Medical Affairs Policy

**Service:** Microprocessor Controlled and Myoelectric Limb Prosthesis [Intelligent Prosthesis (Blatchford, U.K.), the Adaptive (Endolite, England), the Rheo (Ossur, Iceland), the C-Leg and Genium Prosthetic Systems (Otto Bock Orthopedic Industry, Minneapolis, MN), and Seattle Power Knees (models include Single Axis, 4-bar and Fusion, from Seattle Systems) PowerFoot BiOM, iWalk, Bedford, MA; Proprio Foot, Ossur, Aliso Viejo, CA, Power Knee, Ossur, Foothill Ranch, CA, MotoKnee, Electric and Body Powered Fingers]

PUM 250-0026

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<th>Medical Policy Committee Approval</th>
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<td>Prior Authorization Needed</td>
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**Disclaimer:** This policy is for informational purposes only and does not constitute medical advice, plan authorization, an explanation of benefits, or a guarantee of payment. Benefit plans vary in coverage and some plans may not provide coverage for all services listed in this policy. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, and to applicable state and federal law. Some benefit plans administered by the organization may not utilize Medical Affairs medical policy in all their coverage determinations. Contact customer services as listed on the member card for specific plan, benefit, and network status information.

Medical policies are based on constantly changing medical science and are reviewed annually and subject to change. The organization uses tools developed by third parties, such as the evidence-based clinical guidelines developed by MCG to assist in administering health benefits. This medical policy and MCG guidelines are intended to be used in conjunction with the independent professional medical judgment of a qualified health care provider. To obtain additional information about MCG, email medical.policies@wpsic.com.

**Description:**

There are more than 100 different prosthetic lower limb designs currently available. The choice of prosthetic design depends upon the level of amputation and the individual’s physical condition, ability to ambulate safely, and expected functional activity level. Design options include simple prosthetics that function optimally at one walking cadence, heavier hydraulic controlled devices that allow variation of cadence, and microprocessor controlled devices. This policy addresses microprocessor and myoelectric prosthetics.

Microprocessor-controlled prostheses use feedback from sensors to adjust joint movement on a real-time as-needed basis, detecting speed of ambulation and adjusting the performance of the prosthetic knee or ankle and foot based on that speed and the terrain. Active joint control is intended to improve safety and function, particularly for patients who have the capability to maneuver on uneven terrain and with variable gait. Microprocessors such as those in the Genium™ Prosthetic system series utilize a complex sensory system with additional environmental input (e.g., gyroscope and accelerometer) and more sophisticated processing that is intended to create more natural movement.

Myoelectric prosthetics use electromyography signals or signals from voluntary muscle contraction to control the movements of a prosthetic hand, wrist, or elbow. Currently available myoelectric devices include (but are not limited to) the Ottobock myoelectric
prosthesis (Ottobock, Minneapolis, MN), the LTI Boston Digital Arm™ System, (Liberating Technologies Inc., Holliston, MA), and the Utah Arm Systems (Motion Control, Salt Lake City, UT).

Powered prosthetic devices (Power Knee™ by Ossur, BiOm by iwalk, Inc) that use signals from muscle activity in the remaining limb to bend and straighten the device have also been developed.

There is little published evidence addressing improvement in functional capabilities of microprocessor prosthesis users, and fewer studies making a direct comparison of prostheses in a controlled setting. Currently, evidence is limited to conclude that the successive generations of microprocessor prosthesis provide a significant comparative advantage.

The Centers for Medicare and Medicaid Services (CMS) has defined the following 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 their 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. This level is consistent with descriptions of the limited and unlimited household ambulatory.

**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. This level is consistent with descriptions of the limited community ambulatory.

**Level 3:** Has the ability or potential for ambulation with variable cadence. This level is consistent with descriptions 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.

*(Note: the use of a microprocessor controlled prosthetic over a standard prosthetic for home use (for example, to climb stairs at home) or for the limited community ambulator (for example, to climb stairs at work) is considered not medically necessary.)*

**Level 4:** Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. This level is consistent with the prosthetic demands of the child, active adult, or athlete.
Indications of Coverage:

**A. A microprocessor controlled lower limb prosthesis** (e.g. Ottobock C-Leg) is considered medically necessary for an above-the-knee amputee and knee disarticulation amputees when all of the following criteria are met:

1. The individual has expressed a willingness to ambulate and the individual’s current activities exceed the capabilities of a standard lower limb prosthetic device on a daily basis;

2. The patient has used a standard lower limb prosthetic device for independent daily activities for a minimum of three (3) months;

3. Medical, physical therapy (rehabilitation) and prosthetist records indicate:
   a. That the use of the device will enable the individual to reach a minimum of functional level 3 within three months of obtaining the device. The records must document the individual’s current functional level, the expected functional level, and why the expected functional level cannot be achieved with the current device;
   b. That there is no significant cardiovascular, musculoskeletal, or neuromuscular condition that would prohibit maximal use of the device (for example, a cardiac, vascular, orthopedic, or muscular condition that would prevent the individual from achieving a fast walking pace); and
   c. Gait analysis documents that the individual has the ability to ambulate at a rate faster that what can currently be achieved with a standard prosthesis despite appropriate adjustments to the current prosthesis.
   d. Appropriate patient weight and height for the device chosen

**B. A microprocessor controlled lower limb prosthesis with stance –phase or swing and stance phase microprocessors, utilizing complex sensory systems with additional environmental input (e.g., gyroscope and accelerometer (e.g. Genium™) is considered medically necessary for an above-the-knee amputee and knee disarticulation amputees when all of the following criteria are met:**

1. All of the criteria in section A (above)

2. Patient has undergone extensive evaluation using the Hanger Prosthetics & Orthotics Patient Assessment Validation Evaluation Tool (PAVET™) Evaluation for Microprocessor Knee.
3. Documentation from the requesting prosthetist of a total PAVET score between 40-72

4. Documentation of specific activities/difficulties with current prosthetic that can be addressed with the new prosthetic

C. For Myoelectric Upper Limb Prostheses criteria, refer to MCG.

➢ Note: Up to two test (diagnostic) sockets may be required for accurate fitting of an individual prosthesis. In addition, up to two socket inserts may be required per individual prosthesis at the same time. Requests for additional test sockets and/or socket inserts require documentation supporting medical necessity

**Limitations of Coverage:**

A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.

B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental, investigational, and unproven to affect health outcomes.

C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

D. Microprocessor controlled ankle and foot prosthetic devices and braces (including but not limited to Proprio Foot® (Ossur), iPED® (Martin Bionics), PowerFoot BiOM® (iWalk), and Élan® (Endolite) are considered experimental, investigational, and unproven to affect health outcomes.

E. Microprocessor controlled lower limb prosthesis are considered not medically necessary (not the most cost-effective prosthetic) if the patient’s functional needs could be met with a standard non-electronic prosthetic.

F. Microprocessor controlled and power lower limb prosthetics and accessories designed for fitness and specialty sports participation (e.g. Ottobock above the knee X-3 waterproof prosthetic, Moto Knee, Sprinter foot) are considered not medically necessary (not the most cost-effective prosthetic) and may also be an exclusion of the member’s certificate.

G. Myoelectric Lower Limb Prosthetic devices are considered experimental, investigational, and unproven to affect health outcomes.

H. Microprocessor controlled ankle foot prosthetic (e.g. Proprio Foot®) is considered experimental, investigational, and unproven to affect health outcomes.
I. Electric and body-powered partial fingers are considered experimental, investigational, and unproven to affect health outcomes.

J. ReWalk Personal System for home use in Spinal Cord Injury is considered experimental, investigational, and unproven to affect health outcomes.

K. Powered Lower Limb Prosthesis (e.g. Power Knee (Ossur) are considered experimental, investigational, and unproven to affect health outcomes.

L. Microprocessor-controlled leg prostheses (e.g., Ottobock C-Leg, Ottobock Genium Bionic Prosthetic System, Intelligent Prosthesis, and Ossur Rheo Knee) for gait management in spinal cord injury is considered experimental, investigational, and unproven to affect health outcomes.

M. If more than one prosthetic limb meets a patient’s prosthetic rehabilitation needs, the more costly prosthetic will be considered not medically necessary.

N. Genium3x lower limb prosthetic which utilizes multimodal proprioceptive inputs and is able to monitor 500 knee motion possibilities, is considered a device with special features/ additional features and/or not the standard model- These devices have additional features (e.g., specific programming) and have not been demonstrated to be superior to a standard device, and are not considered the lowest-cost alternative.

O. Vacuum–assisted Socket System is considered experimental, investigational, and unproven to affect health outcomes.

**Documentation Required:**

- Office notes: Include additional documentation supporting medical necessity of prosthetic components and additions

- Gait analysis report

- PAVET score (when appropriate)

**References:**


8. Hayes Health Technology Brief. C-leg Prostheses (Ottobock Health Care LP) for Patients with Above Knee Amputation Annual Review Jan 12, 2015, Archived Mar 01, 2016

9. Hayes Search and Summary: ProprioFoot (Ossur) July 8, 2013

10. Hayes Search and Summary: C-Brace Orthotronic Mobility System (Ottobock) February 14, 2014


**Review History:**

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<td>Arise/WPS Policy</td>
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- Note: For review/revision history prior to 2014 see previous Medical Policy or Coverage Policy Bulletin

Approved by the Medical Director