



BlueCross BlueShield
of Alabama

Name of Policy:

Computerized Lower Limb Prosthesis

Policy #: 083

Latest Review Date: August 2007

Category: DME and Prosthetics

Policy Grade: D

Background:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts to have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Coding:

- HCPCS codes: ~~L5847~~ — Addition, endoskeletal knee shin system, microprocessor control feature, stance phase (Code deleted effective 1/1/05)
- ~~L5989~~ — Addition to lower extremity prosthesis, endoskeletal system pylon with integrated electronic force sensors (Code deleted effective 1/1/05)
- L5930 Addition, endoskeletal system, high activity knee control frame
- L5828 Addition, endoskeletal, knee-shin system, single axis, fluid swing and stance phase control
- L5845 Addition, endoskeletal, knee-shin system, stance flexion feature, adjustable
- ~~L5846~~ — Addition, endoskeletal, knee shin system, microprocessor control feature, swing phase only (Code deleted effective 1/1/05)

- 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

Effective for dates of service on or after January 1, 2006:

- L5858** Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type

Effective for dates of service on or after April 1, 2005:

- ~~**K0670** Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type (Code deletes effective January 1, 2006)~~

HCPCS modifiers: **K0** Functional Level 0; *see Key Points*

K1 Functional Level 1; *see Key Points*

K2 Functional Level 2; *see Key Points*

K3 Functional Level 3; *see Key Points*

K4 Functional Level 4; *see Key Points*

Description of Procedure or Service:

The C-leg, currently made by Otto Bock Healthcare, has a hydraulic knee that has both swing and stance controlled by a microprocessor. The C-leg is made of lightweight carbon fiber material and is powered by a rechargeable lithium ion battery with 30-35 hours of functional capacity. The computer-controlled knee takes readings 50 times per second and measures 23-26 different parameters to determine what it should do next. In a traditional single-axis hydraulic system, the patient walks in a lab on level ground and the prosthetist sets the knee's flexion and extension. When the patient walks outside in a different environment, the settings remain the same. The C-leg has a more stable knee, thus patients can achieve a more normal gait. The C-leg can also determine when it should not do something. For the knee to release, the patient must load 66% of his or her weight over the foot. This serves as a safeguard if, for example, the patient stubs or catches his or her toe on the ground.

Policy:

Computerized lower limb prostheses meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage when ordered for persons with above the knee (AKA) amputations and **all** the following indications are met:

- The patient is fit and active with at least a potential Functional Level 3 or 4 (*see Key Points*).

- The patient has the appropriate cognitive abilities ~~and has demonstrated compliance by successfully utilizing a hydraulic knee system for at least 2 years~~ to master use and care requirements for the technology
- The patient does not have additional medical problems that would interfere with maintaining Functional level 3 or 4; i.e. disabling cardiovascular, neuromuscular, peripheral vascular, or musculoskeletal (other than amputation) conditions.

Computerized lower limb prostheses is contraindicated when:

- Patient is historically non-ambulatory or has a potential Functional Level below 3 (*see Key Points*).
- Patient has demonstrated a lack of proper care for existing equipment.
- Patient is not motivated.
- Patient lives or works in a wet environment.

Blue Cross and Blue Shield of Alabama will cover **one** computerized prosthesis per limb **per five years when medically indicated**. Coverage will not be provided if the prosthesis is functioning properly and in good general condition.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administer benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

According to the National Center for Health Statistics study, there are approximately 200,000 new amputations in the United States every year. Approximately 70% are lower-limb amputations.

Potential functional ability is based on the reasonable expectations of the prosthetist and treating physician, considering factors including, but not limited to:

- a) the patient’s past history (including prior prosthetic use if applicable);
- b) the patient’s current condition including the status of the residual limb and the nature of other medical problems; and
- c) the patient’s desire to ambulate.

Clinical assessments of the patient’s rehabilitation potential should be based on the following classification levels. Medical records should document the patient’s current functional capabilities and his/her expected functional potential, including an explanation for the difference, if that is the case.

Functional Levels

Level 0:	Does not have the ability or potential to
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	ambulate or transfer safely with or without assistance and prosthesis does not enhance their quality of life or mobility.
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 traverse 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 traverse most environmental barriers and may have vocational, therapeutic, or exercise activity 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 the active adult.

Otto Bock Healthcare recommends that the C-leg be used for adult patients with at least 15 inches from knee center to floor and for patients that weigh 220 pounds or less.

Key Words:

C-leg, microprocessor control prostheses, computerized leg, computerized lower limb prosthesis, bionic leg

Approved by Governing Bodies:

510(k) FDA approval

Benefit Application:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

BellSouth contracts: No special consideration

FEP contracts: Special benefit considerations may apply. Refer to members’ benefit plan.

Wal-Mart: Special benefit considerations may apply. Refer to members’ benefit plan.

Pre-certification: Not applicable

Pre-determination: Will be done as a courtesy if requested by member or provider.

References:

1. American Orthotic and Prosthetic Association Functional Levels.
2. Blue Cross and Blue Shield Association. *Microprocessor-controlled prosthetic knees. Medical Policy Reference Manual, March 2007.*
3. Chin T, Machida K, et al. *Comparison of difference microprocessor controlled knee joints on the energy consumption during walking in trans-femoral amputees: Intelligent knee prosthesis (IP) versus C-leg.* Prosthet Orthot Int 2006; 30(1): 73-80.
4. Hanger Prosthetic and Orthotics.
5. Orendurff Michael S, Segal AD, et al. *Gait efficiency using the C-leg.* Journal of Rehabilitation Research & Development, March/April 2006, Vol. 43, No. 2, pp. 239-246.
6. Otto Bock Orthopedic Industry, Inc. Otto Bock C-Leg. 510(k) Summary of Safety and Effectiveness. 510 (k) no K99150. Minneapolis, MN: Otto Bock, May 6, 1999. <http://www.fda.gov/cdrh/pdf/k991590.pdf> .
7. United States Department of Veterans Affairs. *VA technology assessment program project report – Patient summary on computerized lower limb prostheses.* <http://www.va.gov/VATAP/patientinfo/prosteticlimb.htm>.
8. United States Department of Veterans Affairs Fact Sheet. *VA’s prosthetics and sensory aids.* February 2006.
9. Wilson M. *Computerized prosthetics.* Ptmagazine 2001; 35-38.

Policy History:

Medical Policy Group, September 2002

Medical Policy Group, November 2002 (2)

Medical Policy Administration Committee, May 2003

Available for comment May 23-July 7, 2003

Medical Policy Group, April 2004

Medical Policy Group, November 2005 (2)

Medical Policy Group, May 2007 (1)

Medical Policy Group, August 2007 (1)

Medical Policy Administration Committee, August 2007

Available for comment August 13-September 27, 2007

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case by case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plans contracts.