MEDICAL POLICY

Excellus

SUBJECT: EXTERNAL PROSTHETIC DEVICES	EFFECTIVE DATE: 07/25/02 REVISED 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
POLICY NUMBER: 1.01.18 CATEGORY: Equipment/Supplies	PAGE: 1 OF: 11

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon the literature and/or available information, external prosthetic devices that replace all or part of an internal organ or replace the function of a permanently inoperative or malfunctioning body part are considered **medically appropriate.**

II. Supplies needed to make a medically necessary prosthetic device functional are considered **medically necessary** when the prosthetic is covered. Examples of covered supplies include tracheostomy kits, urine pouches, and batteries to operate an artificial larynx.

III. Custom prosthetic devices with enhanced features are **not medically necessary** if activities of daily living can be met with standard prosthetic devices. If enhanced devices are requested, the individual medical condition of the member is considered in order to determine medical necessity. Precise clinical information is required for consideration of coverage when non-standard prosthetic devices (e.g., microprocessor-controlled lower limbs, Otto Bock C-leg ®, Intelligent prosthesis, Ossur Rheo) are requested. *(Refer to Policy Guidelines III and IV regarding specific items.)*

IV. A preparatory prosthesis is **medically appropriate** after surgery to prevent edema of the residual limb. Additions such as protective covers, ultralite material, nonstandard components (e.g., microprocessor knees) and flex foot systems (e.g., energy-storing) are not medically necessary for preparatory prosthesis.

V. Lower limb prosthetic devices are **not medically necessary** for individuals with functional level 0. *(Refer to the Description section on page 8 for definitions of functional levels.)*

VI. Prosthetic shoes are **medically appropriate** and may be covered as a terminal device to supplement a substantially absent foot. The function of the prosthetic shoe 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.

VII. Replacement of a medically necessary prosthetic is **eligible for coverage** if:
   A. The patient has experienced a change in his or her physiological condition (e.g., changes in the residual limb or functional need changes).
   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. Replacement or repair needed due to misuse or neglect is ineligible for coverage.
   D. Required repairs would exceed the cost of a replacement device or the parts that need to be replaced.

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 covered prosthetic devices are covered if ordered by a physician and necessary due to normal wear or when required by a change in the patient's condition.

IX. Back-up prosthetic devices are considered **not medically necessary**; more than one prosthetic device is considered a matter of convenience for the member.

X. Replacement or repair covered under a homeowner policy or similar insurance is **ineligible for coverage**.

XI. Devices or implants used primarily for cosmetic purposes are considered **not medically necessary**.

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XII. The initial prescription for eyeglasses or frames following cataract surgery is considered **medically necessary**. Eyeglasses and contact lenses for all other purposes are not considered a prosthetic device, but may be included in a vision care benefit.

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

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

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

Refer to Corporate Medical Policy # 1.01.25 regarding Orthotics.

Refer to Corporate Medical Policy # 7.01.30 regarding Erectile Dysfunction.

POLICY GUIDELINES:

I. Coverage for external prosthetic devices is contract dependent.

II. To be eligible for coverage a prosthetic device must address a permanent problem in which the device is needed for at least 90 days.

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

Lower limb prosthesis		
Component	**Description**	**Recommendations**
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. Soft (made of foam, rubber or leather) Hard (made of acrylic, or thermoplastic).	Necessary to secure the safety of the residual limb. Provides as rigid as possible control of the prosthesis. 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.	Not recommended for: Test sockets for immediate postsurgical or early-fitted prostheses Recommendations: One socket per individual prosthetic Two of the same socket inserts per individual prosthesis at the same time are **medically necessary**.
Suspension mechanism; method which holds the prosthesis to the body. Types: locking pin, TES belt, suspension sleeve, waist belt, suction, and vacuum.	1. 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. 2. A Silesian belt belt fastens to the socket laterally, above the greater trochanter, and wraps around the opposite iliac crest. 3. The gel liner suction system uses a gel elastomeric liner and a pin may or may not be used.	A Silesian belt is **medically appropriate** for the pediatric patient. Gel liner suction system is **medically appropriate** for patients with a transfemoral or transtibial amputation.

Lower limb prosthesis		
Component	**Description**	**Recommendations**
	4. 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 5. Vacuum suspension is created between an airtight sleeve and a one-way air valve located in the bottom of the socket. The vacuum-assisted suspension 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	4. Standard suction is a common suspension choice for transfemoral prostheses. 5. Vacuum is another transtibial suspension option There is insufficient evidence to support the efficacy of Vacuum assisted socket systems (VASS) over standard socket types. However VASS may be considered **medically appropriate** for carefully selected patients when: A. There is a nonhealing skin breakdown on the stump from friction due to an ill-fitting socket; AND B. the current socket can no longer be modified to adequately secure the limb to the prosthesis.
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. Single axis with a simple hinge and a single pivot point. Polycentric axis with multiple centers of rotation.	1. Single-axis knees 2. Polycentric- axis knees 3. Hydraulic knees - chosen by more active amputees 4. Microprocessor controlled knees (Otto Bock C-leg ®) Single or multiaxial energy saving knee with onboard microprocessor. Allows the knee to adjust for variable gait cycles providing more natural movement during stair descent or while ambulating on uneven terrain.	1. Single-axis knees - recommended for: classification level 1 or above. 2. Polycentric-axis knees - recommended for: classification level 3 or above. 3. Hydraulic knees - recommended for: classification level 3 or above. 4. A Microprocessor controlled knee may be considered **medically appropriate** for level 3 transfemoral amputees when ALL of the following criteria are met: 1. Physical ability to use the device which includes: a. sufficient trunk control and adequate posture; and b. good upper body strength with static and dynamic balance; and c. adequate cardiovascular and pulmonary reserve which enable the patient to ambulate at a faster than normal walking speed; and

Lower limb prosthesis		
Component	**Description**	**Recommendations**
		2. The patient has received additional training for use of this technology and has demonstrated adequate cognitive ability to master use and care requirements; and 3. The patient is able to perform ALL the following ADL's at least daily: a. long distance ambulation at variable rates of at least 400 continuous yards; b. regular and frequent ambulation on uneven terrain (e.g. grass, gravel, or curbs); c. regular and frequent ambulation on stairs or ramps; d. lifting and carrying items; e. frequent bending, kneeling or stooping; and f. walking, standing or working in confined areas. Microprocessor controlled knees are contraindicated when: 1. The patient's functional level is less than 3 or has limited ambulation due to poor balance or ataxia; or 2. The patient is unable to tolerate the weight of the prosthesis; or 3. The patient is unable to use the swing and stance features of the knee; or 4 The patients is unable to change the prosthesis or has a condition that would cause inadequate fitting; or 5. Significant hip flexion contracture (over 20 degrees); or 6. Significant deformity of remaining limb that would impair ability to stride; or 7. The prosthesis will be used when the environmental conditions include excessive moisture or dust which invalidates the warranty.

Lower limb prosthesis		
Component	**Description**	**Recommendations**
Pylon; attaches the socket to the terminal device	Allows axial rotation and are able to absorb, store, and release energy.	
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. Non-energy: solid-ankle, cushioned-heel (SACH) foot and the single-axis foot. Energy-returning (energy storing): assist the body's natural biomechanics and allow for greater cadence or less oxygen consumption; multiaxis or dynamic-response	1. The SACH foot; low-cost and low-maintenance. 2. Single Axis foot; increased knee stability. Both SACH and single axis foot used in sedentary patients 3. Multiaxis foot; useful for the individual with a minimal-to-moderate activity level 4. Dynamic-response foot; top-of-the-line foot and is commonly used by young, active persons and by athletic individuals. Made from ultralight materials.	SACH foot: **medically appropriate** for sedentary patients classification level 1 or above. Multiaxis foot - recommended for classification level 3 or above.
Microprocessor-controlled ankle-foot system.	Uses 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®, Sure-Flex® and K2 Sensation®, the Genesis II® and the Seattle Lite®. Proprio-Foot with EVO™ (Ossur)	Literature is still emerging to support the benefits of the microprocessor controlled ankle-foot system; activities of daily living can be met with standard prosthetic devices. A microprocessor controlled ankle-foot system is considered **not medically necessary**.

IV. All conventional body-powered, upper extremity prostheses have the following components: A) socket, B) suspension, C) control-cable system, D) terminal device, and E) 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.

Upper extremity prosthesis		
Component	**Description**	**Recommendations**
Socket: fabricated from lightweight plastic or graphite composite materials.	Rigid inner socket: fitted to the residual limb. Fit of inner socket determines comfort and function. Outer wall: same length and contour as the opposite, sound limb.	

Upper extremity prosthesis		
Component	**Description**	**Recommendations**
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	1. Harnessed-based systems: most commonly used. 2. Self-suspending sockets: commonly utilized with an externally powered, myoelectrically controlled transradial prosthesis. 3. Suction sockets: similar to lower extremity options.	2. Self-suspension sockets limited to wrist or elbow disarticulations and to transradial amputations. 3. Suction sockets are **medically appropriate** for the patient with a transhumeral amputation.
Control system: there are 3 types of prosthesis: 1. Passive, 2. Body-powered, and 3. Myoelectric.	1. Passive: a. Lightweight, b. Must be repositioned manually, typically by moving it with the opposite arm, c. Cannot restore function. 2. Body-powered: a. Utilizes a body harness and cable system to provide functional manipulation of the elbow and hand. b. Voluntary movement of the shoulder and/or limb stump extends the cable and transmits the force to the terminal device. 3. Myoelectric: a. Uses muscle activity from the remaining limb for the control of joint movement. b. 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. c. May be considered the most physiologically natural but may be slow and limited to one joint at a time.	Myoelectric upper arm prosthetic components may be considered **medically necessary** when: 1. Standard body-powered prosthetic devices cannot be used or are insufficient to meet the functional needs of the individual in performing activities of daily living; AND 2. The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device; AND 3. The patient is free of comorbidities that could interfere with function of the prosthesis (neuromuscular disease, etc.); AND 4. The patient has demonstrated sufficient physiological and

Upper extremity prosthesis		
Component	**Description**	**Recommendations**
		cognitive function to allow effective operation of a myoelectric prosthetic device; AND 5. 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 activities of daily living. This evaluation should consider the patient's needs for control, durability (maintenance), function (speed, work capability), and usability.
Terminal devices: 1. Passive or active, 2. Voluntary opening (closed at rest), or 3. Voluntary closing (open at rest). 4. Myoelectric hand with individual control of digits.	1. Passive: more cosmetic than functional and more costly than active terminal devices. 2. Active: more functional than cosmetic and can be either a hook or a hand. Examples of passive terminal device: Child mitt to assist child with crawling. Examples of active terminal devices: Hand: can be powered by cable or external power and is more cosmetically pleasing than hook. Hook: provides active lateral pinch grip. Examples of myoelectric hands with individual control digits include the SensorHand™ by Advanced Arm Dynamics, i-LIMB™ hand and ProDigits™ by Touch Bionics.	Many different options for terminal devices depending on occupation, hobbies or sports. A Myoelectric hand with individual control of digits is considered **investigational** because there is a lack of peer-reviewed literature to evaluate functional outcomes of these devices.

DESCRIPTION:

Prosthetic appliances are devices that are designed to replace all or part of a permanently inoperative, absent, or malfunctioning body organ. External prosthetic devices, which are worn as an anatomic supplement, 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 ostomy bags for a patient with

an artificial stoma become prosthetic devices. Coverage for external prosthetic devices is subject to an individual's contract.

The design of lower limb prosthetic devices is based on the classification level 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 their 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 3-6 months. Once the residual limb is stabilized (e.g., the residual limb volume is unchanged and the socket fit is consistent for 2-3 weeks) a permanent or definitive prosthesis can be fitted.

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 prosthesis uses 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, 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.

RATIONALE:

There is minimal published data on vacuum-assisted-socket systems (VASS) and microprocessor controlled knee prostheses in the peer-reviewed literature. The data is inadequate to define the improvement in health outcomes related to the increased sophistication of these prostheses, and the data is inadequate to suggest which patients may benefit. 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 were found to evaluate functional outcomes of individual digit control in amputees.

CODES: Number Description

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.

****Note: The presence of a code or range of codes on this policy does not indicate coverage. Each Health Plan region will utilize its' individual contract provisions regarding the administration of the prosthetic device benefit.*

CPT: No code(s)

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HCPCS: A4361-A4435 Ostomy supplies (code range)

A5051-A5093	Additional ostomy supplies (code range)
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
L5858	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, stance phase only, includes electronic sense(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)
L6025 (E/I)	Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes and cables, 2 batteries, charger, myoelectric control of terminal device
L6050-L6590	Upper limb prosthetic device (code range)
L6600-L6698	Upper limb prosthetic device (code range)
L6703-L6882	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	Automatic grasp feature, addition to upper limb electric prosthetic terminal device
L6882 **(E/I)**	Microprocessor control feature, addition to upper limb prosthetic terminal device
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, 2 batteries and 1 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, 2 batteries and one charger, myoelectronic control of terminal device
L6930- L7274	External power (base devices) (code range)
L7360-L7499	Battery components (code range)
L7500-L7520	Repairs, prosthetic device (code range)
L8000-L8049	General prosthesis, including breast, midfacial, orbital and repair (code range)

L8400-L8485	Prosthetic socks (shrinker, sheath, stump sock) (code range)
L8500	Artificial larynx, any type
L8501	Tracheostomy speaking valve
L8505	Artificial larynx replacement battery / accessory, any type
L8507	Tracheo-esophageal voice prosthesis, patient inserted, any type, each
L8509	Tracheo-esophageal voice prosthesis, inserted by a licensed health care provider, any type
L8510	Voice amplifier
L8600	Implantable breast prosthesis, silicone or equal
L8610-L8670	Prosthetic implants, head, neck TMJ, upper extremity, lower extremity, miscellaneous, cardiovascular (code range)
L8699	Prosthetic implant NOS
L9900	Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS "L" code
V2623-V2629	Prosthesis, ocular (code range)

ICD9: Numerous diagnosis codes

ICD10: Numerous diagnosis codes

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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 various National (NCD) and Local Coverage Determinations (LCD) for Prosthetics. Please refer to the following NCD or LCD website for Medicare Members:

Prosthetic Shoe (NCD): http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=208&ncdver=1&bc=AgAAgAAAAAAA&

External Breast Prostheses (LCD): http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=5043&ContrId=137&ver=39&ContrVer=1&CntrctrSelected=137*1&Cntrctr=137&name=NHIC%2c+Corp.+(16003%2c+DME+MAC)&s=41&DocType=All&bc=AggAAAIAAAAAAA%3d%3d&

Eye Prosthesis (LCD): http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11529&ContrId=137&ver=17&ContrVer=1&CntrctrSelected=137*1&Cntrctr=137&name=NHIC%2c+Corp.+(16003%2c+DME+MAC)&s=41&DocType=All&bc=AggAAAIAAAAAAA%3d%3d&

Facial Prostheses (LCD): http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=5046&ContrId=137&ver=26&ContrVer=1&CntrctrSelected=137*1&Cntrctr=137&name=NHIC%2c+Corp.+(16003%2c+DME+MAC)&s=41&DocType=All&bc=AggAAAIAAAAAAA%3d%3d&

Lower Limb Prostheses (LCD): http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11464&ContrId=137&ver=42&ContrVer=1&CntrctrSelected=137*1&Cntrctr=137&name=NHIC%2c+Corp.+(16003%2c+DME+MAC)&s=41&DocType=All&bc=AggAAAIAAAAAAA%3d%3d&