BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 07/12/05**
SECTION: Durable Medical Equipment (DME)	**LAST REVIEW DATE: 06/21/07**
	LAST CRITERIA REVISION DATE: 06/21/07
	ARCHIVE DATE:

MICROPROCESSOR CONTROLLED KNEE PROSTHESIS

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.

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.

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.

Description:

A microprocessor controlled prosthetic knee is a computer controlled knee joint system with hydraulic stance and swing phase control. Sensors in the prosthesis detect changes in gait and adjust resistance with every step, allowing the amputee to walk with greater stability and less energy expenditure than traditional prostheses. FDA-approved devices includes the C-Leg® by Otto Bock. The Rheo Knee manufactured by Ossur is not currently FDA approved.

MICROPROCESSOR CONTROLLED KNEE PROSTHESIS (cont.)

Definitions:

Functional Levels:

Level 0:	Does not have the ability or potential to ambulate or transfer safely with or without assistance and prosthesis does not enhance 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.

MICROPROCESSOR CONTROLLED KNEE PROSTHESIS (cont.)

Criteria:

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 performed by an independent certified orthopedic gait laboratory using the individual's existing hydraulic swing and stance control knee prosthesis
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

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

MICROPROCESSOR CONTROLLED KNEE PROSTHESIS (cont.)

History:	**Date:**	**Activity:**
Medical Director review	11/07/07	Reviewed California Technology Assessment Forum with no changes; updated resources
Medical Director review	06/21/07	Reviewed MPRM 1.01.25; biennial review with revisions
Medical Policy Dept review	07/18/06	Updated resources
Medical Policy Panel review	10/05/05	Adopted revisions
Legal Division review	09/14/05	Review
Medical Policy Panel review	07/12/05	Adopted
Medical Director review	06/23/05	Development

Criteria Revisions:

06/21/07	Added:	"decreased pulmonary reserve" and "Adequate cognitive ability to master use and care requirements" to medically necessary criteria
10/05/05	Removed:	Verbiage on replacement benefit

Note:

Resources:

1. DMERC Manual Region B Chapter 17. Accessed 01/20/2005.

2. 1.01.25 BCBS Association Medical Policy Reference Manual. Microprocessor-Controlled Prosthetic Knees. Re-issue date 06/14/2007, issue date 10/09/2003.

3. California Technology Assessment Forum. Microprocessor Controlled Prosthetic Knees. *Blue Shield of California Foundation.* 10/17/2007.

4. FDA. C-Leg. 07/08/1999.

MICROPROCESSOR CONTROLLED KNEE PROSTHESIS (cont.)

Resources: (cont.)

5. Hangar Prosthetics. Inservice: Advances in Prostheses. 01/11/2005.

6. Otto Bock. C-Leg Microprocessor Knee Patient Evaluation Protocol. October 2003.

7. Veteran's Health Administration Prosthetic Clinical Management Program. Clinical Practice Recommendations Microprocessor Knees. 09/24/2004.

8. Wall Street Journal. Bionic Knee 'Learns' How to Walk. 07/06/2004.

FDA 510K Summary for C-Leg® (Otto Bock Orthopedic Industry, Inc.):

- FDA-approved indication: For use in the fitting of lower limb prostheses. It can be used for highly mobile individuals as well as those who need additional stance stability