Subject: Lower Limb Prostheses

Background: A lower limb prosthesis is a device designed to replace the function of a missing lower limb. A microprocessor is a prosthetic component which includes an internal computer and sensors. The microprocessor monitors each phase of an individual's gait pattern and makes real-time adjustments, allowing for a more efficient gait at various speeds, and increased control on varying terrain and/or increased control on slopes, ramps, and stairs.

The microprocessor knee (MPK) component specifically enables rapid adjustments in knee resistance during swing and/or stance phase control to provide real-time adjustment of resistance within the MPK unit and facilitate optimal walking patterns on all surfaces, including uneven terrain, stairs, and inclines/declines.

The microprocessor foot/ankle (MPFA) unit specifically adjusts and controls ankle/foot movement in real time in response to sensor feedback, allowing optimization of plantarflexion and dorsiflexion during stance and swing phases and adaptation to underlying terrain, inclines/declines and stairs. Additional potential benefit of a microprocessor unit includes reduced energy expenditure during ambulation.

Authorization: Prior authorization is required for lower limb prostheses and prosthesis equipment requested for members enrolled in commercial (HMO, POS, and PPO) products.

Policy and Clinical Coverage Criteria:

The Plan requires prior authorization for all new and replacement lower limb prostheses, or part thereof. The Plan will use the following as a guideline for determining the Member's level of function as part of the process to determine medical necessity. It is the expectation provider will conform to manufacture's product-specific recommendations.

According to Medicare Functional Classification Level (MFCL), an individual's functional level is a measurement of the capacity and potential of the individual to accomplish his/her expected post- rehabilitation, daily function. The functional classification is used by The Plan to establish the medical necessity of prosthetic knee, feet, and ankle components. The clinical assessments of the Member's rehabilitation potential should be based on the following classification levels:

K Level	AMPnoPRO score	AMPPRO score	Description
Level K-0	0-8	N/A	Does not have the ability or potential to ambulate or transfer safely with or without assistance, and prosthesis does not enhance the quality of life or mobility.
Level K-1	9-20	15-26	Has the ability or potential to use prosthesis for transfers or ambulation on level services at fixed cadence. Typical of the limited and unlimited household ambulator.
Level K-2	21-28	27-36	Has the ability or potential for ambulation with the ability to transfer low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.

Level K-3	29-36	37-42	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 activities that demands prosthetic utilization beyond simple locomotion.
Level K-4	37-43	43-47	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of a child, active adult, or athlete.

Note: For all initial and replacement lower limb prosthetic requests, the score from the applicable functional mobility prediction tool (e.g., AMPPRO, PROMIS 29) must be submitted to verify Member's K functional level.

Initial Prosthesis

The Plan may authorize coverage of initial lower limb prostheses as reasonable and medically necessary, safe and effective for the intended purpose(s), and prescribed by the attending physician (based on recommendations from an American Board for Certification (ABC) or Board of Certification (BOCP) certified prosthetic clinician) when ALL of the following criteria are met:

1. Covered devices must be fitted and programmed by a board-certified prosthetist [American Board of Certification (ABC) or Board of Certification (BOCP) certified prosthetic clinician]
2. The requested prosthesis or component(s) is the most appropriate, least intensive, medically necessary model that adequately meets the medical needs of the Member
3. Member will reach or maintain a predicted improved functional state (transfers ambulation), with the use of the prescribed prosthesis within a reasonable and predictable period of time.
4. Member is motivated and has adequate cardiovascular reserve and cognitive ability to utilize the device.
5. There is clinical documentation and support for the functional need of the technology or design feature of a given type of foot and/or knee.
6. The component(s) or prosthesis has been prescribed by a physician, and meets the specific criteria listed for each lower limb component described below:
    a. Foot Components
        i. A solid ankle-cushion heel (SACH) foot is considered appropriate for persons whose functional level is 1 or above.
        ii. An external keel SACH foot or single axis ankle/foot is considered appropriate for persons whose functional level is 1 or above.
        iii. A flexible-keel foot or multi-axial ankle/foot is considered appropriate for persons whose functional level is 2 or above.
        iv. A flex foot system, energy storing foot, multi-axial ankle/foot, dynamic response, or flex-walk system or equal is considered appropriate for persons whose functional level is 3 or above.
    b. Knee Components (For coverage guidelines related to microprocessor knee components see below)
        i. A single axis constant friction knee and other basic knee systems are considered appropriate for persons whose functional level is 1 or above.
        ii. A fluid, pneumatic, or electronic knee is considered appropriate for persons whose functional level is 3 or above.
    c. Ankle Components
        i. An axial rotation unit is considered appropriate for persons whose functional level is 2 or above.
    d. Sockets
        i. The Plan will cover up to two (2) test (diagnostic) sockets for an individual prosthesis. Additional documentation of medical necessity is required for more than two test sockets.
7. Documentation of a complete multidisciplinary assessment (e.g., medical record notes, PT assessment, detailed written order completed by certified prosthetist and signed by the attending physician) including

an evaluation by a certified prosthetic clinician with expertise in the evaluation and fitting for the requested device is required.

Microprocessor Controlled Prosthetic Knee as Initial Prosthesis:

The Plan may authorize coverage of a microprocessor knee component as initial prosthesis when criteria for initial prosthesis are met AND when ALL of the following criteria are met:

1. Member is an active K3-K4 individual with a trans-femoral, knee-disarticulation or hip disarticulation amputation
2. Functional assessment indicates the member has the potential to ambulate independently with the requested MPK in a reasonable and predictable period of time
3. Member has no contraindications which prevent immediate training with requested MPK. Contraindications may include but are not limited to pain delay of wound healing of residual limb, inability to fit sockets, co-morbidities
4. Documentation sufficiently demonstrates the reasonable likelihood of member meeting Microprocessor Controlled Prosthetic Knee criteria below:

Microprocessor Controlled Prosthetic Knee

The plan may authorize coverage of a microprocessor knee component when ALL of the following criteria are met:

1. Documentation of ALL:
    a. Member has no cardiovascular, neuromuscular, musculoskeletal or cognitive conditions that could adversely affect the ability to successfully use requested prosthesis.
    b. Member has undergone evaluation by a trained prosthetic clinician with expertise in the evaluation and fitting of members for this device.
    c. Member has adequate strength and balance required to activate the knee unit.
    d. Member has cognitive ability required to master control, operation, and maintenance of requested MPK.

Microprocessor Controlled Prosthetic Knee

<u>MPK for MFCL K3-K4</u>

1. Member is an active K3-K4 adult with a trans-femoral, knee disarticulation or hip disarticulation amputation.
2. Member has a documented need for and use of a microprocessor knee as the primary day to day prosthesis for all the following:
    a. Daily necessary long-distance ambulation (> 400 ft.) at variable speeds
    b. Daily necessary ambulation on outdoor uneven terrain
    c. Daily necessary repetitive use of stairs beyond usual routine limited home or workplace
    d. Daily necessary ambulatory speed greater than normal or usual speed
3. Documentation of all:
    a. Member is in excellent physical condition, has a high exercise capacity
    b. Member has undergone a clinical gait analysis demonstrating the ability to ambulate at a rate faster than the member's baseline rate using a standard prosthetic application swing and stance control
    c. Current non-MPK knee no longer fulfills ambulatory and functional needs of the member

<u>MPK for MFCL K2</u>

1. Member is an MFCL K2 individual with a unilateral trans-femoral amputation
2. Member has received a non-MPK lower limb prosthesis and documentation, including Physical Therapy evaluation, support current prosthetic knee component does not meet member's daily ambulatory and functional requirements
3. Member's use of MPK will result in one or more of the following:
    a. Improved balance
    b. Decreased risk of fall(s)
    c. Increased indoor ambulation
    d. Increased independence in indoor ADLs

e. Increased community ambulation, including uneven terrain, slopes and/or ramps
4. Member has completed a trial using MPK prosthesis
5. Documented peer-reviewed outcome measures from MPK trial (e.g., 2MWT, AMP, TUG, AMPPro, Basic Amputee Mobility Score (BAMS)), support member will achieve desired ambulatory and functional goals

Microprocessor Controlled Prosthetic Foot/Ankle (MPFA): Initial or Replacement

The Plan may authorize coverage of a microprocessor foot/ankle component when criteria for initial lower limb prosthesis are met AND when ALL the following criteria are met:

1. Member is a transtibial amputee whose functional level is K3-K4.
2. Member has undergone evaluation by a board-certified prosthetist [American Board of Certification (ABC) or Board of Certification (BOCP) certified prosthetic clinician trained prosthetic with expertise in the evaluation and fitting of individuals for this device.
3. Non-microprocessor ankle/foot prosthetic components (e.g., multi-axial ankle/foot, dynamic- response foot) have been trialed and submitted clinical documentation supports that trialed component will not meet member's daily ambulatory and functional requirements, OR
4. Member currently utilizes a lower limb prosthesis with a foot/ankle component other than a microprocessor-controlled foot/ankle component, and documentation supports their current prosthetic foot/ankle component no longer meets member's ambulatory daily functional requirements.
5. Daily necessary ambulation on outdoor uneven terrain.
6. Daily necessary ambulation on inclines/declines (e.g., slopes, ramps).
7. Daily necessary repetitive use of stairs beyond usual routine limited home or workplace.
8. Member has cognitive ability required to master control, operation and maintenance of requested foot/ankle microprocessor.

Replacement Prosthesis Authorization

A replacement is the removal and substitution of a prosthesis or a component of a prosthesis

The Plan may authorize the replacement of lower limb prosthesis or the replacement of any part of such device, if an ordering physician determines that the replacement device, or replacement part of such a device, is necessary when **all** the following criteria are met:

- Documentation by Provider that member has demonstrated continuous use of current prosthesis; and
- There is a change in the physiological condition or functional level of the member, which justifies a new prosthesis or replacement part(s) OR there is an irreparable change in the condition of the device, or in a part of the device; and
- The component or prosthesis in need of replacement due to irreparable change in condition of device is not covered under warranty

The Plan may cover the replacement of sockets when there is adequate documentation of functional and/or physiological need, including but not limited to: changes in the residual limb, functional need changes, or irreparable damage or wear/tear due to excessive weight or prosthetic demands of very active amputees.

Covered repairs must be performed by a certified prosthetist as described above, or technician working under the supervision of a certified prosthetist.

Exclusions:

The plan considers the following as not medically necessary:

- The Plan will not authorize a prosthesis for a Member whose potential functional level is 0.
- The Plan will not authorize prosthesis for a Member with intolerance to test socket fitting and/or wear due to residual limb issues, including but not limited to intractable pain, joint contractures and skin/wound complications, as such intolerance will likely predict a poor outcome with a permanent prosthetic.
- The Plan will not cover lower limb adjustable sockets.
- The Plan will not cover upgrade or enhancement of member's current prosthesis or prosthetic component(s) when member's current prosthesis or prosthetic component(s) meets their medical and ambulatory needs and allows the member to perform activities of daily living.
- The Plan will not cover additional or duplicate prosthesis or prosthetic component(s).
- The Plan will not cover repair or replacement of a spare, backup or duplicate prosthesis or prosthetic component(s).
- The Plan will not cover any of the following items, as they are not considered medically necessary:
    - Swim prosthesis
    - Shower prosthesis
    - Devices intended for sports, recreation and/or work-related purposes
    - Test (diagnostic) sockets for immediate prostheses
    - More than two of the same socket inserts per individual prosthesis at the same time
    - Vacuum-assisted socket system (VASS™)
    - Artificial limbs or parts thereof for cosmetic purposes only, including, but not limited to, nonfunctional prosthetics, nonfunctional prosthetic covers and toe prostheses.
    - The Plan will not cover powered knee flexion/extension component (L5859) and power assist ankle-foot or ankle system (L5969) as they are considered to be experimental and investigational according to the The Plan's Evidence of Coverage definition. There is a lack of sufficient evidence in the published peer-reviewed medical literature substantiating their effectiveness in reducing disability and improving function over standard leg prostheses.
    - Hip flexion contracture >30
    - Microprocessor-controlled prostheses for individuals who do not meet recommended weight or height guidelines of manufacturer
    - 3D printed prostheses
    - Osseo-integrated prostheses
    - Myoelectric sensors that can be implanted beneath the skin to improve prosthetic function and control
    - Targeted muscle reinnervation

Additional Limitations – Microprocessor Knee and Microprocessor Foot/Ankle

The Plan will not cover the following, as they relate to microprocessor knee and microprocessor foot/ankle prosthetic component requests, as they are not considered medically necessary:

- Significant deformity of the remaining limb exists, impairing ability to transfer or ambulate stride
- Member is unable to tolerate the weight of the microprocessor unit
- Significant hip flexion contracture of affected residual limb preventing correct knee alignment and MPK activation as per manufacturer's recommendations
- Prosthesis will be utilized in environment contraindicated for microprocessor components, including excessive sand, debris, water, and saltwater
- Gemium X2 microprocessor-controlled knee prosthetic device and Genium X3 waterproof microprocessor-controlled knee prosthetic devices when there is a less intensive MPK device which can safely and effectively meet the member's ambulatory and functional needs
- Waterproof MPK devices

Coding:

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

Code	Description
L5000, L5020, L5050, L5060, L5100, L5105, L5150, L5160, L5200, L5230, L5250, L5270, L5280, L5341, L5500, L5505, L5510, L5600, L5610, L5617, L5618, L5629, L5630, L5653, L5654, L5699, L5700, L5707, L5710, L5782, L5785, L5795, L5810, L5990 L5999	Lower limb prosthetics
L5312	Knee disarticulation (or through knee), molded socket, single axis knee, pylon, SACH foot, endoskeletal system
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
L5857	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type
L5858	Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)

Billing Guidelines:

Member's medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

References:

1. The General Laws of Massachusetts. Chapter 176G: Section 4S. Coverage for prosthetic devices and repairs. Retrieved on December 7 2015 from: www.mass.gov/legis/laws/mgl/176g-4s.htm
2. Cost-Effectiveness of C-Leg Compared With Non–Microprocessor-Controlled Knees: A Modeling Approach (Brodtkorb et al., 2008), Archives of Physical Medicine and Rehabilitation
3. VHA Prosthetic Clinical Management Program (PCMP). Clinical practice recommendations: microprocessor knees, 2004. See: Berry D. Microprocessor prosthetic knees. Phys Med Rehabil Clin N Am 2006; 17:91-113.

Summary of Changes:

Date	Change
1/23	Reviewed by MPAC for effective date June 1, 2023. Clarification to replacement criteria requirements for physiological condition/functional level change vs. irreparable change

3/22	Criteria updated to include criteria for Initial Prosthesis, Microprocessor Knee and Microprocessor Foot/Ankle, and Updated Exclusions for integration purposes with Tufts Health Plan (THP)
5/21	Annual review; no changes
11/20	Annual review; exclusions language updated
5/19	Annual review; no changes
6/17	References updated
1/17	New Policy. Criteria to now require prior authorization

Approved by Medical Policy Committee: 03/16/22
Approved by Clinical Policy Operational Committee: 1/17; 6/17; 5/19; 3/21; 5/21; 3/22; 3/23
Policy Effective Date: 06/01/2023
Initiated: 1/17