

UPMC Health Plan POLICY AND PROCEDURE MANUAL

POLICY NUMBER: MP.012
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SUBJECT: Microprocessor Controlled Knee Prostheses
INDEX TITLE: Medical Management
ORIGINAL DATE: November 2005

This policy applies to the following lines of business: (Check those that apply.)

Commercial:				
HMO ()	POS ()	PPO ()	OOA/DOC ()	
Fully Insured ()	Self-funded/ASO ()	HSA ()	All (X)	
Medicare Select ()	Medicare Supplement ()			
DPW-MA:				
Health Choices ()	Voluntary ()		All (X)	
CMS-MA:				
OH ()	WV ()	PA ()	All (X)	Other ()
HMO (X)	PPO (X)	Specialty Needs Plan (X)	Part D ()	PFFS (X)
PID-CHIP:				
Free ()	Sub ()		All (X)	
APPLICABLE TO:				
Community Care ()	Work Partners ()			

I. POLICY

It is the policy of UPMC Health Plan to cover microprocessor controlled knee prosthesis when it is medically necessary and covered under the member's benefit plan.

UPMC Health Plan recognizes Microprocessor controlled prosthetic knees for lower limb amputees as medically necessary and consistent with good medical practice only in exceptional circumstances outlined below. Coverage will be considered, on a case-by-case basis, for the specific indications detailed in this policy.

All denials are based on medical necessity and appropriateness as determined by a UPMC Health Plan Medical Director (Medical Director).

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the criteria for the Microprocessor Controlled Prosthetic Knee.

IV. SCOPE

This policy applies to various UPMC Health Plan departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims departments.

V. PROCEDURE

A. Medical Description

There are over 100 different prosthetic knee designs currently available. The choice of the most appropriate design for a prosthetic knee from the many different devices available depends on the member's underlying activity level. For example, the requirements of a prosthetic knee in an elderly, largely homebound individual will be quite different than a younger, active person.

In general, key elements of a prosthetic design involve providing stability during both the stance and swing phase of the gait. Prosthetic knees also vary in their ability to alter the cadence of the gait, or the ability to walk on rough or uneven surfaces. The mechanical complexity of these devices allows engineers to optimize selected stance and swing phase features.

Most recently microprocessor-controlled prosthetic knees have become available, including the Intelligent Prosthesis (Blatchford, United Kingdom) C-LEG® (Otto Bock Orthopedic Industry, Minneapolis, MN) and Rheo ® (Ossur, Iceland). These devices are equipped with a sensor that detects when the knee is in full extension allowing for early-stance knee flexion and smooth swing phase kinematics. For example, the prosthetist can specify several different optimal adjustments that the computer later selects and applies according to the pace of ambulation. The C-LEG® (Otto Bock Orthopedic Industry, Minneapolis, MN) and Rheo ® (Ossur, Iceland) knee are specifically designed to improve the stance control; for example, it may be possible for the sensors to recognize a stumble, stiffen the knee, and avoid a fall.

Relevant outcomes for microprocessor-controlled knee prostheses may include the patient's perceptions of subjective improvement attributable to the prosthesis and level of activity/function. In addition, the energy costs of walking or gait analysis may be a more objective measure of the clinical benefit of the microprocessor-controlled prosthesis. There are minimal published data on the microprocessor-controlled knee prostheses; the bulk of the literature focuses on the Intelligent Prosthesis, which, while similar to the C-LEG, is not distributed in this country. However, an article in the August 2005 American Journal PM&R comparing the C-leg, (Otto Bock Orthopedic Industry, Minneapolis, MN) and Rheo ® (Ossur, Iceland) knee and hydraulic-based Mauch SNS knee showed that both microprocessor knees offered advantages over the hydraulic knee for self-selected ambulatory speeds. In regards to energy cost, the Rheo knee produced a statistically significant decrease (5%) compared to the Mauch SNS knee, although no significant difference with energy cost was observed between the C-leg, (Otto Bock Orthopedic Industry, Minneapolis, MN) and Mauch SNS knees.

Functional Levels:

Clinical assessments of member rehabilitation potential are based on the following functional classification levels:

Level 0: The member does not have the ability or potential to ambulate or transfer safely with or without assistance and prosthesis does not enhance their quality of life or mobility.

Level 1: The member 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: The member 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: The member 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: The member 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 the child, active adult, or athlete.

The Pricing, Data, analysis and coding contractor (PDAC) recognizes within the functional classification hierarchy that bilateral amputees often cannot be strictly bound by functional level classifications

B. Specific Indications

A lower limb prosthesis is covered when the member meets general criteria AND specific criteria.

General Criteria

1. The member will reach or maintain a defined functional state within a reasonable period of time, AND
2. The member is motivated to ambulate.

Specific Criteria

C-Leg or Rheo Application:

1. Amputees must weigh ≤ 125 kg. (275.5) lbs,
AND
2. Have a functional level of 3 or higher.

Bilateral Transfemoral Amputees

In addition to the above, the member needs to demonstrate unique activity requirements but in certain instances would qualify if the above criteria are met.

Component Additions to the Prosthesis

In addition to the above, component additions to the prosthesis are based on the member's potential functional abilities. Potential functional ability is based on the reasonable expectations of the prosthetist, and treating physician, considering factors including:

1. The member's past history (including prior prosthetic use if applicable),
AND
2. The member's current condition including the status of the residual limb and the nature of other medical problems.

C. Limitations

The C-leg or Rheo microprocessor knees are **not covered** under the following conditions:

- Members planning for competitive sporting events.
- Members who are not motivated to ambulate or for those who are not expected to reach or maintain a defined functional state within a reasonable period of time.
- When the sole purpose of the device is to enhance the member's athletic capabilities.

D. Information Required for Review

In order for medical necessity to be established, adequate information must be furnished by the treating provider/practitioner. Necessary information includes:

1. Each member under consideration must have an evaluation performed by a physiatrist or orthopedic surgeon knowledgeable in lower limb prosthetic rehabilitation who advocates for a microprocessor knee. Referrals from prosthetic vendors or durable medical equipment (DME) providers without physician support are discouraged.
2. Documentation identifying the member's:
 - Clinical history,
 - Previous use of prosthesis for the current condition when applicable,
 - Current and expected functional level of rehabilitation determined by the prosthetist, including an explanation for the difference, if that is the case.
3. Type of prosthesis to be used, including the Current Procedural Terminology (CPT) and/or Healthcare Common Procedure Coding System (HCPCS) code.
4. Bilateral Transfemoral Amputees- in addition to the above, any unique activity requirements.
5. Component Additions to the Prosthesis - in addition to the above, the member's current condition including the status of the residual limb and the nature of other medical problems

E. Review Process

1. The Medical Management Ancillary Service staff reviews the request according to CRM.001 - Prior Authorization/Pre-Service Review policy. If the case does not meet the established criteria, it is referred to a Medical Director.
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.

3. The Medical Management Ancillary Service staff completes the review process and communicates the review decision.

F. Variations

N/A

G. Records Retention

Records Retention for UPMC Health Plan documents, regardless of medium are provided within the UPMC Health System Policy, and as indicated in the UPMC Insurance Services Division Policy and Procedure.

H. References

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5. Food and Drug Administration: C-Leg (3C100) 510(k) Summary. 1999 July 8.
6. Otto Bock Healthcare – Quality of Life Paper- 3C100 C-Leg System- Unpublished.
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8. Johansson JL, Sherrill DM, Riley PO, et al. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. Am J Phys Med Rehabil. 2005 Aug; 84(8): 563-75.
9. Tricenturion, Local Coverage Determination No. L11464, Lower Limb Prosthesis, revision effective 1-1-06
10. Centers for Medicare & Medicaid Services, Durable Medical Equipment Medicare Administrative Contractor.
http://www.cms.hhs.gov/MedicareContractingReform/08_DurableMedicalEquipmentMedicareAdministrativeContractor.asp
11. NHIC Local Coverage Determination No. L11464, Lower Limb Prosthesis, effective 1/1/09. http://www.medicarenhic.com/dme/medical_review/mr_lcd_current.shtml
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<https://members2.ecri.org/Components/Hotline/Pages/7552.aspx>
13. Otto Block: High-Tech for More Quality of Life- the C-Leg Prosthesis System, 6-5-09.
http://www.ottobock.com/cps/rde/xchg/ob_com_en/hs.xsl/1913.html?openteaser=1
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Block Orthopedic Industry C-Leg, 7-8-99

Disclaimer:

UPMC Health Plan medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of UPMC Health Plan and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

UPMC Health Plan reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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