



Medicare C/D Medical Coverage Policy

Prostheses- Artificial Limbs and Components

Origination: January 28, 2013

Review Date: March 15, 2017

Next Review: March, 2019

DESCRIPTION OF PROCEDURE

Prosthetic devices are devices that replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. Replacements or repairs of such devices are eligible for coverage when furnished incident to physicians' services or on a physician's orders.

POLICY STATEMENT

Coverage will be provided for prostheses (artificial limbs) and components when it is determined to be medically necessary when the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (E.O.C.) for benefit determination. Coverage will be approved according to the E.O.C. limitations, if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (E.O.C.), the E.O.C. always governs the determination of benefits.

INDICATIONS FOR COVERAGE

1. **Preauthorization by the Plan is required;**
2. A lower limb prosthesis is covered when the member:
 - a. Will reach or maintain a defined functional state within a reasonable period of time; and
 - b. Is motivated to ambulate.

3. An upper limb prosthesis is covered to replace all or part of the function of permanently inoperative or malfunctioning extremity.
4. Prosthetic substitutions and/or additions of procedures and components are covered in accordance with the functional level assessment when an initial below knee prosthesis (L5500) or a preparatory below knee prosthesis (L5510-L5530, L5540) is provided.
5. Prosthetic substitutions and/or additions of procedures and components are covered in accordance with the functional level assessment when an initial above knee prosthesis (L5505) or a preparatory above knee prosthesis (L5560-L5580, L5590-L5600) is provided.
6. Stump stockings and harnesses (including replacements) are also covered when these appliances are essential to the effective use of the artificial limb.

Functional Levels

A determination of the medical necessity for certain components/additions to the prosthesis is based on the member'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 member's past history (including prior prosthetic use if applicable); and
- b. The member's current condition including the status of the residual limb and the nature of other medical problems; and
- c. The member's desire to ambulate.

Clinical assessments of the member's rehabilitation potential must be based on the following classification levels:

- a. 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.
- b. 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.
- c. 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.

- d. Level 3: Has the ability or potential for ambulation with variable cadence. Typical of the community ambulatory who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
- e. 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 member'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.

Feet

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 member. Basic lower extremity prostheses include a SACH foot. Other prosthetic feet are considered for coverage based upon the functional classification.

An external keel SACH foot (L5970) or single axis ankle/foot (L5974) is covered for members whose functional level is 1 or above.

A flexible-keel foot (L5972) or multiaxial ankle/foot (L5978) is covered for members whose functional level is 2 or above.

A microprocessor controlled ankle foot system (L5973), 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) is covered for members whose functional level is 3 or above.

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.

Knees

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 member. Basic lower extremity prostheses include a single axis, constant friction knee. Other prosthetic knees are considered for coverage based upon functional classification.

A high activity knee control frame (L5930) is covered for members whose functional level is 4.

A fluid, pneumatic, or electronic knee (L5610, L5613, L5614, L5722-L5780, L5814, L5822-L5840, L5848, L5856, L5857, and L5858) is covered for members whose functional level is 3 or above.

Other knee systems (L5611, L5616, L5710-L5718, L5810-L5812, L5816, and L5818) are covered for members whose functional level is 1 or above.

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.

Ankles

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

Hips

A pneumatic or hydraulic polycentric hip joint (L5961) is covered for members whose functional level is 3 or above.

Sockets

More than 2 test (diagnostic) sockets (L5618-L5628) for an individual prosthesis are not reasonable and necessary unless there is documentation in the medical record which justifies the need. Exception: A test socket is not reasonable and necessary for an immediate prosthesis (L5400-L5460).

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

Socket replacements are considered reasonable and 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 member weight or prosthetic demands of very active amputees.

Repair/Adjustment

A repair is a restoration of the prosthesis to correct problems due to wear or damage. An adjustment is any modification to the prosthesis due to a change in the member's condition or to improve the function of the prosthesis. Adjustments and repairs of prostheses and prosthetic components are covered under the original physician order.

Repairs are eligible for coverage when necessary to make the prosthesis function. These repairs include medically necessary adjustments made more than ninety (90) days after delivery of the prosthesis. Maintenance which may be necessitated by manufacturer's recommendations or the construction of the prosthesis is eligible for coverage when performed by the prosthetist as a repair. Code L7520 is used to bill for labor associated with adjustments and repairs that either do not involve replacement

parts or that involve replacement parts billed with code L7510. Code L7510 is used to bill for a repair for any minor materials without a specific HCPCS code.

Adjustment

Adjustment of prosthetic devices required by wear or by a change in the member's condition is covered when ordered by a physician.

Replacement

Replacement of prosthesis or prosthetic components is eligible for coverage because of any of the following:

1. A change in the physiological condition of the member; or
2. An irreparable change in the condition of the device, or in a part of the device; or
3. The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, of the part being replaced.

WHEN COVERAGE WILL NOT BE APPROVED

- Prostheses coverage is not eligible for member's potential functional level is 0.
- A user-adjustable heel height feature (L5990) will be denied as not reasonable and necessary.
- Routine periodic servicing, such as testing, cleaning, and checking of the prosthesis.
- Prosthetic donning sleeve (L7600)
- Repair time used:
 - Evaluating the member,
 - Taking measurements,
 - Making modifications to a prefabricated item to fit the member,
 - Follow-up visits,
 - Making adjustments at the time of or within ninety (90) days after delivery.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable codes: Lower Extremities: L5000-L5999, L7367, L7368, L7510, L7520, L8400, L8410, L8417, L8420, L8430, L8440
Upper Extremities: L6000-L7259

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful,

but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES

- Coverage exceptions to the potential functional levels will be considered on an individual case basis if documentation justifies the medical necessity.
- A suction valve (L5647, L5652) is rarely needed when a suspension locking mechanism is being used. If both are provided, there should be documentation in the supplier's record that describes the medical necessity of each for the member.

References:

1. Medicare Benefit Policy Manual- Chapter 15-Covered Medical and Other Health Services; accessed via Internet <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15>. 3/15/17.
2. Medicare Local Coverage Determination for Lower Limb Prostheses – CGS Administrators (L33787), Effective date 10/01/2015; accessed via <http://www.cms.gov/medicare-coverage-database/> 3/15/17.
3. Medicare Local Coverage Article for Lower Limb Prostheses (A52496), Effective 10/01/2015, accessed via <http://www.cms.gov/medicare-coverage-database/> 3/15/17.

Policy Implementation/Update Information: New policy

Revision Date: January 28th, 2013. The reference to prosthetics was removed from the Durable Medical Equipment medical coverage policy in 2011 to decrease confusion between the DME and prosthetics benefits. In addition, the Plan requires prior approval on certain prosthetics, not all prosthetics. This policy was created to provide the criteria for coverage of upper and lower extremity prostheses. The criteria were obtained from the Medicare LCDs and NCD.

Revision Date: March 18, 2015: No updates to coverage criteria, removed reference to codes L7260 and L7261, these two codes were deleted from DMEPOS fee schedule files effective January 1, 2015. October 29, 2015 updated LCD due to ICD-10 update only.

Revision Date: March 15, 2017; No updates to coverage criteria, No changes to policy.

Approval Dates:

Medical Coverage Policy Committee: March 15, 2017

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