

## **Medical Policy Manual**

**Topic:** Powered Knee Prosthesis, or Powered Ankle-Foot Prosthesis, and Microprocessor-Controlled Ankle-Foot Prosthesis

**Date of Origin:** May 25, 2010

**Section:** Durable Medical Equipment

**Last Reviewed Date:** December 2013

**Policy No:** 81

**Effective Date:** January 1, 2014

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

#### **Microprocessor-Controlled Prosthetic Foot**

Microprocessor-controlled foot prostheses, which include the ankle joint, use feedback from sensors to adjust ankle movement on a real-time as-needed basis. These devices may also be called bionic or robotic prostheses. Microprocessor-controlled foot prostheses currently being developed for transtibial amputees include the Proprio Foot® (Ossur), the iPED (Martin Bionics LLC / College Park Industries), and the Elan Foot (Endolite). Sensors in the prosthesis send information about the direction and speed of the foot's movement to the microprocessor, which controls the flexion angle of the ankle. The prosthesis is intended to increase gait efficiency and prevent falls by allowing the foot to lift during the swing phase, and potentially adjust to changes in force, speed, and terrain during the step phase.

#### **Powered Knee and Ankle Prostheses**

Powered prostheses use signals from muscle activity in the remaining limb to bend and straighten the prosthetic joint. These devices may also be referred to as myoelectric prostheses. The goal of the

powered ankle-foot and knee prosthesis is to improve gait efficiency, and potentially reduce hip and back problems arising from an unnatural gait required for use of a passive prosthesis. This technology is currently limited by the size and the weight required for the motor and batteries in the prosthesis.

The PowerFoot BiOM Ankle System (Massachusetts Institute of Technology/iWalk) is a myoelectric prosthesis for transtibial amputees that is designed to propel the foot forward as it pushes off the ground during the gait cycle. The Power Knee (Ossur) is designed to replace muscle activity of the quadriceps. It uses artificial proprioception with sensors similar to the Proprio Foot to anticipate and respond with the appropriate movement required for the next step. The Power Knee is currently in the initial launch phase in the United States. Prototypes of prostheses with both powered knee and foot are also in development.

## **Regulatory Status**

Manufacturers must register prostheses with the restorative devices branch of the U.S. Food and Drug Administration (FDA) and keep a record of any complaints but do not have to undergo a full FDA review.

**NOTE:** This policy addresses only powered knee, powered ankle-foot, and microprocessor-controlled ankle-foot prostheses. This policy does not address microprocessor-controlled knee prostheses which are considered medically necessary for select patients with transfemoral (above the knee) amputation.

## **MEDICAL POLICY CRITERIA**

All of the following devices are considered **investigational**:

- A. Microprocessor-controlled foot
- B. Powered knee, ankle, and foot

## **SCIENTIFIC EVIDENCE<sup>[1]</sup>**

Evaluating the effects of the increased sophistication of powered knee, powered ankle-foot, and microprocessor-controlled ankle-foot prostheses requires comparison with body-powered prostheses, passive prostheses, or no prosthesis. The most informative data are prospective comparative studies with objective and subjective measures that directly address function, safety, and health-related quality of life.

## **Literature Appraisal**

### Microprocessor-Controlled Ankle-Foot Prostheses

#### *Cochrane Review*

A 2004 Cochrane review of ankle-foot prostheses (assessed as up-to-date through June 2006) concluded that there was insufficient evidence from high quality comparative studies to determine the overall superiority of any individual type of prosthetic ankle-foot mechanism.<sup>[2]</sup>

- Twenty-six trials, all of cross-over design, with 3-16 participants (total n=245) in each, were reviewed.
- Only one study was considered to be of high methodological quality while the remainders were considered of moderate quality.
- The vast majority of clinical studies on human walking have used standardized gait assessment protocols (e.g., treadmills) with limited “ecological validity”. The authors recommended that for future research, functional outcomes should be assessed for various aspects of mobility such as making transfers, maintaining balance, level walking, stair climbing, negotiating ramps and obstacles, and changes in walking speed.

### Randomized Controlled Trials

A 2012 randomized within-subject crossover study compared self-reported and objective performance outcomes for 4 types of prosthetic feet, including the SACH (solid ankle cushion heel), SAFE (stationary attachment flexible endoskeletal), Talux mechanical foot, and Proprio Foot.<sup>[3]</sup> Ten patients with transtibial amputation were tested with their own prosthesis and then, in random order, each of the other prostheses after training and a 2-week acclimation period. No differences between prostheses were detected for the following measures:

- Prosthesis Evaluation Questionnaire (PEQ) (self-reported subjective rating of ease of use, social and emotional issues, and function over different surfaces)
- Locomotor Capabilities Index (self-reported subjective rating of capability to perform certain activities such as walking in various environments on various surfaces, sitting, standing, bending)
- 6-minute walk test (objective distance measurement)
- Steps per day
- Hours of daily activity

This study is too small to permit conclusions about the comparisons between the various types of foot prostheses. However, it does suggest the need for additional study in larger trials.

### Nonrandomized Comparative Trials

Two comparative trials of the microprocessor-controlled ankle were published since the 2004 Cochrane Review.<sup>[4,5]</sup> Both studies were from the same investigators and included the Proprio Foot in 16 transtibial amputees during stair ascent and descent<sup>[4]</sup> or while walking up and down a ramp<sup>[5]</sup>. These studies were limited to the effect of flexion angles (flexion versus neutral angle). Healthy controls were also used for comparison. The outcomes of these studies were mixed. For example, the adaptive mode (ankle flexion) resulted in more normal gait analysis results during ramp ascent but not during descent; however, some patients reported feeling safer with the adaptive mode ankle than with the Proprio Foot. These studies do not permit conclusions about the clinical benefits and risks of the microprocessor-controlled foot compared with mechanical prostheses due to methodological limitations. These limitations included but were not limited to the small sample size which limits the ability to rule out chance as an explanation of the study findings

### Powered Knee and/or Ankle-Foot Prostheses

- Ferris et al compared the BiOM powered ankle-foot prosthesis with an energy-storing and –returning (ESR) foot in 11 transtibial amputees.<sup>[6]</sup> These results were also compared with 11 matched controls with intact limbs. Compared with the ESR foot, the powered ankle-foot increased walking speed, but there were no significant differences in physical performance measure or conditions on the PEQ.

Compared with the intact limb, the powered ankle-foot had increased step length and greater ankle peak power, but had reduced range of motion. There appeared to be an increase in compensatory strategies at proximal joints with the powered prosthesis; the authors noted that normalization of gait kinematics and kinetics may not be possible with a uniarticular device. Seven patients preferred the PowerFoot BiOM and 4 preferred the ESR prosthesis.

- Another small study of 7 amputees and 7 intact controls reported gross metabolic cost and preferred walking speed to be more similar to non-amputee controls with the powered foot than with the ESR prosthesis.<sup>[7]</sup>
- Mancinelli et al. compared the PowerFoot BiOM with a passive-elastic foot in 5 transtibial amputees.<sup>[8]</sup> At the time of this study the powered prosthesis was a prototype and subjects' exposure to the prosthesis was limited to the laboratory. Laboratory assessment of gait biomechanics showed an average increase of 54% in the peak ankle power generation during late stance. Metabolic cost measured by oxygen consumption while walking on an indoor track was reduced by an average of 8.4% ( $p=0.06$ ). This study did not report the impact of these measurements on patient function.

In summary, the evidence is insufficient to permit conclusions about the benefits of powered lower extremity prostheses compared with other prostheses.

- Powered lower extremity prostheses are in the early development stages and current clinical trial data is limited to pilot studies, the largest of which included eleven patients.
- These small studies are intended only to report feasibility of various prototypes.
- Larger, higher quality studies are needed to determine the impact of these devices on functional outcomes with greater certainty.

## **Safety**

Potential safety concerns for microprocessor-controlled and powered lower extremity prostheses are related to pressure on the stump within the prosthesis socket, and the patient's physical and cognitive ability in correct use and care of the prosthesis.

The current evidence is insufficient to determine the safety of these prostheses.

- Safety data for the microprocessor-controlled ankle was limited to a single study of the impact of biomechanical load on the stump pressure within the socket.<sup>[9]</sup> This small ( $n=16$ ) case series study reported large differences in local pressure between individual patients.
- The feasibility studies of powered lower extremity prostheses did not report on safety issues.

## **Summary**

Microprocessor-controlled foot prostheses are intended to increase gait efficiency and prevent falls. The evidence is insufficient to permit conclusions about the health benefits of the microprocessor-controlled foot prosthesis compared with conventional prostheses. Therefore, these prostheses are considered investigational.

Evidence is insufficient to evaluate the health benefits of powered lower limb prostheses compared with passive prostheses. Therefore, lower limb prostheses with powered knee and/or powered ankle-foot are considered investigational.

## **REFERENCES**

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## CROSS REFERENCES

[Myoelectric Prosthetic Components for the Upper Limb](#), DME, Policy No. 80

CODES	NUMBER	DESCRIPTION
CPT	None	
HCPCS	L5859	Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered
	L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, include power source
	L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)