added reference 4 and 36; others removed.
02/15/2025	Document updated with literature review. The following changes were made to Coverage: 1) Under Microprocessor-Controlled, Powered, or Hydraulic Prosthetics the second bullet was removed. It stated: "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"; 2) Table 2 Foot, Ankle/Foot (except microprocessor ankle/foot), second column added 5 bullets: Flex foot system, Energy-storing foot, Multiaxial ankle/foot, dynamic response, Flex walk system or equal and Shank foot system with vertical loading pylon (columns 2 and 3 should match now); and 3) Modified the waterproof/water-resistant prosthetic knees, feet and components statement to clarify products built exclusively for water activities (e.g., showering, swimming) 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). No new references added.

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. "Élan® (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