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FEP Medical Policy Manual

FEP 1.04.05 Microprocessor-Controlled Prostheses for the Lower Limb

Effective Policy Date: July 1, 2021

Original Policy Date: December 2011

Related Policies:

1.04.04 - Myoelectric Prosthetic and Orthotic Components for the Upper Limb
8.03.01 - Functional Neuromuscular Electrical Stimulation

Microprocessor-Controlled Prostheses for the Lower Limb

Description

Description

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 patients who can maneuver on uneven terrain and with variable gait.

OBJECTIVE

The objective of this evidence review is to determine whether powered prostheses improve the net health outcome in individuals with lower-extremity amputations.

POLICY STATEMENT

A microprocessor-controlled knee may be considered **medically necessary** in individuals with transfemoral amputation 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.

A microprocessor-controlled knee is considered **not medically necessary** in individuals who do not meet these criteria.

A powered knee is considered **investigational**.

A microprocessor-controlled or powered ankle-foot is considered **investigational**.

POLICY GUIDELINES

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 and 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.

Patient Selection and Identification

For patients in whom the potential benefits of the microprocessor knees are uncertain, patients 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.[1,]

1. Contraindications for the use of the microprocessor knee should include the following:
    - 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 K0-no ability or potential to ambulate or transfer
    - Medicare level K1-limited ability to transfer or ambulate on level ground at fixed cadence
    - Medicare level K2-limited community ambulator who 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 (>20)
    - Significant deformity of remaining limb that would impair the 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 the manufacturer
- Specific environmental factors-such as excessive moisture or dust, or inability to charge the prosthesis
- Extremely rural conditions where maintenance ability is limited.

2. Indications for the use of the microprocessor knee should include the following:
    - 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 the device
    - Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral; lower-extremity amputees are candidates if they meet functional criteria as listed
    - The 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 K2-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 the 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 K3-unlimited community ambulator
    - Medicare level K4-active adult, athlete who needs to function as a K3 level in daily activities
    - Potential to lessen back pain by providing more secure stance control, using less muscle control to keep the knee stable
    - Potential to unload and decrease stress on remaining limb
    - Potential to return to an active lifestyle.
3. 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 the socket
    - Immediate postoperative fit is possible
    - Must have potential to return to an active lifestyle

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

New technologies that use microprocessor control are being developed. Based on the currently available evidence, no microprocessor-controlled device has been shown to have better outcomes than other (eg, earlier) models. If more costly, the prosthesis would be considered not medically necessary using the Medical Policy Reference Manual definition of medical necessity.

FDA REGULATORY STATUS

According to the manufacturers, microprocessor-controlled prostheses are considered a class I device by the FDA and are exempt from 510(k) requirements. This classification does not require submission of clinical data regarding efficacy but only notification of FDA prior to marketing. FDA product codes: ISW, KFX.

RATIONALE

Summary of Evidence

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 versus 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 an improvement in the net health outcome.

For individuals who have a transfemoral amputation who receive a prosthesis with a powered knee, the evidence includes no data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a tibial amputation who receive a prosthesis with a microprocessor-controlled 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 microprocessor-controlled 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.

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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in <91>Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Veterans Affairs/Department of Defense Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation

In 2019, the Veterans Affairs/Department of Defense Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation made the following recommendations:[27.]

"We suggest offering microprocessor knee units over non-microprocessor knee units for ambulation to reduce risk of falls and maximize patient satisfaction. There is insufficient evidence to recommend for or against any particular socket design, prosthetic foot categories, and suspensions and interfaces. (From Table 3. Clinical practice guideline evidence - based recommendations and evidence strength)."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
September 2013	Replace policy	Policy updated with literature review; Rationale revised; References added, reordered, some deleted; Policy statements for investigational separated for knee and foot.
June 2014	Replace policy	Policy updated with literature review; references 17, 25, and 27 added; policy statements unchanged
June 2015	Replace policy	Policy updated with literature review; reference 19 added; policy statements unchanged.
March 2017	Replace policy	Policy reviewed. No changes to policy statements.
December 2017	Replace policy	Policy updated with literature review through August 28, 2017; no references added. Policy statements unchanged
June 2018	Replace policy	Policy updated with literature review through February 5, 2018; reference 10 and 26 added. Policy statements unchanged
June 2019	Replace policy	Policy updated with literature review through February 26, 2019; references added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through February 24, 2020; reference added, Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through January 25, 2021; no references added. Policy statements unchanged.