

Document ID#: 2105789  
Subject: Lower Limb Prostheses Including  
Microprocessor-Knee  
Effective Date: January 1, 2012

Clinical Documentation and Prior Authorization Required	√	Type of Review - Case Management	
Not Covered		Type of Review – Precertification Department	√
Special Information		Administrative Process (Internal Use Only)	PT

**Please Note: Depending upon the service, while you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.**

### Overview

A prosthesis is a device or an artificial substitute designed to replace, as much as possible, the function or appearance of a missing limb or body part (Bodeau and Mipro, 2002).

A microprocessor knee is a prosthetic knee component equipped with a sensor that detects when the knee is in full extension and adjusts the swing phase automatically, permitting a more natural pattern of walk of varying speeds.

The microprocessor knee component is designed to improve the stance control. By improving stance control the microprocessor knee provides for increased safety, stability and function.

Other potential benefits are improved ability to navigate stairs, slopes, and uneven terrain, with a reduction in energy expenditure and concentration for ambulation.

### Coverage Guidelines

Tufts Health Plan requires prior authorization for all new and replacement lower limb prostheses, or part thereof. Tufts Health 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.

According to Medicare (2009), the Member's functional level is a measurement of the capacity and potential of the patient to accomplish his/her expected post-rehabilitation, daily function. The functional classification is used by Tufts Health Plan to establish the medical necessity only of prosthetic knees, feet, and ankles. The clinical assessments of the Member's rehabilitation potential should be based on the following classification levels:

Level	Description
Level 0	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	Description
Level 1	Has the ability or potential to use prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
Level 2	Has the ability or potential for ambulation with the ability to transfer low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
Level 3	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to transverse most environmental barriers, and may have vocational, therapeutic, or exercise activities that demands prosthetic utilization beyond simple locomotion.
Level 4	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of a child, active adult, or athlete.

### Initial Prosthesis

Tufts Health Plan may authorize coverage of initial lower limb prosthesis when **all** of the following criteria are met:

1. The requested prosthesis or component(s) is the most appropriate, least intensive, medically necessary model that adequately meets the medical needs of the member (MGL 176G § 4S).
2. Member will reach or maintain a predicted improved functional state, with the use of the prescribed prosthesis within a reasonable and predictable period of time.
3. Member is motivated and has the potential to become a functional ambulator.
4. 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.
5. 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
    - 1) A solid ankle-cushion heel (SACH) foot is considered appropriate in most circumstances for persons whose functional level is 1 or above.
    - 2) An external keel SACH foot or single axis ankle/foot is considered appropriate in most circumstances for persons whose functional level is 1 or above.
    - 3) A flexible-keel foot or multi-axial ankle/foot is considered appropriate in most circumstances for persons whose functional level is 2 or above.
    - 4) A flex foot system, energy storing foot, multi-axial ankle/foot, dynamic response, or flex-walk system or equal is considered appropriate in most circumstances for persons whose functional level is 3 or above.
  - b. Knee Components (For coverage guidelines related to microprocessor knee components see below)
    - 1) A fluid, pneumatic, or electronic knee is considered appropriate in most circumstances for persons whose functional level is 3 or above.
    - 2) A single axis constant friction knee and other basic knee systems are considered appropriate in most circumstances for persons whose functional level is 1 or above.
  - c. Ankle Components

An axial rotation unit is considered appropriate in most circumstances for persons whose functional level is 2 or above.

d. Sockets

Tufts Health 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.

### **Microprocessor Controlled Prosthetic Knee**

Tufts Health Plan may cover a microprocessor knee component when **ALL** of the following criteria are met:

1. Member is a healthy, active K3-K4 adult with a trans-femoral amputation.
2. Member has a documented need for **all**:
  - a. Daily necessary long distance ambulation ( > 400 ft) at variable speeds
  - b. Daily necessary ambulation on 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, and has no cardiovascular, neuromuscular, musculoskeletal or cognitive conditions that could adversely affect the ability to use this prosthesis.
  - b. 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 with swing and stance control.
  - c. Has undergone evaluation by a trained prosthetic clinician with expertise in the evaluation and fitting of members for this device.
  - d. Member has tried and successfully used a lower limb prosthesis with a knee component other than a microprocessor controlled knee component with success for a minimum of one year.

### **Replacement Prosthesis**

1. A replacement is the removal and substitution of a component of a prosthesis that has a HCPCS definition.
2. Tufts Health Plan may authorize the replacement of lower limb prosthesis or the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the replacement device, or replacement part of such a device, is necessary when the following criteria are met:
  - a. There is a change in the physiological condition or functional level of the Member, which justifies a new prosthesis or replacement parts.
  - b. There is an irreparable change in the condition of the device, or in a part of the device.
  - c. The condition of the device, or the part of the device, requires repairs, and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.
  - d. The component or prosthesis in need of replacement is not covered under warranty and is not in need of replacement as a result of improper use.
3. Tufts Health 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.

## Limitations-General

- Tufts Health Plan will not authorize a prosthesis for a Member whose potential functional level is 0.
- Tufts Health Plan will not cover any of the following items, as they are not considered medically necessary:
  - Swim prosthesis
  - Shower prosthesis
  - 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.
  - Tufts Health Plan will not cover microprocessor components for the **ankle** as they are considered to be experimental and investigational according to the Tufts Health 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.

## Limitations-Microprocessor Knee

Tufts Health Plan will not cover the following, as they relate to microprocessor knee requests, as they are not considered medically necessary:

- Amputees with the following functional levels : K0 , K1 or K2 where limited community ambulation is compromised by cardiovascular reserve, strength and balance to improve stability in stance that permits increased independence, decreased risk of falls and potential to advance to a less restrictive walking device.
- Primary benefit of the limb is to allow the member to perform leisure or recreational activities
- Significant deformity of the remaining limb exists impairing ability to stride
- Member falls outside of recommended weight guidelines (≤ 275 lbs.)

## Codes

The following HCPCS/CPT code(s) require prior authorization:

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 – 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,

Code	Description
	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

## References

1. Bodeau, V. S., Mipro, R. C. Lower limb prosthetics. Emedicine. August 22, 2002. Retrieved on December 26, 2006 from: <http://www.emedicine.com/pmr/topic175.htm>.
2. Centers for Medicare and Medicaid Services. Article for lower limb **prosthesis** (A10439). Medicare Coverage Database. Retrieved on January 28, 2009 from: [http://www.cms.hhs.gov/mcd/viewarticle.asp?article\\_id=10439&article\\_version=4&basket=article%3A10439%3A4%3ALower+Limb+Prosthesis%3ADME+MAC%3ANHIC%7C%7C+Corp%2E+%2816003%29](http://www.cms.hhs.gov/mcd/viewarticle.asp?article_id=10439&article_version=4&basket=article%3A10439%3A4%3ALower+Limb+Prosthesis%3ADME+MAC%3ANHIC%7C%7C+Corp%2E+%2816003%29)
3. Chin, T., Sawamura, S., Shiba, R., et al. Energy expenditure during walking in amputees after disarticulation of the hip: A microprocessor-controlled swing-phase control knee versus a mechanical-controlled stance-phase control knee. *Journal of Bone and Joint Surgery British*. 2005; 87(1):117-119.
4. Swanson, E., Stube, J., Edman, P. Function and body image levels in individuals with transfemoral amputations using the C-Leg. *Journal of Prosthetics & Orthotics*. 2005;17(3):80-84.
5. Centers for Medicare and Medicaid Services. LCD for Lower Limb Prostheses (L11464). Medicare Coverage Database. Retrieved on January 28, 2009 at: [http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd\\_id=11464&lcd\\_version=27&basket=lcd%3A11464%3A27%3ALower+Limb+Prostheses%3ADME+MAC%3ANHIC%7C%7C+Corp%2E+%2816003%29%3A](http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=11464&lcd_version=27&basket=lcd%3A11464%3A27%3ALower+Limb+Prostheses%3ADME+MAC%3ANHIC%7C%7C+Corp%2E+%2816003%29%3A)
6. The General Laws of Massachusetts. Chapter 176G: Section 4S. Coverage for prosthetic devices and repairs. Retrieved on January 28, 2009 from: <http://www.mass.gov/legis/laws/mgl/176g-4s.htm>
7. Centers for Medicare and Medicaid Services. Article for lower limb prosthesis (A10439). Medicare Coverage Database. [Http://www.cms.hhs.gov/mcd/viewarticle.asp?article\\_id=10439&article\\_version=4&basket=article%3A10439%3A4%3ALower+Limb+Prosthesis%3ADME+MAC%3ANHIC%7C%7C+Corp%2E+%2816003%29](http://www.cms.hhs.gov/mcd/viewarticle.asp?article_id=10439&article_version=4&basket=article%3A10439%3A4%3ALower+Limb+Prosthesis%3ADME+MAC%3ANHIC%7C%7C+Corp%2E+%2816003%29)
8. Comparison of non microprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference (Kahle et al., 2008), *Journal of Rehabilitation Research & Development (JRRD)*
9. Computerized Lower Limb Prosthesis (VA Technology Assessment Program VATAP, reviewed 2008)
10. Cost-Effectiveness of C-Leg Compared With Non–Microprocessor-Controlled Knees: A Modeling Approach (Brodtkorb et al., 2008), *Archives of Physical Medicine and Rehabilitation*
11. 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.
12. [www.ottobockus.com](http://www.ottobockus.com)

## Approval History

Reviewed by the Clinical Coverage Criteria Committee on January 3, 2007: New criteria.

Subsequent Endorsement Date(s) and Changes Made:

- February 28, 2007: Reviewed and renewed, without changes
- February 27, 2008: Reviewed and renewed, without changes
- March 26, 2008: Reviewed and renewed, without changes
- October 8, 2008: Special Information box added to MNG format.
- March 16, 2009: Limitation for non coverage of cosmetic, nonfunctional prostheses added.
- March 2010: Reviewed by MASPAC, Medical Policy-Medical Affairs. Microprocessor knee component criteria added as they are now covered; ankle microprocessor limitation added these components are still considered experimental.
- April 2011: Reviewed by MSPAC, without changes
- January 1, 2012: New CPT code added

## Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for Tufts Health Plan benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. Tufts Health Plan makes coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan revises and updates Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Medical Necessity Guidelines apply to all fully insured Tufts Health Plan products unless otherwise noted in this guideline or the Member's benefit document. This guideline does not apply to Tufts Health Plan Medicare Preferred or to certain delegated service arrangements. For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. Providers in the New Hampshire service area are subject to CIGNA HealthCare's provider arrangement for the purpose of CareLink<sup>SM</sup>.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.