

# MEDICAL POLICY

| MEDICAL POLICY DETAILS  |  |
|-------------------------|--|
| Medical Policy Title    | External Prosthetic Devices  |
| Policy Number           | 1.01.18  |
| Category                | Contract Clarification   |
| Original Effective Date | 07/25/02   |
| Committee Approval Date | 10/23/03, 05/27/04, 04/28/05, 04/27/06, 04/26/07, 02/26/09, 02/25/10, 06/24/11, 08/23/12, 06/27/13, 06/26/14, 02/26/15, 02/25/16, 02/16/17, 02/22/18, 02/28/19, 02/27/20, 02/25/21, 02/17/22, 02/16/23, 02/22/24   |
| Current Effective Date  | 02/22/24   |
| Archived Date           | N/A  |
| Archive Review Date     | N/A  |
| Product Disclaimer      | <ul style="list-style-type: none"> <li>Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</li> <li>If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.</li> <li>If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.</li> <li>If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</li> <li>If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.</li> </ul> |

## POLICY STATEMENT

### General Criteria

- I. Based upon our criteria and assessment of the peer-reviewed literature, external prosthetic devices are considered **medically appropriate** to replace all or part of an internal organ or replace the function of a permanently inoperative or malfunctioning body part. (Refer to [Lower Extremity](#) and [Upper Extremity](#) sections regarding specific criteria.)
- II. Based upon our criteria and assessment of the peer-reviewed literature, supplies needed to make a covered, medically appropriate external prosthetic device functional are considered **medically appropriate**. Examples of covered supplies include tracheostomy kits, ostomy supplies, urine pouches, and batteries to operate an artificial larynx.
- III. Based upon our criteria and assessment of the peer-reviewed literature, custom prosthetic devices with enhanced features are considered **not medically necessary** when activities of daily living (ADLs) can be met with standard prosthetic devices. Precise clinical information demonstrating that ADLs cannot be performed with standard devices is required, when non-standard prosthetic devices (e.g., microprocessor-controlled lower limbs) are requested. (Refer to [Lower Extremity](#) and [Upper Extremity](#) sections regarding specific items.)
- IV. Back-up prosthetic devices are considered **not medically necessary**; more than one prosthetic device is considered a matter of convenience for the member.
- V. Devices or implants used primarily for cosmetic purposes are considered **not medically necessary**.

### Preparatory Prosthesis

- VI. Based upon our criteria and assessment of the peer-reviewed literature, a preparatory prosthesis is considered **medically appropriate** and eligible for coverage after surgery to prevent edema of the residual limb.
- VII. Based upon our criteria and assessment of the peer-reviewed literature, additions such as protective covers, ultralight

## Medical Policy: EXTERNAL PROSTHETIC DEVICES

Policy Number: 1.01.18

Page: 2 of 12

material, nonstandard components (e.g., microprocessor knees), and flex foot systems (e.g., energy storing) are considered **not medically necessary** for a preparatory prosthesis.

### Lower Extremity Prosthesis

- VIII. Based upon our criteria and assessment of the peer-reviewed literature, a basic preparatory or permanent (definitive) lower limb prosthetic device has been medically proven to be effective and, therefore, is considered **medically appropriate** for individuals with a function level 1 or greater. (*Refer to the Description section for definitions of [functional levels](#).*)
- IX. Based upon our criteria and assessment of the peer-reviewed literature, lower limb prosthetic devices do not improve patient outcomes and, therefore, are considered **not medically necessary** for individuals with functional level 0. (*Refer to the Description section for definitions of [functional levels](#).*)
- X. Based upon our criteria and assessment of the peer-reviewed literature, a socket for a lower limb prosthetic device has been medically proven to be effective and, therefore, is considered **medically appropriate** for:
- One socket per individual prosthetic;
  - Two of the same socket inserts per individual prosthesis at the same time;
  - Up to two test sockets when fitting for a socket;
- A test socket is not recommended for immediate postsurgical or early fitting prostheses.
- XI. Based upon our criteria and assessment of the peer-reviewed literature, a vacuum-assisted socket systems (VASS) for a lower limb prosthetic device has been medically proven to be effective and, therefore, is considered **medically appropriate** in the following situations:
- There is a nonhealing skin breakdown on the stump from friction due to an ill-fitting socket; **and**
  - The current socket can no longer be modified to adequately secure the limb to the prosthesis.
- XII. Based upon our criteria and assessment of the peer-reviewed literature, a microprocessor-controlled knee has been medically proven to be effective and, therefore, is considered **medically appropriate** for [functional level 3](#) transfemoral amputees, when **ALL** of the following criteria are met:
- The patient has the physical ability to use the device which includes:
    - sufficient trunk control and adequate posture; and
    - good upper body strength with static and dynamic balance; and
    - adequate cardiovascular and pulmonary reserve which enable the patient to ambulate at a faster than normal walking speed; **and**
  - The patient has received additional training for use of this technology and has demonstrated adequate cognitive ability to master use and care requirements; **and**
  - The patient is able to perform **ALL** of the following ADLs at least daily:
    - long distance ambulation at variable rates of at least 400 continuous yards;
    - regular and frequent ambulation on uneven terrain (e.g., grass, gravel, or curbs);
    - regular and frequent ambulation on stairs or ramps;
    - lifting and carrying items;
    - frequent bending, kneeling, or stooping;
    - walking, standing, or working in confined areas.
  - Microprocessor-controlled knees are **contraindicated** when:
    - The patient's [functional level](#) is less than 3 or has limited ambulation due to poor balance or ataxia; or
    - The patient is unable to tolerate the weight of the prosthesis; or
    - The patient is unable to use the swing and stance features of the knee; or
    - The patient is unable to change the prosthesis or has a condition that would cause inadequate fitting; or
    - The patient has significant hip flexion contracture (over 20 degrees); or
    - The patient has significant deformity of the remaining limb that would impair ability to stride; or
    - The prosthesis will be used when the environmental conditions include excessive moisture or dust which invalidates the warranty.

## Medical Policy: EXTERNAL PROSTHETIC DEVICES

Policy Number: 1.01.18

Page: 3 of 12

- XIII. Based upon our criteria and assessment of the peer-reviewed literature, a terminal device for a lower limb prosthetic has been medically proven to be effective and, therefore, is considered **medically appropriate** for the following devices:
- A. Solid-ankle cushioned-heel (SACH) foot appropriate for sedentary patients with a [functional level](#) 1 or above.
  - B. Multi-axis foot appropriate for [functional level](#) 3 or above.
- XIV. Based upon our criteria and assessment of the peer-reviewed literature, a prosthetic shoe has been medically proven to be effective and, therefore, is considered **medically appropriate** as a terminal device to supplement a substantially absent foot.
- XV. Based upon our criteria and assessment of the peer-reviewed literature, a microprocessor-controlled ankle-foot system (e.g., Proprio-Foot with EVO [Ossur], Triton smart ankle [OttoBock]), does not improve patient outcomes and, therefore, is considered **not medically necessary**.

### Upper Extremity Prosthesis

- XVI. Based upon our criteria and assessment of the peer-reviewed literature, a conventional body-powered, upper extremity prostheses, has been medically proven to be effective and, therefore, is considered **medically appropriate** to replace all or part of an upper extremity or replace the function of a permanently inoperative or malfunctioning upper extremity.
- XVII. Based upon our criteria and assessment of the peer-reviewed literature, myoelectric upper arm prosthetic components have been medically proven to be effective and, therefore, are considered **medically appropriate** when **ALL** of the following are met:
- A. Standard body-powered prosthetic devices cannot be used or are insufficient to meet the functional needs of the individual in performing ADLs;
  - B. The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device;
  - C. The patient is free of comorbidities that could interfere with function of the prosthesis (neuromuscular disease, etc.);
  - D. The patient has demonstrated sufficient physiological and cognitive function to allow effective operation of a myoelectric prosthetic device;
  - E. Functional evaluation indicates that with training, use of a myoelectric prosthesis is likely to meet the functional needs of the individual (e.g., gripping, releasing, holding, and coordinating movement of the prosthesis) when performing ADLs. This evaluation should consider the patient's needs for control, durability (maintenance), function (speed, work capability), and usability.
- XVIII. Based upon our criteria and the lack of peer-reviewed literature, a myoelectric hand with individual control of digits (e.g., Michelangelo hand [OttoBock], AxonArm Ergo [OttoBock]) has not been medically proven to be effective and, therefore, is considered **investigational**.

**This policy does not address custom orthotic devices with enhanced features such as, those containing electronic features for stance control and powered exoskeletons. Please refer to the policy for orthotics referenced below.**

**This policy addresses external prosthetics only. Please refer to specific policies for implantable prosthetic devices.**

*Refer to Corporate Medical Policy #1.01.00 Durable Medical Equipment –Standard and Non-Standard*

*Refer to Corporate Medical Policy #1.01.25 Orthotics*

*Refer to Corporate Medical Policy #7.01.30 Erectile Dysfunction*

### **POLICY GUIDELINES**

- I. Coverage for external prosthetic devices is contract dependent. Please contact your local Customer Care (Member/Provider) Department, to determine coverage under a member's subscriber contract.
- II. To be eligible for coverage a prosthetic device must address a problem in which the device is needed for at least 90

## Medical Policy: EXTERNAL PROSTHETIC DEVICES

Policy Number: 1.01.18

Page: 4 of 12

days.

- III. Coverage of ostomy equipment and supplies is required under the New York Insurance Law, subject to applicable cost-sharing (copayments, deductibles and/or coinsurance), when the equipment and/or supplies are prescribed by a physician or any other health care provider legally authorized to prescribe under Title VIII of the New York Education Law.
- IV. Polishing and resurfacing of an eye prosthesis (V2624) may be performed up to two times per year.
- V. Synthetic wigs are covered when there is a severe hair loss due to injury, disease, or as a side effect of the treatment of a disease (e.g., chemotherapy and/or hormonal therapy for the treatment of breast cancer). Wigs made from human hair are not covered unless there is an allergy to all synthetic wig materials.
- VI. Replacement of a medically appropriate prosthetic is **eligible for coverage** when **ALL** of the following are met:
  - A. The patient has experienced a change in his or her physiological condition (e.g., a change in the residual limb or in functional need).
  - B. There has been irreparable change in the device's condition or in a part of the device, due to normal wear and tear.
  - C. The required repairs would exceed the cost of a replacement device or the parts that must be replaced.
- VII. Replacement or repair needed due to misuse or neglect is **ineligible for coverage**.
- VIII. Necessary repairs and maintenance of covered prosthetic devices are eligible for coverage; unless covered by a manufacturer's warranty or purchase agreement. Adjustments to approved prosthetic devices are eligible for coverage when ordered by a physician and necessary due to normal wear, or when required by a change in the patient's condition.
- IX. Replacement or repair covered under a homeowner policy or similar insurance is **ineligible for coverage**.

### DESCRIPTION

External prosthetic devices, which are worn as anatomic supplements, are used to replace non-functioning or absent body parts. Examples of external prosthetic devices include artificial limbs, removable artificial eyes, external breast prostheses or prosthetic bras for post mastectomy patients, external pacemakers, and electronic speech aids for post-laryngectomy patients. Some HCPCS "A" code items such as ostomy bags for a patient with an artificial stoma, become prosthetic devices.

The design of lower limb prosthetic devices is based on the functional level classification of the individual as described by Medicare Guidelines.

- I. Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance quality of life or mobility.
- II. Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
- III. 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.
- IV. 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.
- V. 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 child, active adult, or athlete.

Lower limb prosthetic devices are either preparatory or permanent (definitive). A preparatory prosthesis is a temporary device fitted while the residual limb is still remolding after surgery. The preparatory prosthesis is used until the residual limb has reached its final shape and size, typically within three to six months. Once the residual limb is stabilized (e.g., the residual limb volume is unchanged, and the socket fit is consistent for two to three weeks) a permanent or definitive

## Medical Policy: EXTERNAL PROSTHETIC DEVICES

Policy Number: 1.01.18

Page: 5 of 12

prosthesis can be fitted.

A basic preparatory or permanent (definitive) lower limb prosthetic device consists of the following components: 1) socket, 2) suspension mechanism, 3) knee joint, 4) pylon, and 5) terminal device (foot). Described below are definitions of each component and usual indications. The listing is not all-inclusive.

1. Socket; the interface between the residual limb and the prosthesis, functions to protect the residual limb and transmits the forces associated with ambulation and standing. They can be soft made of foam, rubber, or leather, or hard made of acrylic or thermoplastic. A socket is necessary to secure the safety of the residual limb and provides a rigid control of the prosthesis. The socket should cause minimal discomfort during its usage. Additions, such as liners, sleeves, and socks to provide improved fit of the socket to the residual limb.
2. Suspension mechanism: method which holds the prosthesis to the body. There are several types which include locking pin, TES belt, suspension sleeve, waist belt, suction, and vacuum. A shuttle lock/pin comprised of a liner with a pin placed into the end and a locking mechanism. The liner improves contact between the limb and the prosthesis. The pin improves suspension from the deficient limb. A Silesian belt fastens to the socket laterally, above the greater trochanter, and wraps around the opposite iliac crest. A Silesian belt is appropriate for the pediatric patient as well. The gel liner suction system uses a gel elastomeric liner, and a pin may or may not be used. Gel liner suction system is appropriate for patients with a transfemoral or transtibial amputation. Standard suction contains a one-way air valve in the distal end; air is expelled after the socket is donned creating a seal from the development of a small negative pressure. Standard suction is a common suspension choice for transfemoral prostheses. Vacuum suspension is created between an airtight sleeve and a one-way air valve located in the bottom of the socket. Vacuum suspension is another transtibial suspension option. Lastly, the vacuum-assisted socket system (VASS) works by use of a vertical shock pylon that acts as a vacuum pump and continually withdraws air from the sealed socket during ambulation. There is insufficient evidence to support the efficacy of vacuum-assisted socket systems (VASS) over standard socket types for all patients, however VASS may be appropriate for individuals where the current socket can no longer be modified to adequately secure the limb to the prosthesis or there is non-healing skin breakdown on the stump due to an ill-fitting socket.
3. Knee joint: provides support during the stance phase of ambulation, produces smooth control during the swing phase, and maintains unrestricted motion for sitting and kneeling. There are several types of knee joints including single-axis knees, polycentric-axis knees, hydraulic knees, and microprocessor-controlled knees. Single-axis knees - recommended for: classification level 1 or above. Polycentric-axis knees -recommended for: classification level 3 or above. Hydraulic knees are chosen by more active amputees. Hydraulic knees - recommended for: classification level 3 or above. A microprocessor controlled knee (e.g., Otto Bock C-leg, Otto Bock Genium X3) are single- or multi-axial energy saving knee with onboard microprocessor. This allows the knee to adjust for variable gait cycles providing more natural movement during stair descent or while ambulating on uneven terrain.
4. Pylon; attaches the socket to the terminal device. Allows axial rotation and is able to absorb, store, and release energy.
5. Terminal device (foot); functions to provide a stable, weight-bearing surface, absorb shock, replace lost muscle function, replicate the anatomic joint, and to restore cosmetic appearance. There are several types of terminal devices including non-energy, energy- returning and microprocessor-controlled ankle foot systems. Non-energy devices are the solid-ankle cushioned-heel (SACH) foot and the single-axis foot. The SACH foot is low cost and low maintenance. The single axis foot provides increased knee stability. Either SACH or single axis foot is used in sedentary patients. Energy-returning (energy storing) devices assist the body's natural biomechanics and allow for greater cadence or less oxygen consumption with a multi-axis or dynamic-response. The multi-axis foot is useful for the individual with a minimal to moderate activity level and is recommended for classification level 3 or above. The dynamic response foot is the top of the line foot and is commonly used by young, active persons and by athletic individuals. These are made from ultralight materials. Microprocessor-controlled ankle-foot systems use a sensor device (Terrain Logic), which enables the ankle prosthesis to respond appropriately and immediately to variations in ground surface and activity. Examples: Flex Foot Assure, and K2 Sensation, Genesis II and the Seattle Lite. Proprio-Foot with EVO (Ossur), Triton smart ankle (Ottobock). Microprocessor-controlled ankle-foot system is

## Medical Policy: EXTERNAL PROSTHETIC DEVICES

Policy Number: 1.01.18

Page: 6 of 12

considered not medically necessary as ADLs can be met with standard prosthetic devices. A prosthetic shoe can function as a terminal device to supplement a substantially absent foot. The function of prosthetic shoes is quite distinct from that of non-covered orthopedic shoes and supportive foot devices, which are used by individuals whose feet, although impaired, are essentially intact.

Upper limb functional prostheses generally can be divided into two categories: body-powered prostheses or externally electrically powered prostheses. Body-powered prostheses are controlled by cables and require gross limb movement. Externally electrically powered prostheses use the electrical activity from select residual limb muscle contractions as a signal to activate the electric motor of the prosthesis using either a myoelectrically controlled or a switch-controlled prostheses. A hybrid system, which is a combination of body-powered and myoelectric components, may be used for high level amputations (at or above the elbow). Hybrid systems allow control of two joints at once (i.e., one body-powered and one myoelectric) and are generally lighter and less expensive than a prosthesis composed entirely of myoelectric components.

All conventional body-powered, upper extremity prostheses have the following components: 1) socket, 2) suspension, 3) control-cable system, 4) terminal device, and 5) components for any interposing joints as needed according to the level of amputation. Described below are definitions of each component. The listing is not all-inclusive.

1. Socket: fabricated from lightweight plastic or graphite composite materials. This is composed of a rigid inner socket fit to the residual limb which determines comfort and function, and the outer wall which is the same length and contour as the opposite sound limb.
2. Suspension system: holds prosthesis securely to the residual limb; accommodates and distributes the forces associated with the weight of the prosthesis and any superimposed lifting loads. There are several types of systems available including harness-based systems, self-suspending sockets, and suction sockets. Harness based systems are the most commonly used. Self-suspension sockets are limited to wrist or elbow disarticulations and to transradial amputations. They are commonly utilized with an externally powered, myoelectrically controlled, transradial prosthesis. Suction sockets are similar to lower extremity options which contain a one-way air valve in the distal end; air is expelled after the socket is donned creating a seal from the development of a small negative pressure. Suction sockets are appropriate for the patient with a transhumeral amputation.
3. Control-cable system: There are 3 types including passive, body-powered, and myoelectric. Passive systems are lightweight, cannot restore function and must be repositioned manually, typically by moving it with the opposite arm. Body-powered systems utilize a harness and cable to provide functional manipulation of the elbow and hand. Voluntary movement of the shoulder and/or residual limb extends the cable and transmits the force to the terminal device. Myoelectric systems use muscle activity from the remaining limb for the control of joint movement. Electromyographic signals from the limb stump are detected by surface electrodes, amplified, and then processed by a controller to drive battery-powered motors that move the hand, wrist, or elbow. These may be considered the most physiologically natural but may be slow and limited to one joint a time.
4. Terminal devices: can be passive or active, voluntary opening (closed at rest), voluntary closing (open at rest), and myoelectric hand with individual control of digits. There are many different options available for terminal devices depending on occupation, hobbies, or sports. A passive terminal device is more cosmetic than functional and more costly than active terminal devices. An example of a passive terminal device is a child mitt to assist child with crawling. An active terminal device is more functional than cosmetic and can be either a hook or hand. A hand can be powered by cable or external power and is more cosmetically pleasing than a hook. A hook provides active lateral pinch grip. A myoelectric hand with individual control of digits includes the SensorHand by Advanced Arm Dynamics, ProDigits, i-digits quantum, i-limb quantum, i-limb ultra, Michelangelo hand, and AxonArm Ergo, and Select Myoelectric Hand. There is a lack of peer-reviewed literature to evaluate functional outcomes of these myoelectric devices.
5. Components for any interposing joints as needed according to the level of amputation.

## **Medical Policy: EXTERNAL PROSTHETIC DEVICES**

**Policy Number: 1.01.18**

**Page: 7 of 12**

### **RATIONALE**

#### Lower Extremity Prosthesis

In 2019, clinical practice guidelines (Webster J, et al.) published by US Department of Veterans Affairs and US Department of Defense regarding rehabilitation of individuals with lower limb amputation recommended 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.

#### Microprocessor Prosthetic Knees

Thibaut et al. (2022) conducted a systematic review including studies of microprocessor prosthetic knees in patients with lower limb amputation. The review included 18 studies (seven (7) RCTs, six (6) cross-sectional studies, and five (5) follow-up studies). Overall, the authors found better functional status and mobility with microprocessor prosthetic knees, but it remains unclear whether there are differences among various models of microprocessor prosthetic knees.

Hahn et al. (2022) performed a systematic review and meta-analysis which included 13 published studies of microprocessor prosthetic knees in limited community ambulators. Microprocessor prosthetic knees had improved outcomes in terms of falls, fear of falling, risk of falling, and mobility grade when compared with non-microprocessor prosthetic knees in limited community ambulators.

Alzeer et al. (2022) conducted a cross-sectional study with a total of 76 adult unilateral transfemoral amputees classified into two groups. The participants in the first group (38) used the microprocessor-controlled prosthetic knee (Genium, Otto Bock, Minneapolis, MN, USA), and the participants in the second group (38) used various non-microprocessor-controlled prosthetic knee (hydraulic and total knee joints). The microprocessor-controlled prosthetic knee participants shoed significantly improved utility, appearance, ambulation, and total Prosthetic Evaluation Questionnaire outcome scores. This study is limited by its small size and observational nature.

#### Microprocessor-Controlled Ankle-Foot Prostheses

Thomas-Pohl et al. (2021) compared three (3) types of microprocessor prosthetic ankles, including the Proprio Foot Ossur, Elan Endolite, and Meridium Ottobock, in a crossover study. The six (6) participants were transtibial amputees usually fit with an energy storing and returning foot. The participants tested all devices for a two (2) week period. The primary outcome was to evaluate the ability of these prostheses to adapt to ground inclination. Overall, the study found that microprocessor prostheses allowed for better posture and a reduction of residual knee moment on positive and/or negative slope when compared to the patients' energy storing and returning feet. This study is limited by its small sample size.

Colas-Ribas et al. (2022) conducted a multicenter, randomized, controlled cross-over study in 45 patients with ankle prosthesis in France. Each ankle-foot prosthesis (microprocessor-controlled Proprio Foot or non-microprocessor standard prescribed ankle prosthesis) was worn for a total of 34 days. Energy expenditure was assessed by oxygen uptake measured at the maximum level reached with the two prostheses during treadmill walking at progressively increasing incline and speed. Quality of life and satisfaction was assessed by a questionnaire after wearing each of the two prostheses. The authors found energy expenditure was similar between prostheses (19.4 mL/kg/min with Proprio Foot and 19.1 mL/kg/min with other prostheses) with no statistical difference observed. Quality of life questionnaire physical scores with Proprio Foot were significantly better than with other prostheses (68.5 vs. 62.1;  $p=.005$ ) as were mental scores (72.0 vs. 66.2;  $p=.006$ ).

Several small studies have been reported with microprocessor-controlled prostheses for transtibial amputees. The evidence to date is insufficient to support an improvement in functional outcomes compared with the same device in the off-mode or compared with energy-storing and energy-returning prostheses. Larger, higher-quality studies are needed to determine the impact of these devices on health outcomes with greater certainty.

#### Upper Extremity Prosthetic

In 2022, clinical practice guidelines (Crunkhorn A, et al.) published by US Department of Veterans Affairs and US

**Medical Policy: EXTERNAL PROSTHETIC DEVICES**

**Policy Number: 1.01.18**

**Page: 8 of 12**

Department of Defense regarding management of upper limb amputation rehabilitation recommend the use of body-powered or externally powered prosthesis to improve independence and reduce disability for patients with major unilateral upper limb amputation (i.e., through or proximal to the wrist). They state there is insufficient evidence to recommend for or against any specific control strategy, socket design, suspension method or component. There is insufficient evidence to recommend for or against the use of any particular recent treatment advances including hardware, software, surgical, technology, or supplemental surgical interventions, such as: targeted muscle reinnervation (TMR), regenerative peripheral nerve interfaces (RPNI), vascularized composite allotransplantation (VCA), agonist-antagonist myoneural interface (AMI), implantable myoelectric sensor system (IMES), or osseointegration (OI).

Myoelectric Hand with Individual Digit Control

Although the availability of a myoelectric hand with individual control of digits has been widely reported in lay technology reports, video clips, and basic science reports, no peer-reviewed publications have been found that evaluate functional outcomes of individual digit control in amputees.

**CODES**

- Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.
- **CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
- Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

**CPT Codes**

| Code       | Description |
|------------|-------------|
| No code(s) |             |

Copyright © 2024 American Medical Association, Chicago, IL

**HCPCS Codes**

| Code                          | Description  |
|-------------------------------|--|
| A4361-A4437                   | Ostomy supplies (code range)   |
| A5051-A5093                   | Additional ostomy supplies (code range)  |
| A9282                         | Wig, any type, each  |
| L5615<br>(Effective 01/01/24) | Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control ( <i>Effective 01/01/24</i> ) ( <i>Replacing code K1014</i> )     |
| K1014<br>(Termed 12/31/23)    | Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control   |
| L3250                         | Orthopedic footwear, custom molded shoe, removable inner mold, prosthetic shoe, each   |
| L5000-L5855                   | Lower limb prosthetic (code range)   |
| L5856                         | Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control knee 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             |



**Medical Policy: EXTERNAL PROSTHETIC DEVICES****Policy Number: 1.01.18****Page: 9 of 12**

| <b>Code</b> | <b>Description</b>  |
|-------------|---|
| L5858       | Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type   |
| L5859       | Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)  |
| L5910-L5972 | Lower limb prosthetic (code range)  |
| L5973 (NMN) | Endoskeletal ankle foot system, microprocessor-controlled feature, dorsiflexion and/or plantar flexion control, includes power source   |
| L5974-L5999 | Lower limb prosthetic (code range)  |
| L6000-L6020 | Upper limb prosthetic device (code range)   |
| L6026 (E/I) | Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes, and cables, two batteries, charger, myoelectric control of terminal device, excludes terminal device(s) |
| L6050-L6698 | Upper limb prosthetic device (code range)   |
| L6703-L6810 | Terminal devices (hooks) (code range)   |
| L6880 (E/I) | Electric hand, switch or myoelectric controlled, independently articulating digits, any grasp pattern or combination of grasp patterns, includes motor(s)   |
| L6881 (E/I) | Automatic grasp feature, addition to upper limb electric prosthetic terminal device   |
| L6882 (E/I) | Microprocessor control feature, addition to upper limb prosthetic terminal device   |
| L6883-L6885 | Replacement socket (code range)   |
| L6890-L6915 | Hand – gloves – hand restoration (code range)   |
| L6920       | Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal switch, cables, two batteries and one charger, switch control of terminal device  |
| L6925 (E/I) | Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device   |
| L6930-L6975 | External power (base devices) (code range)  |
|             | Missing codes   |
| L7259       | Electronic wrist rotator, any type  |
| L7360-L7368 | Battery components (code range)   |
| L7499       | Upper extremity prosthesis, not otherwise specified   |
| L7510       | Repair of prosthetic device, repair or replace minor parts  |
| L7520       | Repair prosthetic device, labor component, per 15 minutes   |
| L7700       | Gasket or seal, for use with prosthetic socket insert, any type, each   |

**Medical Policy: EXTERNAL PROSTHETIC DEVICES****Policy Number: 1.01.18****Page: 10 of 12**

| Code        | Description   |
|-------------|---|
| L8000–L8039 | General prosthesis; breast (code range)   |
| L8040-L8049 | General prosthesis; face and ear (code range)   |
| L8400-L8499 | Prosthetic socks (shrinker, sheath, stump sock) (code range)                                  |
| L8500–L8515 | Larynx and trachea prosthetics and accessories (code range)                                   |
| L9900       | Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS “L” code |
| V2623-V2629 | Prosthesis, ocular (code range)   |

**ICD10 Codes**

| Code                     | Description |
|--------------------------|-------------|
| Numerous diagnosis codes |             |

**REFERENCES**

\*Alzeer AM, et al. Impacts of microprocessor-controlled versus non-microprocessor-controlled prosthetic knee joints among transfemoral amputees on functional outcomes: a comparative study. Cureus Apr 2022; 14(4): e24331.

Colas-Ribas C, et al. Effects of a microprocessor-controlled ankle-foot unit on energy expenditure, quality of life, and postural stability in persons with transtibial amputation: An unblinded, randomized, controlled, cross-over study. Prosthet Orthot Int 2022 Dec;46(6):541-548.

\*Crunkhorn A, et al. Management of upper limb amputation rehabilitation: synopsis of the 2022 US Department of Veterans Affairs and US Department of Defense clinical practice guideline for acquired amputation. Am J Phys Med Rehabil 2023 Mar 1;102(3):245-253.

\*Darter BJ, et al. Energetic consequences of using a prosthesis with adaptive ankle motion during slope walking in persons with a transtibial amputation. Prosthet Orthot Int 2014; 38(1):5-11.

\*Eberly VJ, et al. Impact of a stance phase microprocessor-controlled knee prosthesis on level walking in lower functioning individuals with a transfemoral amputation. Prosthet Orthot Int 2014 Dec;38(6):447-55.

\*Ferris AE, et al. Evaluation of a powered ankle-foot prosthetic system during walking. Arch Phys Med Rehabil 2012;93(11):1911-8.

\*Gailey RS, et al. Application of self-report and performance-based outcome measures to determine functional differences between four categories of prosthetic feet. J Rehabil Res Dev 2012;49(4):597-612.

\*Hahn A, et al. The effect of microprocessor controlled exo-prosthetic knees on limited community ambulators: systematic review and meta-analysis. Disabil Rehabil Dec 2022; 44(24): 7349-7367.

\*Herr HM, et al. Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation. Proc Biol Sci 2012;279(1728):457-64.

\*Highsmith MJ, et al. Ramp descent performance with the C-Leg and interrater reliability of the Hill Assessment Index. Prosthet Orthot Int 2013 Oct;37(5):362-8.

Johansen D, et al. Hybrid tongue-myoelectric control improves functional use of a robotic hand prosthesis. IEEE Trans Biomed Eng 2021 Jun;68(6):2011-2020.

\*Kaufman KR, et al. Gait asymmetry of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. Clin Biomech (Bristol) 2012 Jun;27(5):460-5.

## **Medical Policy: EXTERNAL PROSTHETIC DEVICES**

**Policy Number: 1.01.18**

**Page: 11 of 12**

Li S, et al. Physiological parameters analysis of transfemoral amputees with different prosthetic knees. Acta Bioeng Biomech 2019;21(3):135-142.

\*Schmalz T, et al. Energy expenditure and biomechanical characteristics of lower limb amputee gait: the influence of prosthetic alignment and different prosthetic components. Gait Posture 2002;16:255-63.

Stevens PM and Wurdeman SR. Prosthetic knee selection for individuals with unilateral transfemoral amputation: a clinical practice guideline. J Prosthet Orthot 2019 Jan;31(1):2-8.

\*Theeven PJ, et al. Influence of advanced prosthetic knee joints on perceived performance and everyday life activity level of low-functional persons with a transfemoral amputation or knee disarticulation. J Rehabil Med 2012; 44(5):454-61.

\*Theeven P, et al. Functional added value of microprocessor-controlled knee joints in daily life performance of Medicare Functional Classification Level-2 amputees. J Rehabil Med 2011; 43(10):906-15.

\*Thibaut A, et al. Impact of microprocessor prosthetic knee on mobility and quality of life in patients with lower limb amputation: a systematic review of the literature. Eur J Phys Rehabil Med Jun 2022; 58(3): 452-461.

\*Thomas-Pohl M, et al. Microprocessor prosthetic ankles: comparative biomechanical evaluation of people with transtibial traumatic amputation during standing on level ground and slope. Disabil Rehabil Assist Technol Jan 2021; 16(1): 17-26.

\*Webster JB, et al. Clinical practice guidelines for the rehabilitation of lower limb amputation: an update from the Department of Veterans Affairs and Department of Defense. Am J Phys Med Rehabil Sep 2019; 98(9): 820-829.

\*Key Article

### **KEY WORDS**

C-leg, Intelligent Prosthesis, microprocessor-controlled lower limbs, Ossur Rheo, Vacuum-assisted-socket system (VASS).

### **CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently a National Coverage Determination (NCD) for Prosthetic Shoe (280.10). Please refer to the following NCD website for Medicare Members: [<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=208&ncdver=1&bc=AgAAgAAAAAA&>] accessed 01/09/24.

There is currently a Local Coverage Determination (LCD) for External Breast Prostheses (L33317). Please refer to the following LCD website for Medicare Members: [[https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33317&ver=31&CntrctrSelected=389\\*1&Cntrctr=389&s=41&DocType=1&bc=AAQAAAIAIAAA&=+](https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33317&ver=31&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAQAAAIAIAAA&=+)] accessed 01/09/24.

There is currently a Local Coverage Determination (LCD) for Eye Prostheses (L33737). Please refer to the following LCD website for Medicare Members: [[https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33737&ContrId=389&ver=20&ContrVer=1&CntrctrSelected=389\\*1&Cntrctr=389&s=41&DocType=1&bc=AAIAACAAAA&](https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33737&ContrId=389&ver=20&ContrVer=1&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAIAACAAAA&)] accessed 01/09/24.

There is currently a Local Coverage Determination (LCD) for Facial Prostheses (L33738). Please refer to the following LCD website for Medicare Members: [[https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33738&ContrId=389&ver=18&ContrVer=1&CntrctrSelected=389\\*1&Cntrctr=389&s=41&DocType=1&bc=AAIAACAAAA&](https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33738&ContrId=389&ver=18&ContrVer=1&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAIAACAAAA&)] accessed 01/09/24.

There is currently a Local Coverage Determination (LCD) for Lower Limb Prostheses (L33787). Please refer to the following LCD website for Medicare Members: [[https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33787&ver=26&ContrId=389&ContrVer=1&CntrctrSelected=389\\*1&Cntrctr=389&s=41&DocType=1&b%20armc=AAIAACAAAA&=](https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33787&ver=26&ContrId=389&ContrVer=1&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&b%20armc=AAIAACAAAA&=)] accessed 01/09/24.

**Medical Policy: EXTERNAL PROSTHETIC DEVICES**

**Policy Number: 1.01.18**

**Page: 12 of 12**

Based on our review, Upper Extremity Prosthesis is not addressed in National or Regional Medicare coverage determinations or policies.