

Subject: Lower Limb Prostheses

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 Coverage Criteria:

Harvard Pilgrim Health Care (HPHC) considers 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) for individuals who:

- Have the potential to use the prosthesis for transfers and or ambulation; and
- Can reasonably be expected to reach or maintain a predicted improved functional state (with the use of the prescribed prosthesis) within a reasonable period of time; and
- Have adequate cardiovascular reserve and cognitive ability to effectively utilize the device.

Harvard Pilgrim Health Care (HPHC) considers sockets, stump stockings, prosthetic sheaths/socks (including gel cushion layers/ prosthetic gel stockings) and replacements as medically necessary and essential to the effective use of an artificial limb.

HPHC does not cover:

- Prosthetic devices or components that are not designed for use in performing ordinary activities of daily living, or that otherwise exceed the medical needs of the individual member;
- Replacement prostheses unless the current device is not meeting the individual's medical needs, or the current device is broken and cannot be repaired.

Criteria:**Microprocessor-Controlled Leg Prostheses:**

Harvard Pilgrim Health Care (HPHC) considers microprocessor-controlled leg prostheses as reasonable and medically necessary for individuals who have the ability or potential for ambulation with variable cadence, or for prosthetic ambulation that exceeds basic ambulation skills.

- Covered devices (e.g., Otto Bock C-Leg, Intelligent Prosthesis, Ossur Rheo Knee, Freedom Plie) must be fitted and programmed by an appropriate, qualified prosthetist, and criteria (below) must be met.

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. This assessment must include clinical gait analysis demonstrating the member has ability to transfer and ambulate safely, and objectively confirm that the member meets ALL the following:

- Desires and requires the requested prosthesis for daily ambulation and activities of daily living;
- Does not exceed the manufacturer's recommended weight/height restrictions for the requested device;
- Has adequate strength and stride balance to activate the microprocessor-controlled knee unit;
- Has Level 2- 4 rehabilitation potential (based on Classification of Rehabilitation Potential Table below).

In addition, documentation must confirm that none of the following would limit the member's ability to use and benefit from use of the microprocessor-controlled lower limb prosthesis:

- Inability to tolerate the weight of the prosthesis;

- Hip flexion contracture > 30 degrees;
- Deformity of remaining limb that would impair ability to stride;
- Condition that prevents socket fitting (e.g., complicated wound), or precludes socket wear (e.g., intractable pain);
- Specific environmental factors (e.g., excessive moisture or dust, inability to charge the device, extreme rural conditions where maintenance ability is limited) that preclude appropriate care of the device.

Requests for coverage for microprocessor devices developed specifically for individuals with Level 1 rehabilitation potential are reviewed on a case by case basis, and may be approved when clinical documentation clearly demonstrates the device or component is medically necessary, and the least intensive prosthesis or component(s) to adequately meet the medical needs of the member.

Foot Prostheses:

Harvard Pilgrim Health Care (HPHC) considers microprocessor-controlled foot prostheses as medically necessary when medical record documentation (including prosthetist notes) confirms a member with Level 2-4 rehabilitation potential (based on Classification of Rehabilitation Potential Table below) has a functional need for the technologic or design feature of the requested device (with type of foot determined by the treating physician and/or the certified prosthetist based upon the member's functional needs). Covered devices may include:

- Ankle Foot System
- Energy Storing Foot
- Dynamic Response Foot with Multiaxial Ankle
- Flex Foot System
- Flex-Walk System (or equivalent)
- Shank Foot System with Vertical Loading Pylon
- Hydraulic Ankle-Foot systems

Medical record documentation must confirm that none of the following would limit the member's ability to use, or benefit from use of, the requested microprocessor-controlled device:

- Condition that prevents socket fitting (e.g., complicated wound) or precludes socket wear (e.g., intractable pain);
- Limb deformity that would impair ability to stride;
- Inability to tolerate the weight of the prosthesis;
- Specific environmental factors (e.g., excessive moisture or dust, inability to charge the device, extreme rural conditions where maintenance ability is limited) that preclude appropriate care of the device.

Repairs and Adjustments

Harvard Pilgrim Health Care (HPHC) considers maintenance (consistent with manufacturer recommendations) and repairs/adjustments required (to make the covered prosthesis functional) due to wear and tear, or a change in the individual's condition as reasonable and necessary.

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

Replacement Devices and Components:

Harvard Pilgrim Health Care (HPHC) considers replacement devices and components as reasonable and necessary when a certified prosthetist determines:

- There is an irreparable change in the condition of the member's current device (or a component of the device), and the device/component is not covered under warranty; AND
- The device/component needs to be replaced due to a change in the member's physiological condition or functional level (i.e., not as a result of negligence or improper use); AND
- The cost of repairs is expected to exceed 60% of the replacement cost of the device or component.

Medical record documentation must support the need for the new prosthesis or replacement part(s).

Exclusions:

Harvard Pilgrim Health Care (HPHC) considers the following as not medically necessary:

- Lower limb prostheses for individuals who do not have the ability or potential to ambulate or transfer safely with or without assistance (Functional level: 0)
- Microprocessor-controlled prostheses in situations where criteria above are not met
- Microprocessor-controlled prostheses for individuals who do not meet recommended weight or height guidelines of manufacturer

In addition, Harvard Pilgrim Health Care (HPHC) considers the following devices as experimental and investigational due to insufficient evidence (in peer-reviewed literature) demonstrating they improve health outcomes:

- Microprocessor-controlled leg prostheses for gait management for members with spinal cord injury;
- Microprocessor controlled foot-ankle system addition with power assist (including any type motor- L5969)
- User-adjustable heel height feature on a microprocessor foot

Guidelines:

Classification of Rehabilitation Potential

Clinical assessment of rehabilitation potential is based on the following classification levels:	
Level 0:	Individual does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthetic device does not enhance his/her quality of life or mobility.
Level 1:	Individual has the ability or potential to use a prosthetic device for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
Level 2:	Individual has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
Level 3:	Individual has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
Level 4:	Individual as the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

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,	Lower limb prosthetics

HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members’ unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.

Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g. Benefit Handbook, Certificate of Coverage) for member-specific benefit information.

Code	Description
L5280, L5341, L5500, L5505, L5510, L5600, L5610, L5617, L5618, L5629, L5630, L5653, L5654, L5699, L5700, L5707, L5710, L5782, L5785, L5795, L5810, L5999	
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
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: 05/14/2019

Approved by Clinical Policy Operational Committee: 1/17; 6/17; 5/19

Policy Effective Date: 05/30/2019

Initiated: 1/17