

MEDICAL POLICY



SUBJECT: PROSTHETIC DEVICES	EFFECTIVE DATE: 07/25/02
POLICY NUMBER: 1.01.18	REVISED DATE: 10/23/03, 05/27/04, 04/28/05,
CATEGORY: Equipment/Supplies	04/27/06, 04/26/07
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- *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, internal and/or external prosthetic devices that replace all or part of an internal organ or replace the function of a permanently inoperative or malfunctioning organ 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.
 - IV. Replacement of a medically necessary prosthetic is **eligible for coverage** if:
 - A. The patient has experienced a change in his or her physiological condition;
 - B. Required repairs would exceed the cost of a replacement device or the parts that need to be replaced; or
 - C. There has been irreparable change in the device's condition or in a part of the device, due to normal wear and tear.
 - V. 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.
 - VI. Replacement or repair needed due to misuse or neglect is **ineligible for coverage**.
 - VII. Replacement or repair covered under a homeowner policy or similar insurance is **ineligible for coverage**.
- 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 #7.01.26 regarding Cochlear Implants.*
- Refer to Corporate Medical Policy # 7.01.30 regarding Erectile Dysfunction.*

POLICY GUIDELINES:

- I. Prior authorization is contract dependent. Please contact your local Customer (Member/Provider) Service Department to determine contract coverage.
- II. Coverage for internal prosthetic devices is available under an individual's medical benefit. Coverage for external prosthetic devices is contract dependent.
- III. To be eligible for coverage a prosthetic device must address a permanent problem in which the device is needed for at least 90 days.
- IV. Devices or implants used primarily for cosmetic purposes are considered **not medically necessary**.
- V. Coverage is limited to those prosthetic devices that meet the patient's functional needs for activities of daily living (e.g., dressing, getting in and out of bed or a chair, using the toilet and eating). If enhanced devices are requested,

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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.

- VI. 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.
- VII. 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.

DESCRIPTION:

Prosthetic appliances are devices that are designed to replace all or part of a permanently inoperative, absent, or malfunctioning body organ. Internal prosthetic devices are surgically implanted and are necessary for anatomical repair or reconstructive purposes. Examples of internal prosthetic devices include cardiac pacemakers, breast implants for post mastectomy reconstruction, implanted cataract lenses, and surgically implanted hardware necessary for joint repair or reconstruction. Internal prosthetic devices are covered under an individual’s medical benefit. 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.

RATIONALE:

There is minimal published data on 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.

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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<u>HCPCS:</u>	A4361- A4434	Ostomy supplies (code range)
	A5051-A5093	Additional ostomy supplies (code range)
	D5914	Auricular prosthetic
	L8045	
	D5931-D5933	Obturator prosthesis (code range)
	D5936	
	D5934-D5935	Mandibular resection prosthesis range

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L8041	Midfacial prosthetic
L8043	Upper facial prosthesis
L8046	Partial facial prosthesis
L8047	Nasal septal prosthesis
L3250	Orthopedic footwear, custom molded shoe, removable inner mold, prosthetic shoe, each
L5000 - L5999	Lower limb prosthetic (code range)
L6000 - L6590	Upper limb prosthetic device (code range)
L6600 - L6693	Upper limb prosthetic device (code range)
L6703- L6882	Terminal devices (hooks) (code range)
L6890 - L6915	Hand – gloves – hand restoration (code range)
L6920 - 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
V2627-V2629	Prosthesis, ocular (code range)

ICD9: Numerous diagnosis codes

REFERENCES:

BlueCross BlueShield Association. Microprocessor-controlled prosthetic knees. Medical Policy Reference Manual Policy #1.01.25. 2006 Apr 25.

BlueCross BlueShield Association. Prosthetics. Medical Policy Reference Manual Policy #1.04.01. 2004 Apr 16.

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Heller BW, et al. A pilot study comparing the cognitive demand of walking for transfemoral amputees using the Intelligent Prosthesis with that using conventionally damped knees. Clin Rehab 2000 Oct;14(5):518-22.

Home Medical Equipment Answer Book, 2002 edition.

Johansson JL et al. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. Am J Phys Med Rehabil 2005 Aug;84(8):563-757.

KEY WORDS:

C-leg, Intelligent Prosthesis, microprocessor-controlled lower limbs, Ossur Rheo.

SYNOPSIS OF CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

The information contained in this section provides a synopsis of Medicare coverage. For complete National Medicare coverage please refer to the following: <http://www.cms.hhs.gov/mcd/indexes.asp>. For complete Upstate Medicare coverage please refer to the following: <http://www.umd.nycpic.com/lmrp.html>.

Title: National Coverage Determination for Prosthetic Shoe

Contractor Policy Number: 280.10

Original Determination Effective Date: This is a longstanding national coverage determination. The effective date of this version has not been posted.

Indications and limitations of coverage: a prosthetic shoe (a device used when all or a substantial portion of the front of the foot is missing) can be covered as a terminal device; i.e., a structural supplement replacing a totally or substantially absent hand or foot. The coverage of artificial arms and legs includes payment for terminal devices such as hands or hooks even though the patient may not require an artificial limb. The function of the prosthetic shoe is quite distinct from that of excluded orthopedic shoe and supportive foot devices which are used by individuals whose feet, although impaired, are essentially intact.

Title: LCD for External Breast Prostheses

Contractor Policy Number: L5043

Original Determination Effective Date: 0/1/1993

Revision Effective Date: 01/01/2007

Indications and Limitations of Coverage and/or Medical Necessity

- I. A breast prosthesis is covered for a patient who has had a mastectomy, ICD-9-CM diagnosis codes V45.71, 174.0-174.9, or 233.0.
- II. An external breast prosthesis garment, with mastectomy form (L8015) is covered for use in the postoperative period prior to a permanent breast prosthesis or as an alternative to a mastectomy bra and breast prosthesis.
- III. The additional features of a custom fabricated prosthesis (L8035), compared to a prefabricated silicone breast prosthesis, are not medically necessary.
- IV. A mastectomy sleeve (L8010) is denied as noncovered, since it does not meet the definition of a prosthesis.
- V. The useful lifetime expectancy for silicone breast prostheses is 2 years. For fabric, foam or fiber filled breast prostheses, the useful lifetime expectancy is 6 months. Replacement sooner than the useful lifetime because of ordinary wear and tear will be denied as noncovered.
- VI. An external breast prosthesis of the same type can be replaced at any time if it is lost or is irreparably damaged (this does not include ordinary wear and tear). An external breast prosthesis of a different type can be covered at any time if there is a change in the patient's medical condition necessitating a different type of item. The Medicare program will pay for only one breast prosthesis per side for the useful lifetime of the prosthesis. Two prostheses, one

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per side, are allowed for those persons who have had bilateral mastectomies. More than one external breast prosthesis per side will be denied as not medically necessary.

Title: LCD for Eye Prosthesis
Contractor Policy Number: L11529
Original Determination Effective Date: 10/1/1993
Revision Effective Date: 3/1/2006

Indications and Limitations of Coverage and/or Medical Necessity

- I. An eye prosthesis is covered for a patient with absence or shrinkage of an eye due to birth defect, trauma or surgical removal.
- II. Polishing and resurfacing (V2625) is covered on a twice per year basis
- III. One enlargement (V2625) or reduction (V2626) of the prosthesis is covered without documentation. Additional enlargements or reductions are rarely medically necessary and are therefore covered only when there is information in the medical record which supports medical necessity. This information must be available to the DMERC on request.

Title: LCD for Facial Prostheses
Contractor Policy Number: L5046
Original Determination Effective Date: 11/1/1996
Revision Effective Date: 3/1/2006

A facial prosthesis is covered when there is loss or absence of facial tissue due to disease, trauma, surgery or a congenital defect.

Title: LCD for Lower Limb Prostheses
Contractor Policy Number: L11464
Original Determination Effective Date: 3/1/1995
Revision Effective Date: 3/1/2006

Indications and Limitations of Coverage and/or Medical Necessity

- I. A lower limb prosthesis is covered when the patient:
 - A. Will reach or maintain a defined functional state within a reasonable period of time; and
 - B. Is motivated to ambulate.
- II. FUNCTIONAL LEVELS:

A determination of the medical necessity for certain components/additions to the prosthesis is based on the patient's potential functional abilities. Potential functional ability is based on the reasonable expectations of the prosthetist, and treating physician, considering factors including, but not limited to:

 - A. The patient's past history (including prior prosthetic use if applicable); and
 - B. The patient's current condition including the status of the residual limb and the nature of other medical problems; and
 - C. The patient's desire to ambulate.
- III. Clinical assessments of patient rehabilitation potential must be based on the following classification levels:
 - 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.
 - 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.
 - 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.
 - 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.

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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.

The records must document the patient's current functional capabilities and his/her expected functional potential, including an explanation for the difference, if that is the case. It is recognized within the functional classification hierarchy that bilateral amputees often cannot be strictly bound by functional level classifications.

IV. GENERAL:

- A. If a prosthesis is denied as not medically necessary, related additions will also be denied as not medically necessary.
- B. When an initial below knee prosthesis (L5500) or a preparatory below knee prosthesis (L5510-L5530, L5540) is provided, prosthetic substitutions and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5629, L5638, L5639, L5646, L5647, L5704, L5785, L5962, and L5980 which will be denied as not medically necessary. When a below knee preparatory prefabricated prosthesis (L5535) is provided, prosthetic substitutions and/or additions of procedures are covered in accordance with the functional level assessment except for codes L5620, L5629, L5645, L5646, L5670, L5676, L5704, and L5962 which will be denied as not medically necessary.
- C. When an above knee initial prosthesis (L5505) or an above knee preparatory (L5560-L5580, L5590-L5600) prosthesis is provided, prosthetic substitution and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5610, L5631, L5640, L5642, L5644, L5648, L5705, L5706, L5964, L5980, and L5710-L5780, L5790-L5795 which will be denied as not medically necessary. When an above knee preparatory prefabricated prosthesis (L5585) is provided, prosthetic substitution and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5624, L5631, L5648, L5651, L5652, L5705, L5706, L5964, and L5966 which will be denied as not medically necessary.
- D. In the following sections, the determination of coverage for selected prostheses and components with respect to potential functional levels represents the usual case. Exceptions will be considered in an individual case if additional documentation is included which justifies the medical necessity. Prostheses will be denied as not medically necessary if the patient's potential functional level is 0.

V. FEET:

- A. A determination of the type of foot for the prosthesis will be made by the treating physician and/or the prosthetist based upon the functional needs of the patient. Basic lower extremity prostheses include a SACH foot. Other prosthetic feet are considered for coverage based upon functional classification.
- B. An external keel SACH foot (L5970) or single axis ankle/foot (L5974) is covered for patients whose functional level is 1 or above.
- C. A flexible-keel foot (L5972) or multiaxial ankle/foot (L5978) is covered for patients whose functional level is 2 or above.
- D. A flex foot system (L5980), energy storing foot (L5976), multiaxial ankle/foot, dynamic response (L5979), flex-walk system or equal (L5981), or shank foot system with vertical loading pylon (L5987) is covered for patients whose functional level is 3 or above.
- E. Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of foot. This information must be retained in the physician's or prosthetist's files.

VI. KNEES:

- A. A determination of the type of knee for the prosthesis will be made by the treating physician and/or the prosthetist based upon the functional needs of the patient. Basic lower extremity prostheses include a single axis, constant friction knee. Other prosthetic knees are considered for coverage based upon functional classification.
- B. A high activity knee control frame (L5930) is covered for patients whose functional level is 4.
- C. A fluid, pneumatic, or electronic knee (L5610, L5613, L5614, L5722 - L5780, L5814, L5822-L5840, L5848,

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L5856, L5857, L5858) is covered for patients whose functional level is 3 or above.

- D. Other knee systems (L5611, L5616, L5710-L5718, L5810-L5812, L5816, L5818) are covered for patients whose functional level is 1 or above.
- E. Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of knee. This information must be retained in the physician's or prosthetist's files.

VII. ANKLES:

An axial rotation unit (L5982-L5986) is covered for patients whose functional level is 2 or above.

VIII.SOCKETS:

- A. More than 2 test (diagnostic) sockets (L5618-L5628) for an individual prosthesis are not medically necessary unless there is documentation in the medical record which justifies the need. Exception: A test socket is not medically necessary for an immediate prosthesis (L5400-L5460).
- B. No more than two of the same socket inserts (L5654-L5665, L5673, L5679, L5681, L5683) are allowed per individual prosthesis at the same time.
- C. Socket replacements are considered medically necessary if there is adequate documentation of functional and/or physiological need. It is recognized that there are situations where the explanation includes but is not limited to: changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to excessive patient weight or prosthetic demands of very active amputees.