

09-L0000-05

Original Effective Date: 07/15/99

Reviewed: 10/26/23

Revised: 04/01/24

## Subject: Prosthetics

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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### DESCRIPTION:

A prosthesis or prosthetic is an artificial device that replaces a missing body part. Examples of prostheses include eyes, maxillofacial (jaw and face), arms, breasts, ears, legs, hands, and feet.

### POSITION STATEMENT:

Prosthetic devices are covered services, according to the member's individual contract benefit.

The following prosthetic devices and prosthetic-related services **meet the definition of medical necessity**:

#### Surgical Prostheses

- Artificial joints necessary for joint repair and reconstructive surgery
- Breast, internal or external (including a surgical brassiere), post-mastectomy reconstruction
- Cardiac pacemaker, atomic or electronic
- Facial prostheses when there is a loss or absence of facial tissue due to disease, trauma, surgery, or a congenital defect
- Maxillofacial prostheses
- Oral splints or appliance following surgery performed on the jaw **OR** facial bones or structures contiguous to the jaw
- Orthopedic prostheses, including hardware
- Prosthetic nose, ears
- Temporary prostheses

- Cystourethroscopy, with insertion of permanent urethral stent (e.g., UroLume endourethral prosthesis) (52282)
- Penile prosthesis and surgery to insert a penile prosthesis when necessary in the treatment of organic impotence resulting from diseases such as:
  - Prostate cancer
  - Diabetes mellitus
  - Peripheral neuropathy
  - Medical endocrine causes of impotence
  - Arteriosclerosis/postoperative bilateral sympathectomy
  - Spinal cord injury
  - Pelvic-perineal injury
  - Post-prostatectomy
  - Post-priapism
  - Epispadias
  - Exstrophy
- Artificial limbs replacing all or part of absent extremities
- Breast (post mastectomy)
- Electronic speech aids (post-laryngectomy or permanently inoperative larynx)
- Maxillary obturator **OR** opposing mandibular prosthesis (non-dental)
- Parenteral feeding devices (artificial gut system)
- Speech aids (refer to **MCG 01-92506-01, Speech Therapy** and **MCG 09-E0000-51, Speech Generating Devices** for additional coverage criteria)
- Stump socks
- Terminal devices (structural supplements – hand hook)
- Urinary collection and retention systems (Foley catheters, tubes, bags, etc.) in cases of permanent urinary incontinence.

The following prosthetic appliances **are not eligible for coverage** and are typically considered contract exclusions, according to the individual's Florida Blue contract benefits:

- Dentures replacing teeth or structures directly supporting teeth
- Hairpieces for male-pattern alopecia
- Hearing aids
- Implants for cosmetic purposes

### **Breast Prostheses**

Breast prostheses (L8000, L8001, L8002, L8010, L8020, L8030, L8032, L8039) meet the definition of medical necessity for individuals who have had a mastectomy.

An external prosthesis garment with mastectomy form (L8015) meets the definition of medical necessity when used in the postoperative period prior to permanent breast prosthesis or as an alternative to a mastectomy bra and breast prosthesis.

Breast prostheses, silicone or equal, with integral adhesive (L8031) do not meet the definition of medical necessity.

A custom breast prosthesis (L8035) provided in place of a prefabricated silicone breast prosthesis does not meet the definition of medical necessity and is generally considered a contract exclusion.

### **Lower Limb Prostheses**

Lower limb prostheses meet the definition of medical necessity when the individual demonstrates specific functional levels as defined by CMS:

- 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.
- 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 medical record must document the individual's current functional capabilities and expected functional potential, including an explanation for any existing difference. It is recognized within the functional classification hierarchy that bilateral amputees often cannot be strictly bound by functional level classifications.

When an initial below the knee prosthesis (L5500) or preparatory below the knee prosthesis (L5510 – L5530, or L5540) is provided, prosthetic substitutions and/or additional components are covered according to the functional level assessment except for the following codes: L5629, L5638, L5639, L5646, L5647, L5704, L5785, L5962, L5980, which do not meet the definition of medical necessity.

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 the following codes: L5620, L5629, L5645, L5646, L5670, L5676, L5704, and L5962 which do not meet the definition of medical necessity.

When an above the knee prosthesis (L5505) or above the knee preparatory prosthesis (L5560 – L5580, L5590-L5600) is provided, prosthetic substitutions and/or additional components are covered according to the functional level assessment except for the following codes: L5610, L5631, L5640, L5642, L5644, L5648, L5705, L5706, L5964, L5980, L5710 – L5780, L5790-L5795, which do not meet the definition of medical necessity.

When an above the knee prosthesis (L5585) is provided, prosthetic substitutions and/or additional components are covered according to the functional level assessment except for the following codes: L5624, L5631, L5648, L5651, L5652, L5705, L5706, L5964, L5966, which do not meet the definition of medical necessity.

If the individual's potential functional level is 0, prostheses do not meet the definition of medical necessity according to the above level criteria.

Vacuum-Assisted Socket Systems (e.g., eVAC, Harmony Vacuum Management System Vacuum Assisted Socket System [VASS], LimbLogic VS Prosthetic Vacuum Suspension System) (L5781, L5782) do not meet the definition of medical necessity as the published literature is insufficient to determine the device's effectiveness for maintaining limb volume.

## **Feet**

Foot prostheses meet the definition of medical necessity when the following criteria are met:

- An external-keel SACH foot (L5970) or single-axis ankle/foot (L5974) meets the definition of medical necessity for an individual whose functional level is 1 or above.
- A flexible-keel foot (L5972) or multiaxial ankle/foot (L5978) meets the definition of medical necessity for an individual whose functional level is 2 or above.
- An energy storing foot (L5976), dynamic response foot with multi-axial ankle (L5979), flex foot system (L5980), flex-walk system or equal (L5981), or shank foot system with vertical loading pylon (L5987) meets the definition of medical necessity for an individual whose functional level is 3 or above.

User-adjustable heel height features (L5990) do not meet the definition of medical necessity and are generally a contract exclusion.

## **Knees**

Knee prostheses meet the definition of medical necessity when the following criteria are met:

- A high activity knee control frame (L5930) meets the definition of medical necessity for individuals whose functional level is 4.
- Fluid or pneumatic knees (L5610, L5613, L5614, L5722 – L5780, L5814, L5822 – L5841, L5848, L5856, L5857, and L5858) meet the definition of medical necessity for individuals whose functional level is 3 or above.
- Other knee systems (L5611, L5616, L5710 – L5718, L5810 – L5812, L5816, L5818) meet the definition of medical necessity for individuals whose functional level is 1 or above.

## **Ankles**

Axial rotation units (L5982 – L5986) meet the definition of medical necessity for individuals whose functional level is 2 or above.

## **HIPS**

A pneumatic or hydraulic polycentric hip joint (L5961) meets the definition of medical necessity for individuals whose functional level is 3 or above.

## **Sockets**

More than 2 test (diagnostic) sockets (L5618-L5628) for an individual prosthesis do not meet the definition of medical necessity, unless there is documentation in the medical record which justifies the need. Exception: A test socket does not meet the definition of medical necessity for an immediate prosthesis (L5400-L5460).

No more than two of the same socket inserts (L5654-L5665, L5673, L5679, L5681, L5683) are allowed per individual prosthesis at the same time.

Socket replacements meet the definition of medical necessity if there is adequate documentation of functional or physiological need. Situations when socket replacements may meet the definition of medical necessity include, but are not limited to the following:

- Changes in the residual limb;
- Changes in functional need; OR
- Irreparable damage or wear/tear due to excessive weight or prosthetic demands of very active amputees

### **Additions, Modifications, Replacements, Repairs**

Components and/or additions to the prosthesis may meet the definition of medical necessity based on the individual's functional ability and expected functional potential as defined by the prosthetist and the ordering physician.

Additional documentation supporting medical necessity must accompany claims submitted for prosthetic components and/or additions.

Additions or modifications do not meet the definition of medical necessity if the related prosthesis is not covered.

Replacement of a prosthetic device is eligible for coverage provided the need for replacement is documented by the attending physician and is due to a change in condition, loss, or irreparable damage as a result of normal wear and tear.

### **Deluxe/convenience items**

Deluxe prosthetic devices do not meet the definition of medical necessity and are not eligible for coverage.

## **BILLING/CODING INFORMATION:**

Prosthetic devices may be described using the HCPCS Level II code range L5000 – L9999. Modifier –LT or –RT should be appended to the appropriate code describing the prosthetic device.

Repairs of prosthetic devices are to be coded by adding modifier –RP to the applicable procedure code for the device.

Adhesive used to attach a breast prosthesis to the chest wall should be reported using A4280.

NOTE: Coverage of some prosthetics may be addressed individually in separate policies (e.g., cochlear implants, intra-ocular lenses, peripheral nerve stimulators) and are listed below in the section entitled RELATED GUIDELINES.

## REIMBURSEMENT INFORMATION:

Reimbursement for the following is included in the allowance for the covered prosthetic device:

- Professional services for preparation and fitting (this includes the use of tuning devices such as the Smart Pyramid™)
- Hospital visits rendered in conjunction with an amputation procedure
- Cement, cleansers, and other supplies used in "initial" implantation or insertion or application
- Travel time

Reimbursement for stump socks (L8420, L8430, L8435, L8470, L8480, or L8485) is limited to twelve (12) socks purchased within a twelve (12) month period unless documented as to medical necessity for Medical Review.

The following information may be required documentation to support medical necessity: Physician history and physical, treatment plan, treatment notes including documentation of symptoms, behavioral or pharmacologic interventions, and prior test stimulation (if applicable).

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician Initial Assessment	18736-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physical therapy initial assessment	18735-1	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Treatment Plan, Plan of Treatment	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

## PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

### **Medicare Advantage products:**

The following National Coverage Determinations (NCDs) were reviewed on the last guideline reviewed date: Prosthetic Shoe (280.10) and Diagnosis and Treatment of Impotence (230.4) located at cms.gov.

The following Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: External Breast Prostheses (L33317), Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686), Eye Prostheses (L33737), Facial Prostheses (L33738), and Lower Limb Prostheses (L33787), and Vacuum Erection Devices (VED) (L34824), located at cgsmedicare.com.

### **DEFINITIONS:**

**Convenience items:** any object/device that increases physical comfort without serving a medically necessary purpose. Although they may be associated with secondary medical uses, the principal or primary use of a convenience item is usually not medical. Additional or duplicate items used for the same purpose, but not at the same time, are considered convenience. (Florida Blue DME MCG)

**Comfort (personal) items:** items that do not contribute meaningfully to the treatment of an illness or injury or the functioning of a malformed body part. (CMS)

**Custodial services:** serves to assist an individual in their activities of daily living (e.g., walking, bathing, dressing, feeding, getting in and out of bed, using the toilet, supervision of medication that can be self-administered, and preparation of meals); personal care not requiring continuing attention of trained medical or paramedical personnel. (CMS)

**Deluxe items:** items with features that enhance basic equipment/devices (i.e., electrical or mechanical features) (Florida Blue DME MCG)

### **RELATED GUIDELINES:**

[Cochlear Implants, 02-69000-03](#)

[Lower Limb Microprocessor-Controlled Prosthetics, 09-L0000-06](#)

[Myoelectric Prosthetic and Orthotic Components for the Upper Limb, 09-L0000-07](#)

[Prosthetic Eyes and Lens Implants, 09-V0000-01](#)

[Reconstructive SurgeryCosmetic Surgery, 02-12000-01](#)

[Speech Generating Devices, 09-E0000-51](#)

### **OTHER:**

None applicable.

### **REFERENCES:**

1. Blue Cross Blue Shield Association Evidence Positioning System®. 1.04.01 – Prosthetics (Archived 12/11).

2. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) Prosthetic Shoe (280.10) (Longstanding policy).
3. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686) (Revised 01/01/20).
4. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) Eye Prostheses (L33737) (10/01/15) (Revised 01/01/20).
5. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) External Breast Prostheses (L11554) (Retired 09/30/15).
6. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) External Breast Prostheses (L33317) (10/01/15) (Revised 01/01/20).
7. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) Facial Prostheses (L11556) (Retired 09/30/15).
8. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) Facial Prostheses (L33738) (10/01/15) (Revised 01/01/20).
9. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) Lower Limb Prostheses (L11442) (Retired 09/30/15).
10. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) Lower Limb Prostheses (L33787) (10/01/15) (Revised 01/01/20).
11. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) Vacuum Erection Devices (VED) (L34824) (10/01/15) (Revised 01/01/20).
12. Fard B, Persoon S, Jutte PC, Daemen JHC, Lamprou DA, Hoope WT, Prinsen EC, Houdijk H, Olsman J, Holling T, De Wever HPPR, Schrier E, Donders N, Rietman JS, Geertzen JHB. Amputation and prosthetics of the lower extremity: The 2020 Dutch evidence-based multidisciplinary guideline. *Prosthet Orthot Int.* 2023 Feb 1;47(1):69-80. doi: 10.1097/PXR.000000000000170. Epub 2022 Sep 15.
13. Komolafe O, Wood, S, et al. Methods for characterization of mechanical and electrical prosthetic vacuum pumps. *J Rehabil Res Dev.* 2013;50(8):1069-78. doi: 10.1682/JRRD.2012.11.0204.
14. Østlie K, Lesjø IM, et al. Prosthesis use in adult acquired major upper-limb amputees: patterns of wear, prosthetic skills and the actual use of prostheses in activities of daily life. *Disabil Rehabil Assist Technol.* 2012 Nov;7(6):479-93. doi: 10.3109/17483107.2011.653296.
15. Özcan F, Yüksel İ, Kamacı GK, Korkmaz N, Arslan E, Demir Y, Aydemir K. The use of myoelectric prosthesis in a sample of veterans with unilateral upper extremity amputation: prosthesis satisfaction and quality of life. *Ir J Med Sci.* 2023 Apr;192(2):839-845. doi: 10.1007/s11845-022-03062-2. Epub 2022 Jun 17. PMID: 35715662.
16. Samuelsson KA, Töytäri O, et al. Effects of lower limb prosthesis on activity, participation, and quality of life: a systematic review. *Prosthet Orthot Int.* 2012 Jun;36(2):145-58. doi: 10.1177/0309364611432794.
17. UpToDate. Overview of geriatric rehabilitation: Program components and settings for rehabilitation. 2021. Accessed at [uptodate.com](https://www.uptodate.com).
18. Washington State Department of Labor and Industries. Office of Medical Director. Health Technology Assessment Brief. Otto Bock Harmony Vacuum Assisted Socket System (VASS). Updated 2003 Apr 3.



## COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 10/26/23.

## GUIDELINE UPDATE INFORMATION:

07/15/99	Reformatted, revised Medical Coverage Guideline
12/30/99	HCPCS update
01/01/00	Revised to include additional coding
09/15/01	Revised to include additional covered indications and procedure codes
04/15/02	Cross-reference added for vacuum tumescence / constriction penile prosthetic devices
09/15/03	Reviewed; no change in coverage
01/01/04	Annual HCPCS coding update
07/15/04	Added cross-reference to new MCG for Speech Generating Devices.
09/15/05	Scheduled review; no changes in coverage statement.
08/15/07	Scheduled review; removed references to cochlear implants and intra-ocular lens implants that are addressed in separate guidelines; added facial prostheses to listed covered prosthetics; reformatted guideline; updated references.
06/15/09	Scheduled review; no change in position statement; references updated.
01/01/10	Annual HCPCS coding update: revised descriptor for 52282.
04/15/10	Revisions consisting of addition of reimbursement information for additions, components, modifications, deluxe items, and specific types of prosthetics; update definitions section; update references.
05/15/11	Revisions consisting of adding information regarding tuning devices and vacuum-assisted socket systems (L5781, L5782); references updated.
09/15/11	Revision to add cross-reference regarding SpeechEasy® devices; formatting changes.
01/15/13	Revision to add coding for breast prostheses.
05/11/14	Revision: Program Exceptions section updated.
11/01/15	Revision: ICD-9 references deleted.
05/15/19	Revision: Deleted coverage statement regarding mastectomy sleeves (L8010).
11/15/19	Scheduled review. Revised description and position statement (minor revisions to breast, lower limb, feet, and sockets; added coverage statement for pneumatic or hydraulic polycentric hip joint). Updated Medicare Advantage program exception and references.
11/15/21	Scheduled review. Maintained position statement and updated references.
11/15/22	Revision: Deleted "electronic" from the KNEES section.
11/15/23	Scheduled review. Maintained position statement and updated references.
04/01/24	Quarterly CPT/HCPCS coding update. Added L5841.