MASSACHUSETTS

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Medical Policy

Microprocessor-Controlled Prostheses for the Lower Limb

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Policy Number: 133

BCBSA Reference Number: 1.04.05 (For Plan internal use only)

Related Policies

- Myoelectric Prosthetic Components for the Upper Limb, #227
- Neuromuscular Electrical Stimulation, #201

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

A microprocessor-controlled knee may be considered **MEDICALLY NECESSARY** in amputees who meet the following requirements:

- Demonstrated need for long distance ambulation at variable rates (use of the limb in the home or for basic community ambulation is not sufficient to justify provision of the computerized limb over standard limb applications) OR demonstrated patient need for regular ambulation on uneven terrain or for regular use on stairs (use of the limb for limited stair climbing in the home or employment environment is not sufficient evidence for prescription of this device over standard prosthetic application), AND
- Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed, AND
- Adequate cognitive ability to master use and care requirements for the technology.

Amputees should be evaluated by an independent qualified professional to determine the most appropriate prosthetic components and control mechanism. A trial period may be indicated to evaluate the tolerability and efficacy of the prosthesis in a real-life setting. Decisions about the potential benefits of microprocessor-knees involve multiple factors including activity levels, as well as the patient's physical and cognitive ability. A patient's need for daily ambulation of at least 400 continuous yards, daily and frequent ambulation at variable cadence or on uneven terrain (eg, gravel, grass, curbs), and daily and frequent use of ramps and/or stairs (especially stair descent) should be considered as part of the decision. Typically, daily and frequent need of 2 or more of these activities would be needed to show benefit.

For individuals in whom the potential benefits of the microprocessor knees are uncertain, individuals may first be fitted with a standard prosthesis to determine their level of function with the standard device.

The following are guidelines from the Veterans Health Administration Prosthetic Clinical Management Program Clinical Practice Recommendations for Microprocessor Knees (Berry 2000).

PATIENT SELECTION AND IDENTIFICATION

A. Contraindications for use of the microprocessor knee should include:
- Any condition that prevents socket fitting, such as a complicated wound or intractable pain which precludes socket wear.
- Inability to tolerate the weight of the prosthesis.
- 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 improve stability in stance to permit increased independence, less risk of falls, and potential to advance to a less-restrictive walking device.
- Inability to use swing and stance features of the knee unit.
- Poor balance or ataxia that limits ambulation.
- Significant hip flexion contracture (over 20°).
- Significant deformity of remaining limb that would impair ability to stride.
- Limited cardiovascular and/or pulmonary reserve or profound weakness.
- Limited cognitive ability to understand gait sequencing or care requirements.
- Long distance or competitive running.
- Falls outside of recommended weight or height guidelines of manufacturer.
- Specific environmental factors—such as excessive moisture or dust, or inability to charge the prosthesis.
- Extremely rural conditions where maintenance ability is limited.

B. Indications for use of the microprocessor knee should include:
- Adequate cardiovascular and pulmonary reserve to ambulate at variable cadence.
- Adequate strength and balance in stride to activate the knee unit.
- Should not exceed the weight or height restrictions of the device.
- Adequate cognitive ability to master technology and gait requirements of device.
- Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral; lower extremity amputees are candidates if they meet functional criteria as listed.
- Patient is an active walker and requires a device that reduces energy consumption to permit longer distances with less fatigue.
- Daily activities or job tasks that do not permit full focus of concentration on knee control and stability—such as uneven terrain, ramps, curbs, stairs, repetitive lifting, and/or carrying.
- Medicare Level K 2—limited community ambulator, but only if improved stability in stance permits increased independence, less risk of falls, and potential to advance to a less restrictive walking device, and patient has cardiovascular reserve, strength, and balance to use the prosthesis. *The microprocessor enables fine-tuning and adjustment of the hydraulic mechanism to accommodate the unique motor skills and demands of the functional level K2 ambulator.*
- 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.
- Potential to lessen back pain by providing more secure stance control, using less muscle control to keep knee stable.
- Potential to unload and decrease stress on remaining limb.
- Potential to return to an active lifestyle.

C. Physical and Functional Fitting Criteria for New Amputees:
- New amputees may be considered if they meet certain criteria as outlined above.

- Premorbid and current functional assessment important determinant.
- Requires stable wound and ability to fit socket.
- Immediate postoperative fit is possible.
- Must have potential to return to active lifestyle.

A microprocessor-controlled knee is considered **NOT MEDICALLY NECESSARY** in individuals who do not meet the above criteria.

A powered knee is considered **INVESTIGATIONAL**.

A microprocessor-controlled or powered foot is considered **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed inpatient.

Outpatient

- For services described in this policy, see below for situations where prior authorization **might be required** if the procedure is performed **outpatient.**

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.
Commercial PPO	Prior authorization is **required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

HCPCS Codes

HCPCS codes:	Code Description
K1014	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control
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
L5858	Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type

ICD-10-PCS Procedure Codes

ICD-10-PCS procedure codes:	Code Description
F07Z9CZ	Gait Training/Functional Ambulation Treatment using Mechanical Equipment
F07Z9DZ	Gait Training/Functional Ambulation Treatment using Electrotherapeutic Equipment
F07Z9EZ	Gait Training/Functional Ambulation Treatment using Orthosis
F07Z9FZ	Gait Training/Functional Ambulation Treatment using Assistive, Adaptive, Supportive or Protective Equipment
F07Z9GZ	Gait Training/Functional Ambulation Treatment using Aerobic Endurance and Conditioning Equipment
F07Z9UZ	Gait Training/Functional Ambulation Treatment using Prosthesis
F07Z9YZ	Gait Training/Functional Ambulation Treatment using Other Equipment
F07Z9ZZ	Gait Training/Functional Ambulation Treatment
F0DZ6EZ	Dynamic Orthosis Device Fitting using Orthosis
F0DZ6FZ	Dynamic Orthosis Device Fitting using Assistive, Adaptive, Supportive or Protective Equipment
F0DZ6UZ	Dynamic Orthosis Device Fitting using Prosthesis
F0DZ6ZZ	Dynamic Orthosis Device Fitting
F0DZ7EZ	Static Orthosis Device Fitting using Orthosis
F0DZ7FZ	Static Orthosis Device Fitting using Assistive, Adaptive, Supportive or Protective Equipment
F0DZ7UZ	Static Orthosis Device Fitting using Prosthesis
F0DZ7ZZ	Static Orthosis Device Fitting
F0FZDEZ	Caregiver Training in Application, Proper Use and Care of Devices using Orthosis
F0FZDFZ	Caregiver Training in Application, Proper Use and Care of Devices using Assistive, Adaptive, Supportive or Protective Equipment
F0FZDUZ	Caregiver Training in Application, Proper Use and Care of Devices using Prosthesis
F0FZDZZ	Caregiver Training in Application, Proper Use and Care of Devices
F0FZFEZ	Caregiver Training in Application, Proper Use and Care of Orthoses using Orthosis
F0FZFFZ	Caregiver Training in Application, Proper Use and Care of Orthoses using Assistive, Adaptive, Supportive or Protective Equipment
F0FZFUZ	Caregiver Training in Application, Proper Use and Care of Orthoses using Prosthesis
F0FZFZZ	Caregiver Training in Application, Proper Use and Care of Orthoses
F0FZGEZ	Caregiver Training in Application, Proper Use and Care of Prosthesis using Orthosis
F0FZGFZ	Caregiver Training in Application, Proper Use and Care of Prosthesis using Assistive, Adaptive, Supportive or Protective Equipment
F0FZGUZ	Caregiver Training in Application, Proper Use and Care of Prosthesis using Prosthesis
F0FZGZZ	Caregiver Training in Application, Proper Use and Care of Prosthesis

The following HCPCS codes are considered investigational for <u>Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:</u>

HCPCS Codes

HCPCS codes:	Code Description
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)

L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source

Description

Lower-Extremity Prosthetics

More than 100 different prosthetic ankle-foot and knee designs are currently available. The choice of the most appropriate design may depend on the patient's underlying activity level. For example, the requirements of a prosthetic knee in an elderly, largely homebound individual will differ from those of a younger, active person. Key elements of a prosthetic knee design involve providing stability during both the stance and swing phase of the gait. Prosthetic knees vary in their ability to alter the cadence of the gait, or the ability to walk on rough or uneven surfaces. In contrast to more simple prostheses, which are designed to function optimally at one walking cadence, fluid and hydraulic-controlled devices are designed to allow amputees to vary their walking speed by matching the movement of the shin portion of the prosthesis to the movement of the upper leg. For example, the rate at which the knee flexes after "toe-off" and then extends before heel strike depends in part on the mechanical characteristics of the prosthetic knee joint. If the resistance to flexion and extension of the joint does not vary with gait speed, the prosthetic knee extends too quickly or too slowly relative to the heel strike if the cadence is altered. When properly controlled, hydraulic or pneumatic swing-phase controls allow the prosthetist to set a pace adjusted to the individual amputee, from very slow to a race-walking pace. Hydraulic prostheses are heavier than other options and require gait training; for these reasons, these prostheses are prescribed for athletic or fit individuals. Other design features include multiple centers of rotation, referred to as "polycentric knees." The mechanical complexity of these devices allows engineers to optimize selected stance and swing-phase features.

Summary

Microprocessor-controlled prostheses use feedback from sensors to adjust joint movement on a real-time as-needed basis. Active joint control is intended to improve safety and function, particularly for individuals who can maneuver on uneven terrain and with variable gait.

For individuals who have a transfemoral amputation who receive a prosthesis with a microprocessor-controlled knee, the evidence includes a number of within-subject comparisons of microprocessor-controlled knees vs non-microprocessor-controlled knee joints. Relevant outcomes are functional outcomes, health status measures, and quality of life. For K3- and K4-level amputees, studies have shown an objective improvement in function on some outcome measures, particularly for hill and ramp descent, and strong patient preference for microprocessor-controlled prosthetic knees. Benefits include a more normal gait, an increase in stability, and a decrease in falls. The evidence in Medicare level K2 ambulators suggests that a prosthesis with stance control only can improve activities that require balance and improve walking in this population. For these reasons, a microprocessor-controlled knee may provide incremental benefit for these individuals. The potential to achieve a higher functional level with a microprocessor-controlled knee includes having the appropriate physical and cognitive ability to use the advanced technology. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a transfemoral amputation who receive a prosthesis with a powered knee, the evidence includes limited data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The limited evidence available to date does not support an improvement in functional outcomes using a powered knee prostheses with standard prostheses. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have a tibial amputation who receive a prosthesis with a powered ankle-foot, the evidence includes limited data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The limited evidence available to date does not support an improvement in functional outcomes using powered ankle-foot prostheses compared with standard prostheses. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
6/2022	Prior authorization information clarified for PPO plans. Effective 6/1/2022.
4/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2021	Annual policy review. Policy statements unchanged.
4/2021	Clarified coding information.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
5/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2018	Annual policy review. Background and summary clarified.
1/2018	Coding information clarified.
11/2016	Annual policy review. Policy updated to align patient selection and identification guideline with National policy. Effective 11/1/2016.
9/2016	Clarified coding information.
11/2015	Added coding language.
6/2015	New references added from Annual policy review.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
5/2014	Annual policy review. New references added.
1/2014	Updated to add new HCPCS code L5969.
5/2013	Annual policy review. New references added.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/01/2010	Updated to require prior authorization for commercial products for this service.
5/18/2010	Annual policy review. New references added
11/1/2009	New policy, effective 11/1/2009, describing covered and non-covered indications.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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