



MEDICAL COVERAGE GUIDELINES  
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 04/04/12  
LAST REVIEW DATE: 05/01/18  
LAST CRITERIA REVISION DATE: 05/01/18  
ARCHIVE DATE:

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## MICROPROCESSOR CONTROLLED LOWER LIMB PROSTHESES

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Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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## **MICROPROCESSOR CONTROLLED LOWER LIMB PROSTHESES (cont.)**

### **Description:**

#### **Microprocessor-Controlled Prosthetic Knee:**

Microprocessor controlled prosthetic knee is a computer controlled knee joint system equipped with sensors to detect changes in gait and adjust resistance with every step allowing a more natural walking pattern of various speeds. The sensors detect when the knee is in full extension and adjust the swing phase automatically resulting in greater stability and less energy expenditure than traditional prostheses. Microprocessor controlled prosthetic knees include the Adaptive, the C-Leg®, Genium™ Bionic Prosthetic System, the Intelligent Prosthesis, the Rheo Knee®, the Seattle Power Knees (3 models include Single Axis, 4-bar and Fusion) and the X2 and X3 prostheses. In addition, these devices use microprocessor control in both the swing and stance phases of gait. (The C-Leg Compact provides only stance control.)

Next-generation devices such as the Genium Bionic Prosthetic System the X2 and X3 prostheses use additional environmental input (e.g., gyroscope and accelerometer) and more sophisticated processing that is intended to create more natural movement. One improvement in function is step-over-step stair and ramp ascent. They also allow the user to walk and run forward and backward. The X3 is a more rugged version of the X2 that can be used in water, sand, and mud. The X2 and X3 were developed by Otto Bock as part of the Military Amputee Research Program.

#### **Microprocessor-Controlled Ankle-foot Prostheses:**

Microprocessor controlled ankle-foot prostheses are being developed for transtibial amputees. These include the Proprio Foot®, the iPED and the Elan Foot. Sensors determine the direction and speed of the foot's movement, allowing the foot to lift during the swing phase and adjust to changes in force, speed and terrain during the step phase. The Proprio Foot and the Elan Foot are commercially available microprocessor controlled foot prostheses and are considered class I devices that are exempt from FDA 510(k) marketing clearance.

#### **Powered Prostheses:**

The Power Knee™ powered knee has been investigated to replace muscle activity of the quadriceps to bend and straighten the knee as needed to propel the user forward. The prosthesis is designed to lift the heel from the ground, support the user while ascending inclines and power them up stairs. Sensors within the prosthesis monitor and regulate gait.

The PowerFoot BiOM® powered foot is a myoelectric prosthesis for transtibial amputees that uses muscle activity from the remaining limb for the control of ankle movement. The prosthesis is designed to propel the foot forward as it pushes off the ground during the gait cycle.

#### **Helix3D Hip Joint System:**

The Helix3D Hip Joint System is suitable for hip disarticulation and hemipelvectomy amputees. The multi-axis joint structure produces a three-dimensional hip movement to compensate for pelvic rotation and promotes a symmetrical and natural gait pattern. The Helix3D Hip Joint System is used in combination with the C-Leg or the Genium knee joints and the specified prosthetic feet.



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**Definitions:**

Functional Levels:

Medicare Level K 0:	No ability or potential to ambulate or transfer.
Medicare Level K 1:	Limited ability to transfer or ambulate on level ground at fixed cadence.
Medicare Level K 2:	Limited community ambulator that does not have the cardiovascular reserve, strength, and balance to improved stability in stance to permit increased independence, less risk of falls, and potential to advance to a less-restrictive walking device.
Medicare Level K 3:	Unlimited community ambulator.
Medicare Level K 4:	Active adult, athlete who has the need to function as a K 3 level in daily activities.

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## **MICROPROCESSOR CONTROLLED LOWER LIMB PROSTHESES (cont.)**

### **Criteria:**

#### **Knee Prostheses:**

**All requests for microprocessor controlled knee prosthesis will be reviewed by the medical director(s) and/or clinical advisor(s).**

- Microprocessor controlled knee prosthesis is considered **medically necessary** with documentation of **ALL** of the following:
  1. Demonstrates success utilizing and maintaining a hydraulic swing and stance control knee prosthesis to walk at a faster than baseline rate
  2. Demonstrates potential for improved gait efficiency (e.g., functionality, performance and safety) as determined by gait analysis
  3. Documented current and potential functional level and, if applicable, an explanation for the difference
  4. Potential functional level of 3 or 4
  5. No additional medical conditions that would interfere with maintaining functional level 3 or 4 (e.g., decreased pulmonary reserve, disabling cardiovascular, neuromuscular, peripheral vascular or musculoskeletal conditions)
  6. Meets the manufacturer's specifications and limitations for a microprocessor controlled knee prosthesis AND must be fitted by a prosthetist certified by the manufacturer
  7. Ambulates greater than 400 yards daily OR ambulates regularly on uneven terrain or stairs for specific activities other than basic home or community purposes
  8. Individual does not live or work in a wet environment
  9. Adequate cognitive ability to master use and care requirements
- If above criteria not met, microprocessor controlled knee prosthesis is considered **not medically necessary**.
- Power Knee is considered **experimental or investigational** based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.



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## MICROPROCESSOR CONTROLLED LOWER LIMB PROSTHESES (cont.)

Criteria: (cont.)

### Foot Prostheses:

- The following foot prostheses are considered *experimental or investigational* based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

These foot prostheses include, *but are not limited to*:

- Microprocessor controlled ankle-foot prosthesis
- Power foot

### Helix3D Hip Joint System:

**All requests for Helix3D Hip Joint System will be reviewed by the medical director(s) and/or clinical advisor(s).**

- Helix3D Hip Joint System is considered *medically necessary* with documentation of **ALL** of the following:
  1. Individual has undergone hip disarticulation or hemipelvectomy
  2. Used in combination with the C-Leg or Genium and the specified prosthetic feet



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### Resources:

Literature reviewed 05/01/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 1.04.05 BCBS Association Medical Policy Reference Manual. Microprocessor-Controlled Prostheses for the Lower Limb. Re-issue date 04/12/2018, issue date 10/09/2003.
2. California Technology Assessment Forum. Microprocessor Controlled Prosthetic Knees. *Blue Shield of California Foundation*. 10/17/2007.
3. Centers for Medicare & Medicaid Services. DMERC Manual Region B Chapter 17. Accessed 01/20/2005.
4. Hangar Prosthetics. Inservice: Advances in Prostheses. 01/11/2005.
5. Otto Bock. C-Leg Microprocessor Knee Patient Evaluation Protocol. October 2003.
6. Veteran's Health Administration Prosthetic Clinical Management Program. Clinical Practice Recommendations Microprocessor Knees. 09/24/2004.
7. Wall Street Journal. Bionic Knee 'Learns' How to Walk. 07/06/2004.



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### Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

