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Subject: Lower Limb Prostheses
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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

Note: Background, product, and disclaimer information is located at the end of this document.

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).

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 1	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 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.

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)

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 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
 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.
 3. Microprocessor knee components are not covered by Tufts Health Plan (see [Limitations](#)).
 - 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.

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.
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

- 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 leg 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.

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

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

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
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>

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.

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 CareLinkSM.

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.