

MEDICAL POLICY

Medical Policy Title	External Prosthetic Devices
Policy Number	1.01.18
Current Effective Date	August 15, 2025
Next Review Date	April 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to [Product Disclaimer](#))

POLICY STATEMENT(S)

General Criteria

- I. 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. 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. 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. Prosthetics used for activities other than normal activities of daily living, including, but not limited to, those utilized for leisure or sporting activities such as skiing or swimming are considered **not medically necessary**.
- VI. Devices or implants used primarily for cosmetic purposes are considered **not medically necessary**.
- VII. Osseointegration surgery and/or prosthesis for upper and/or lower limbs (e.g., Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA) Implant System, Axor II connection device) are considered **investigational**.

Preparatory Prosthesis

- VIII. Preparatory prostheses are considered **medically appropriate** after surgery to prevent edema of the residual limb and to enhance functional recovery.
- IX. Additions such as protective covers, ultralight material, nonstandard components (e.g., microprocessor knees), and flex foot systems (e.g., energy storing) are considered **not medically necessary** for a preparatory prosthesis.

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Lower Extremity Prosthesis

- X. Basic preparatory or permanent (definitive) lower limb prosthetic devices are considered **medically appropriate** for individuals with a function level 1 or greater including but not limited to the following: (Refer to the Description section for definitions of [functional levels](#).)
- A. A single axis constant friction knee and other basic knee systems for persons whose functional level is 1 or above;
 - B. A fluid, pneumatic, or electronic knee for persons whose functional level is 3 or above;
 - C. A high-activity knee control frame for members whose function level is 4;
 - D. Solid-ankle cushioned-heel (SACH) foot (L5970) or single axis ankle/foot (L5974) appropriate for sedentary patients with a functional level 1 or above;
 - E. Flexible-keel foot (L5972) or multi-axial ankle/foot (L5978) for a functional level of 2 or above;
 - F. Energy storing foot (L5976), dynamic response foot with multi-axial ankle (L5979), flex foot system (L5980), flexwalk system or equal (L5981) or shank foot system with vertical loading pylon (L5987) for a functional level of 3 or above;
 - G. A prosthetic shoe as a terminal device to supplement a substantially absent foot (L3250).
- XI. A socket for a lower limb prosthetic device is considered **medically appropriate** for **ANY** of the following:
- A. One socket per individual prosthetic;
 - B. Two of the same socket inserts per individual prosthesis at the same time;
 - C. Up to two test sockets when fitting for a socket;
- A test socket is not recommended for immediate postsurgical or early fitting prostheses.
- XII. A vacuum-assisted socket systems (VASS) for a lower limb prosthetic device is considered **medically appropriate** for **ANY** of the following situations:
- A. There is a nonhealing skin breakdown on the stump from friction due to an ill-fitting socket;
 - B. The current socket can no longer be modified to adequately secure the limb to the prosthesis.
- XIII. A microprocessor-controlled knee is considered **medically appropriate** when **ALL** of the following criteria are met:
- A. For persons with a knee disarticulation amputee OR transfemoral amputee;
 - B. Functional level 3;
 - C. The patient has adequate cardiovascular and pulmonary reserve which enable the patient to ambulate at a faster than normal walking speed;
 - D. The patient has received additional training for use of this technology and has demonstrated adequate cognitive ability to master use and care requirements;

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- E. The patient demonstrated a need to perform **ALL** of the following:
 - 1. long distance ambulation at variable rates;
 - 2. regular and frequent ambulation on uneven terrain (e.g., grass, gravel, or curbs);
 - 3. regular and frequent ambulation on stairs or ramps;
- F. Microprocessor-controlled knees are **contraindicated** for **ANY** of the following:
 - 1. The patient's [functional level](#) is less than 3 or has limited ambulation due to poor balance or ataxia;
 - 2. The patient is unable to tolerate the weight of the prosthesis;
 - 3. The patient is unable to use the swing and stance features of the knee;
 - 4. The patient is unable to change the prosthesis or has a condition that would cause inadequate fitting;
 - 5. The patient has significant hip flexion contracture (over 20 degrees);
 - 6. The patient has significant deformity of the remaining limb that would impair ability to stride;
 - 7. The prosthesis will be used when the environmental conditions include excessive moisture or dust which invalidates the warranty.

XIV. Lower limb prosthetic devices are considered **not medically necessary** for individuals with functional level 0. (Refer to the Description section for definitions of [functional levels](#).)

XV. A microprocessor-controlled ankle-foot system (e.g., Proprio-Foot with EVO [Ossur], Triton smart ankle [Ottobock]), (e.g., PowerFoot BiOM, iWalk, Bedford, MA; Proprio Foot, Ossur, Aliso Viejo, CA) is considered **not medically necessary**.

Upper Extremity Prosthesis

XVI. A conventional body-powered, upper extremity prostheses 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. Myoelectric upper arm prosthetic components 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;

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- 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. The following upper extremity prosthetics are considered **investigational**:

- A. Myoelectric hand (including partial hand) with individual control of digits (e.g., Michelangelo hand [OttoBock], AxonArm Ergo [OttoBock], ProDigits);
- B. Enhanced dexterity upper-limb prosthetic components with both sensor and myoelectric control (e.g., LUKE Arm).

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

RELATED POLICIES

Corporate Medical Policy

1.01.00 Durable Medical Equipment –Standard and Non-Standard

1.01.25 Orthotics

7.01.30 Erectile Dysfunction

10.01.01 Breast Reconstruction Surgery and Prophylactic Breast Cancer Risk-Reducing Mastectomy

POLICY GUIDELINE(S)

- I. Documentation Requirements include **ALL** of the following:
 - A. General description of the prosthetic including but not limited to a HCPCS code, a HCPCS code narrative, and a brand name, make, model, and description of the requested device features;
 - B. Description of all additional ordered options, accessories, or features that are separately billed or require an up-graded code (List each separately and include quantity);
 - C. Specify whether the prosthetic is an initial, replacement, preparatory, or definitive, or a request to upgrade.
- II. To be eligible for coverage a prosthetic device must address a problem in which the device is needed for at least 90 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.

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- V. Synthetic wigs **are eligible for coverage** when there is a severe hair loss due to injury, disease, or as a side effect of the treatment of a disease (e.g., chemo/radiotherapy, burns, chronic inflammatory conditions such as alopecia). 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 **EITHER** 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;
 - 1. 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

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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 remodeling 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 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

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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. A flexible-keel foot or multi-axial ankle/foot is appropriate for a functional level of 2 or above. An energy storing foot, dynamic response foot with multi-axial ankle, flex foot system, flexwalk system or equal or shank foot system with vertical loading pylon is appropriate for a functional level of 3 or above (Agrawal 2015). 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 immediate 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 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

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prosthesis composed entirely of myoelectric components.

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 at a time.
4. **Terminal devices:** can be passive or active, voluntary opening (closed at rest), voluntary closing (open at rest), myoelectric hand with individual control of digits, and partial hand prosthesis. 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.

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A type of advanced upper limb prosthetic device has been developed that incorporates both sensor components and myoelectric control (e.g., Life Under Kinetic Evolution [LUKE] Arm [previously known as the DEKA Arm System, Mobius Bionics, LLC. Manchester, NH] and SensorHand Speed [OttoBock, Austin, TX]) The LUKE Arm was developed in a joint effort between DEKA Research & Development and the U.S. Department of Defense Advanced Research Projects Agency program. It is the first commercially available myoelectric upper limb that can perform complex tasks with multiple simultaneous powered movements. These include up to 10 active degrees of freedom (DOF) or movements, including shoulder abduction, shoulder flexion/extension, humeral rotation, elbow flexion/extension, wrist pronation/supination, wrist flexion/extension, index finger flexion/extension, flexion/extension of other fingers, thumb flexion/extension, and thumb abduction/adduction. In addition to the electromyographic electrodes, the LUKE Arm contains a combination of mechanisms, including switches, movement sensors, and force sensors including grip force feedback. The primary control resides with motion sensors on top of the feet, attached to the user's shoe.

An osseointegrated prosthesis for the rehabilitation of amputees (OPRA), is an implant system for direct skeletal anchorage of amputation prostheses. OPRA constitutes a rehabilitation alternative for transfemoral amputees when treatment with socket prostheses is insufficient. This bone anchored device is intended for skeletally mature individuals who have transfemoral amputation due to trauma or cancer. The OPRA Implant System consists of seven components that are implanted during two surgeries. The overall time commitment for surgery, recovery and rehabilitation is anticipated to be greater than one year. Compared to socket suspension techniques, direct skeletal attachment of a prosthetic limb through osseointegration offers many potential advantages including improved mechanical transfer of motion, reduced skin irritation from a prosthetic socket, improved joint range-of-motion, and enhanced comfort. Osseointegration also presents the risk of serious complications such as infection, failure of the implant, and bone fracture.

SUPPORTIVE LITERATURE

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 showed significantly improved utility, appearance, ambulation, and total Prosthetic Evaluation Questionnaire outcome scores. This

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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.

Myoelectric Hand with Individual Digit Control and Partial Hand Prosthesis

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.

Kerver et al. (2023) compared the multi-grip myoelectric hand prosthesis (MHP) to that of a standard myoelectric hand prostheses (SHP) in all categories of the International Classification of Functioning, Disability, and Health-model (ICF-model). MHP users (N=14, 64.3% male, mean age=48.6 years) performed physical measurements with their MHP (i-Limb Quantum/Ultra (Touch Bionics; Livingston, United Kingdom), BeBionic (Ottobock; Duderstadt, Germany) or VINCENT (Vincent Systems, Karlsruhe, Germany)) and an SHP to compare the joint angle coordination, dexterity, and prosthetic hand function. In addition, comparisons on user experience, satisfaction and quality of life were performed. The SHP group (N=19, 68.4% male, mean age=58.1 years) utilized a Myohand Variplus Speed (Ottobock; Duderstadt, Germany) or Motion Control Hand (Fillauer, USA), which has a movable thumb, index finger, and middle finger that can open and close in only one grip. The authors found no superior benefit of the MHP devices compared to SHP. The SHP scored better than

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the MHP in several outcome measures. MHP users experienced more pain or limitations due to pain. Limitations of the study include small sample size and lack of randomization.

In a single case study, Widehammar et al. (2022) evaluated the effect of a multi-grip myoelectric hand prosthetic performance of daily activities, pain-related disability, and prosthesis use, in comparison with a single-grip myoelectric hand prosthetic. Nine (9) adults participated in the study, and all had previous experience of single-grip myoelectric prostheses and were prescribed a prosthesis with multi-grip functions (Bebionic multi-grip hand, Ottobock, Vienna, Austria). To assess the changes in daily activities, pain-related disability and prosthesis use between single-grip and multi-grip myoelectric prosthetic hands, the Canadian Occupational Performance Measure, Pain Disability Index, and prosthesis wearing time were measured at multiple time-points. At 6 months' follow-up self-perceived performance and satisfaction scores had increased, prosthesis wearing time had increased, and pain-related disability had reduced in participants with musculoskeletal pain at baseline. There was some missing data of the performance tests due to the breakdown and repair of the multi-grip hands. Participants had access to temporary hands, though it was sometimes not possible to conduct the tests, as the temporary hands also required repairs at times. The authors concluded that the multi-grip myoelectric prosthetic hand can be more useful than a single grip model for performance of specific, individually chosen activities, however the poor durability of the multi-grip hand was problematic for daily use. A durable single-grip myoelectric prosthetic hand may still be needed for heavier physical activities. With structured training, a standard 2-site electrode control system can be used to operate a multi-grip myoelectric prosthetic hand. Further studies are needed into the user's perspective of using multi-grip hands in daily life, to provide valuable information to both clinicians and prosthetic developers.

In a cross-sectional study, (Wanamaker 2019) investigated changes in upper limb function and kinematics in 10 men with partial-hand amputations performing a functional assessment by comparing results with and without a multi-articulating hand prosthesis. Five (5) participants with four-digit loss (thumb intact) and five (5) participants with five-digit loss were included in the study. Three-dimensional kinematics were collected as the participants performed a functional assessment using the Southampton Hand Assessment Procedure (SHAP) with and without a prosthesis. All participants had the i-digits prosthesis from Touch Bionics by Össur. The i-digits is an externally powered partial hand prosthesis with individual articulating digits. Significantly larger joint motions were seen without the prosthesis than with for all participants, which may be an indicator of higher risk for overuse injury. Significant improvement was seen in SHAP scores in the five-digit limb loss participants using the prosthesis compared with not using the device ($p < 0.05$ for 6 of 7 SHAP score categories) though there were no statistical differences in SHAP scores for those with four-digit limb loss. The prosthesis reduced functional deficits and decreased joint range of motion in individuals with partial hand loss. Results showed reduced compensatory motions throughout the upper limb and torso which may reduce the risk of overuse injury. Limitations of the study include the small sample size, the inclusion/exclusion criteria may have resulted in the recruitment of highly functional four-digit limb loss participants and a cohort with good control and strength of the residual limb and may not be representative of the general population. In addition, only one specific prosthesis was investigated, limiting the generalizability to other prostheses for individuals with partial hand loss.

Whelan and Farley (2018) published findings of a case series evaluating an externally powered partial

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hand prosthesis and the ability to complete functional tasks. Fifteen individuals (12 males) with four- (with thumb remaining) or five-digit partial hand limb loss or absence were fit with the multi-articulating, externally powered i-digits partial hand prostheses. The participants were evaluated using the Southampton Hand Assessment Procedure (SHAP) and Patient-Specific Functional Scale (PSFS). All participants demonstrated a clinically significant change in scores on both the PSFS and the SHAP. The individuals with five-digit absence demonstrated marked improvement in comparison with those with four-digit absence; however, both were far superior to the minimal detectable change score for the SHAP, with 42.33 and 19.16 average improvement scores, respectively. The results indicate that use of the partial hand prosthesis demonstrated functional improvements in objective hand function and individualized goals. The small sample size of 15 participants represents mostly young men with acquired amputations, which may not represent the entire partial-hand population. The individual's remaining range of motion, strength, and function in the thumb and wrist were not fully accounted as potentially influencing results between subjects.

Luke Arm

For individuals who have a missing limb at the wrist or higher who receive sensor and myoelectric controlled upper-limb prosthetic components, the evidence includes a series of publications from a 12-week home study (Resnik 2017, 2017, 2018). Relevant outcomes are functional outcomes and quality of life. The prototypes for the advanced prosthesis were evaluated by the U.S. military and Veterans Administration. Demonstration of improvement in function has been mixed. After several months of home use, activity speed was shown to be similar to the conventional prosthesis, and there were improvements in the performance of some activities, but not all. There were no differences between the prototype and the participants' prostheses for outcomes of dexterity, prosthetic skill, spontaneity, pain, community integration, or quality of life. Study of the current generation of the sensor and myoelectric controlled prosthesis is needed to determine whether newer models of this advanced prosthesis lead to consistent improvements in function and quality of life. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. The use of such devices has been limited due to their weight, complexity, and learning curve, and are not generally accepted in clinical practice at this time.

Osseointegrated

A retrospective observational cohort study (Muderis 2024) reports the changes in mobility, quality of life (QOL), and the safety profile of the largest described cohort of patients with unilateral Trans-Tibial osseointegration (TTOI) following traumatic amputation. The cohort consisted of patients with data outcomes collected before and after osseointegration intervention. Participants included twenty-one skeletally mature adults who had failed socket prosthesis rehabilitation, with at least two years of post-osseointegration follow-up. All patients demonstrated statistically significant improvement post osseointegration surgery though three (3) patients had four (4) unplanned surgeries: two (2) soft tissue refashioning, and one (1) soft tissue debridement followed eventually by implant removal. No deaths, postoperative systemic complications, more proximal amputations, or periprosthetic fractures occurred. The authors concluded TTOI is likely to confer mobility and quality of life improvements to patients dissatisfied with traditional socket prosthesis rehabilitation following unilateral traumatic transtibial amputation. Adverse events were found to be infrequent and not further disabling. This study is limited by its small sample size. The authors acknowledge the study is not large enough to

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definitively understand TTOI outcomes or fully establish definitive indications or contraindications for osseointegrated reconstruction. Further prospective study of transtibial osseointegration is needed.

A retrospective analysis (Black 2023) was performed on all patients who underwent single-stage lower limb osseointegration at the single study site institution between 2017 and 2021. Patient demographics, medical history, operative data, and outcomes were collected. Sixty patients met the study criteria: 42 males and 18 females with 35 transfemoral and 25 transtibial amputations. The cohort had an average age of 48 years (range, 25–70 years) and follow-up period of 22 months (range, 6–47 months). Indications for amputation were trauma (50), prior surgical complication (5), cancer (4), and infection (1). Postoperatively, 25 patients developed soft tissue infections, five (5) developed osteomyelitis, six (6) had symptomatic neuromas, and seven (7) required soft tissue revisions. Soft tissue infections were positively correlated with obesity and female sex. Neuroma development was associated with increased age at osseointegration. Neuromas and osteomyelitis were both associated with decreased center experience. Notably, hypertension (15), tobacco use (27), and prior site infection (23) did not correlate with worse outcomes. Forty-seven percent of soft tissue infections occurred in the one (1) month after implantation, and 76% occurred in the first 4 months. The authors concluded the data provides preliminary insights into risk factors for postoperative complications arising from lower limb osseointegration. These factors are both modifiable (body mass index, center experience), and unmodifiable (sex, age). Such results are necessary to inform best practice guidelines and optimize outcomes though further prospective studies are needed.

In a nonrandomized, prospective cohort study (Hagberg 2022), patients with TFAs treated between 1999 and 2007 with the Osseointegrated Prosthesis for the Rehabilitation of Amputees (OPRA) system (n = 51) (28 men/23 women; mean age at amputation: 32 years old; mean age at treatment: 44 years old) in a single university hospital, were followed for 10 years. The objectives were to determine patient-reported outcomes (PROs), and complications after 10 years compared to before treatment and to compare the first five (5) year period with the later five (5) year period with regard to the outcomes. PROs showed statistically significant mean improvements between baseline and the 10 year follow-up. No PROs showed a statistically significant deterioration. Over the 10 years, 12 patients were lost (one (1) lost to follow-up, one (1) dropped out of the study, two (2) died, and eight (8) had implants removed (four (4) before five (5) years and four (4) between five (5) and 10 years). At 10 years, the revision-free survival rates were 83% (CI: 69%-91%), 65% (CI: 49%-77%) and 17% (CI: 7%-29%) for implant revision, deep infection, and mechanical complications, respectively. Mechanical complications, 3.9 per 10 person-years (CI: 2.2-5.1) constituted the most common serious adverse event and were more common during the last five (5) years than during the first five (5) years (p < 0.001). No significant difference in the incidence of deep infections was observed between the earlier and the later five (5) year periods: 0.3 per five (5) person-years (CI: 0.1-0.5) vs. 0.3 per person-years (CI: 0.1-0.5) (p = 0.740). Correlation analyses between the earlier and later five (5) years revealed a positive association between deep infections and implant removal (0.57, p < 0.001) and between mechanical complications and adverse events (0.65, p < 0.001). The authors discuss limitations of the study include the number of superficial infections. This data should be interpreted with caution as this adverse event did not need to be diagnosed or treated at the study hospital, and information might be lacking in the records. Other limitations of the study include the lack of a comparable control, small sample size, mixture of patients having both unilateral and

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bilateral TFAs, and the absence of systematically registered prosthetic device details (i.e., type of prosthetic knee and foot components). Finally, this 10 year follow-up did not include details about other complications commonly reported among individuals living for decades with a lower-limb amputation, such as low back pain, phantom limb pain, falls, and arthrosis in the lower extremity. The authors concluded that improved PROs were demonstrated 10 years after the introduction of a bone anchorage of amputation prostheses. Nevertheless, an increasing rate of mechanical complications is of concern and further clinical study is warranted.

PROFESSIONAL GUIDELINE(S)

In 2018, the American Academy of Orthotists and Prosthetists (AAOP) clinical practice guideline (Stevens 2018) was developed to present current evidence and to provide associated clinical recommendations on prosthetic foot selection for individuals with lower-limb amputation.

- Recommendation 1: For patients ambulating at a single speed who require greater stability during weight acceptance because of weak knee extensors or poor balance, a single-axis foot should be considered.
- Recommendation 2: Patients at elevated risks for overuse injury (i.e., osteoarthritis) to the sound-side lower limb and lower back are indicated for an energy-storage-and-return (ESAR) foot to reduce the magnitude of the cyclical vertical impacts experienced during weight acceptance.
- Recommendation 3: Neither patient age nor amputation etiology should be viewed as primary considerations in prosthetic foot type.
- Recommendation 4: Patients capable of variable speed and/or community ambulation are indicated for ESAR feet.

In 2019, the AAOP (Stevens 2019) clinical practice guideline was developed to present the evidence and provide clinical recommendations on prosthetic knee selection for unilateral amputation at the knee disarticulation or transfemoral level.

- Recommendation 1. Fluid knee benefits and indications: Knees with hydraulic or pneumatic swing resistance are indicated for active walkers, permitting increased walking comfort, speed, and symmetry.
- Recommendation 2. Microprocessor knee benefits: Compared with non-microprocessor knees:
 - With respect to self-report indices and measures, microprocessor knees are indicated to reduce stumbles, falls, and associated frustrations as well as the cognitive demands of ambulation.
 - With respect to self-report indices and measures, microprocessor knees are indicated to increase confidence while walking, self-reported mobility, satisfaction, well-being, and quality of life.
 - With respect to physical performance indices and measures, microprocessor knees are indicated to increase self-selected walking speed, walking speed on uneven terrain, and metabolic efficiency during gait.

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- Recommendation 3. Microprocessor knee equivalence: Given the comparable values observed with the use of microprocessor and non-microprocessor knees with regard to daily step counts, temporal and spatial gait symmetry, self-reported general health, and total costs of prosthetic rehabilitation, these parameters may not be primary indications in prosthetic knee joint selection.
- Recommendation 4. Microprocessor knees for limited community ambulators: Among limited community ambulators, microprocessor knees are indicated to enable increases in level ground walking speed and walking speed on uneven terrain while substantially reducing uncontrolled falls and increasing both measured and perceived balance.

In 2019, clinical practice guidelines (Webster 2019) 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.

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

REGULATORY STATUS

Manufacturers must register prostheses with the Restorative and Repair 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.

Available myoelectric devices include, but are not limited to, ProDigits and i-limb (Touch Bionics), the SensorHand Speed and Michelangelo Hand (Otto Bock), the LTI Boston Digital Arm System (Liberating Technologies), the Utah Arm Systems (Motion Control), and bebionic (Ottobock).

In 2014, the DEKA Arm System (DEKA Integrated Solutions, now DEKA Research & Development), now called the LUKE Arm (Mobius Bionics), was cleared for marketing by FDA through the de novo 513(f)(2) classification process for novel low- to moderate-risk medical devices that are first-of-a-kind.

In 2015, The OPRA Implant System was approved by the Food and Drug administration (FDA) via humanitarian device exemption. It is indicated for patients who have trans-femoral amputation due to trauma or cancer and who have rehabilitation problems with, or cannot use, a conventional socket

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prosthesis. The effectiveness of this device for this use has not been demonstrated.

FDA weblink for new or recalled devices: Available from: [Medical Devices | FDA](#) [accessed 2025 Mar 25]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
	None

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HCPCS Codes

Code	Description
A4361-A4437	Ostomy supplies (code range)
A5051-A5093	Additional ostomy supplies (code range)
A9282	Wig, any type, each
L3250	Orthopedic footwear, custom molded shoe, removable inner mold, prosthetic shoe, each
L5000-L5855	Lower limb prosthetic (code range)
L5615	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control
L5827	Endoskeletal knee-shin system, single axis, electromechanical swing and stance phase control, with or without shock absorption and stance extension damping
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

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Code	Description
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)
L5991 (E/I)	Addition to lower extremity prostheses, osseointegrated external prosthetic connector (effective 10/01/2023)
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)
L6028	Partial hand including fingers, flexible or non-flexible interface, endoskeletal system, molded to patient model, for use without external power, not including inserts described by L6692
L6029	Upper extremity addition, test socket/interface, partial hand including fingers
L6030	Upper extremity addition, external frame, partial hand including fingers
L6031	Replacement socket/interface, partial hand including fingers, molded to patient model, for use with or without external power
L6032	Addition to upper extremity prosthesis, partial hand including fingers, ultralight material (titanium, carbon fiber or equal)
L6033	Addition to upper extremity prosthesis, partial hand including fingers, acrylic material
L6037	Immediate post-surgical or early fitting, application of initial rigid dressing, including fitting alignment and suspension of components, and one cast change, partial hand including fingers

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Code	Description
L6050-L6698	Upper limb prosthetic device (code range)
L6700	Upper extremity addition, external powered feature, myoelectronic control module, additional emg inputs, pattern-recognition decoding intent movement
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)
L7259	Electronic wrist rotator, any type
L7360-L7368	Battery components (code range)
L7406	Addition to upper extremity, user adjustable, mechanical, residual limb volume management system
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
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)

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Code	Description
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

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SEARCH TERMS

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

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

[Prosthetic Shoe \(NCD 280.10\)](#) [accessed 2025 Jan 23]

[External Breast Prostheses \(LCD L33317\)](#) [accessed 2025 Jan 23]

[Eye Prostheses \(LCD L33737\)](#) [accessed 2025 Jan 23]

[Facial Prostheses \(LCD L33738\)](#) [accessed 2025 Jan 23]

[Lower Limb Prostheses \(LCD L33787\)](#) [accessed 2025 Jan 23]

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

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.

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- 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.
- 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.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
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, 04/17/25	
Date	Summary of Changes
04/17/25	<ul style="list-style-type: none">• Annual review, policy statement added for prosthetics not for ADLs as not medically necessary, osseointegrated, myoelectric partial hand, and enhanced dexterity upper limb prosthetic devices as investigational, revision to Policy Guidelines, code edit, added L5991.
01/01/25	<ul style="list-style-type: none">• Summary of changes tracking implemented.
07/25/02	<ul style="list-style-type: none">• Original effective date