Medical Policy Manual Durable Medical Equipment, Policy No. 18

Definitive Lower Limb Prostheses

Effective: September 1, 2024

Next Review: July 2025
Last Review: July 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

A prosthesis is a fabricated substitute for a missing body part. Lower limb prostheses may include a number of components, such as prosthetic feet, ankles, knees, and socket insertions and suspensions. A definitive prosthesis is provided after the surgical wound has healed and the residual limb has matured.

MEDICAL POLICY CRITERIA

Notes:

- This policy does not address microprocessor-controlled prostheses. Please refer to the *Cross References* section below for the appropriate medical policy.
- Preauthorization is only required for definitive (permanent) prostheses. Please check the preauthorization website to confirm requirements.
- This policy does not address preparatory prostheses, which may be considered medically necessary.
- This policy applies to the codes listed in the policy criteria as noted. Unlisted codes should not be used if there is a specific code that is applicable (see Coding Note below).

I. A definitive lower limb prosthesis may be considered **medically necessary** when all of the following criteria (A. – B.) are met:

A. All of the following general criteria are met:

1. The patient is motivated to ambulate using the requested prosthesis; and
2. The prosthesis is furnished incident to a physician's services or on a physician's order; and
3. The residual limb has matured; and
4. The member has been using a prosthesis, has achieved a defined functional state and is cognitively capable of using the prosthesis to ambulate effectively at the determined functional level (K0 – K4); and
5. The member had an in-person medical evaluation with the ordering physician to establish their overall functional capabilities and functional level (K level). (NOTE: The ordering physician might delegate this assessment to a licensed/certified medical professional (LCMP) defined as a physical therapist (PT) or occupational therapist (OT), or physician with training and expertise in the functional evaluation of beneficiaries with amputations.)

B. One or more of the following are met:

1. The request is for a lower limb prosthesis (L5010-L5341).
2. The request is for one of the following prosthetic feet:
    a. Request is for an external keel SACH foot (L5970) or single axis ankle/foot (L5974) for patients demonstrating a functional Level 1 or above.
    b. Request is for a flexible-keel foot (L5972) or multiaxial ankle/foot (L5978) for patients demonstrating a functional Level 2 or greater.
    c. Request is for a flex foot system (L5980), energy storing foot (L5976), multiaxial ankle/foot, dynamic response foot (L5979), or flex walk system or equal (L5981) or shank foot system with vertical loading pylon (L5987) for patients demonstrating a functional Level 3 or above.
3. Request is for one of the following prosthetic knees:
    a. Request is for a high activity knee control frame (L5930) for patients demonstrating a functional Level 4.
    b. Request is for a fluid (hydraulic) or pneumatic knee (L5610, L5613, L5614, L5722 - L5780, L5814, L5822-L5841, L5848) for patients demonstrating a functional Level 3 or above.
    c. Request is for other knee system (L5611, L5616, L5710-L5718, L5810-L5812, L5816-L5818) for patients demonstrating a functional Level 1 or above.
4. Request is for an axial rotation unit (L5982-L5986) or a multiaxial rotation unit with swing phase (L5968) for patients demonstrating a functional level 2 or above.
5. Request is for up to two test (diagnostic) sockets (L5618–L5628) for an

individual prosthetic. Additional documentation of medical necessity is required for more than two test sockets.

6. Request is for prosthesis replacement when one or more of the following criteria are met:
    a. A change in the physiological condition of the patient; or
    b. An irreparable change in the condition of the device, or in a part of the device; or
    c. 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, as the case may be, of the part being replaced.
7. Request is for socket replacements (L5700–L5703) when both of the following criteria are met:
    a. The member has an existing prosthesis
    b. One of the following is met:
        i. Changes in the residual limb that cannot be accommodated through the use of socket inserts and/or liners and/or stump stockings, and/or modifications to the existing socket; or
        ii. The existing socket is irreparable due to damage or wear.

II. Definitive prostheses are considered **not medically necessary** if Criterion I. is not met.

III. Replacement is considered **not medical necessary** for the following:
    A. Criterion I. is not met.
    B. Replacement is covered under manufacturer warranty and maintenance services.

IV. Replacement requests for same/similar items which include upgraded features or components (additional or deluxe features which exceed the member's medical need) or upgrades to DME, prosthetics, or orthotics already in use are considered **not medically necessary**.

V. Definitive prostheses are considered **not medically necessary** if the patient's potential functional level is "0."

VI. More than two of the same socket inserts (L5654-L5665, L5673, L5679, L5681, L5683) per individual prosthesis at the same time are considered **not medically necessary**.

VII. Use of a mechanical reel-based socket volume adjustment system, including but not limited to the RevoFit®, is considered **not medically necessary.**

VIII. Prostheses are considered **not medically necessary** if the member is unable or unwilling to use the prosthesis.

IX. Accessories for any non-covered DMEPOS item are considered **not medically necessary** (See the health plan’s Reimbursement Policy for “Associated Claims,” Administrative 119). Note, accessories in this situation would be non-covered regardless of whether the original DMEPOS item was billed to the health plan.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

DEFINITIONS

For purposes of this policy, the following definitions apply:

Preparatory Prosthesis. An unfinished, functional replacement for an amputated limb, fitted and aligned to accelerate the rehabilitation process, control edema, and prepare the residual limb for the external forces associated with wearing a prosthesis on a day to day basis.[1]

Permanent (i.e. definitive) Prosthesis. A permanent prosthesis is an artificial limb used by amputees whose residual limb has matured and the amputee has satisfactorily completed the temporary limb phase. The socket and components are manufactured to provide lasting durability and a proper cosmetic appearance.[2]

Mature Residual Limb: A mature residual limb is defined as one that has healed, reached its optimal volume, and been shaped appropriately to accommodate the chosen socket configuration

FUNCTIONAL CLASSIFICATION LEVELS

Following are the functional classification levels used to determine patient rehabilitation potential:[3]

Functional 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 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.

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes (including prior prosthetic use)
    - Medical records should document the patient's current functional capabilities and expected functional potential, including an explanation for any difference. Bilateral amputees cannot be strictly bound by functional level classifications.
- Current condition, including the status of the residual limb and the nature of other medical problems
- Functional level
- Desire to ambulate
- Physician's order (if applicable)
- Product information (manufacturer name, model number)
- For replacement items:
    - Comparative limb measurements (if applicable) or specific physiological change that necessitates replacement.
    - The date of service the prosthesis or component was provided.
    - The make/model and serial number (if applicable) for the component(s)
    - Warranty information
    - A repair vs. replacement analysis (i.e. cost to replace vs. cost to repair)

CROSS REFERENCES

1. Durable Medical Equipment, Prosthetic and Orthotic Replacements, Duplicates, Repairs, and Upgrades to Existing Equipment, Durable Medical Equipment, Policy No. 75
2. Myoelectric Prosthetic and Orthotic Components for the Upper Limb, Durable Medical Equipment, Policy No. 80
3. Powered and Microprocessor-Controlled Knee and Ankle-Foot Prosthesis and Microprocessor-Controlled Ankle-Foot Orthoses, Durable Medical Equipment, Policy No. 81
4. General Medical Necessity Guidance for Durable Medical Equipment, Prosthetic, Orthotics and Supplies (DMEPOS), Durable Medical Equipment, Policy No. 88
5. Powered Exoskeleton for Ambulation and Rehabilitation, Durable Medical Equipment, Policy No. 89
6. Associated Claims, Reimbursement Policy, Administrative, No. 119

BACKGROUND

In 2005, there were 1.6 million people living with limb loss in the U.S., and the number is predicted to be 3.6 million by 2050.[4] Common causes of lower limb amputation are dysvascular complications from diabetes, arteriosclerosis, smoke, or a combination of factors, and less commonly, traumatic injury, such as motor vehicle and industrial accidents, congenital limb development deficiency, and tumors.[5]

A standard timeline of amputation and prosthetic use includes multiple stages, including recovery and healing, maturation, and prosthetic selection and adjustments. Initially following an amputation, there is a period of limb management, where a variety of dressings may be used. Then a preparatory prosthesis is used while the limb volume stabilizes. Once the residual limb has matured and the patient's functional level has been determined, a definitive prosthesis is fitted.

PRACTICE GUIDELINE SUMMARY

Department of Veterans Affairs and the Department of Defense

A 2017 clinical practice guideline from the Department of Veterans Affairs and the Department of Defense (VA/DoD) included the following recommendation:[5]

- We suggest that in the perioperative phase following amputation, patients receive physical rehabilitation and appropriate durable medical equipment/assistive technology. (Weak strength of evidence)
- We recommend the use of valid, reliable, and responsive functional outcome measures, including, but not limited to, the Comprehensive High-level Activity Mobility Predictor, Amputee Mobility Predictor, 10-meter walk test, and 6-minute walk test. (Strong strength of evidence)
- We suggest the use of a combination of measures with acceptable psychometric properties to assess functional outcomes. (Weak strength of evidence)

SUMMARY

Definitive lower limb prosthetics improve health outcomes for select individuals missing part of a lower limb. Therefore, they may be considered medically necessary when policy criteria are met. When policy criteria are not met, the requested items are considered not appropriate in these individuals and are considered not medically necessary.

REFERENCES

1. Amputee Coalition National Limb Loss Resource Center. [cited 07/17/2024]. 'Available from:' https://www.amputee-coalition.org/limb-loss-resource-center/resources-filtered/resources-by-topic/definitions/.
2. Veterans Affairs Prosthetics Handbook. [cited 07/17/2024]. 'Available from:' https://helpdesk.vetsfirst.org/index.php?pg=kb.book&id=53.
3. Local Coverage Determination (LCD): Lower Limb Prostheses (L33787). Centers for Medicare and Medicaid Services. . [cited 07/17/2024]. 'Available from:' https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=33787.
4. Ziegler-Graham K, MacKenzie EJ, Ephraim PL, et al. Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Arch Phys Med Rehabil.* 2008;89(3):422-9. PMID: 18295618
5. VA/DoD Clinical Practice Guidelines. Rehabilitation of Lower Limb Amputation (2017). [cited 07/17/2024]. 'Available from:' https://www.healthquality.va.gov/guidelines/Rehab/amp/.

CODES

NOTE: All items must be reported with the appropriate Healthcare Common Procedure Coding System (HCPCS) code. Most prosthetics and accessories have an applicable, specific HCPCS code available. Only when there is no appropriate descriptive code to use may an “unlisted code” (e.g., HCPCS codes E1399) be reported. Inappropriate use of unlisted codes or failure to use specific codes when available may result in inaccurate reviews. The health plan will defer to the Medicare Pricing, Data Analysis, and Coding (PDAC) contractor (Palmetto GBA) for proper code assignment of most items.

Codes	Number	Description
CPT	None	
HCPCS	L5010	Partial foot, molded socket, ankle height, with toe filler
	L5020	Partial foot, molded socket, tibial tubercle height, with toe filler
	L5050	Ankle, Symes, molded socket, SACH foot
	L5060	Ankle, Symes, metal frame, molded leather socket, articulated ankle/foot (SACH)
	L5100	Below knee (BK), molded socket, shin, SACH foot
	L5105	Below knee (BK), plastic socket, joints and thigh lacer, SACH foot
	L5150	Knee disarticulation (or through knee), molded socket, external knee joints, shin, SACH foot
	L5160	Knee disarticulation (or through knee), molded socket, bent knee configuration, external knee joints, shin, SACH foot
	L5200	Above knee (AK), molded socket, single axis constant friction knee, shin, SACH foot
	L5210	Above knee (AK), short prosthesis, no knee joint (stubbies), with foot blocks, no ankle joints, each
	L5220	Above knee (AK), short prosthesis, no knee joint (stubbies), with articulated ankle/foot, dynamically aligned, each
	L5230	Above knee (AK), for proximal femoral focal deficiency, constant friction knee, shin, SACH foot
	L5250	Hip disarticulation, Canadian type; molded socket, hip joint, single axis constant friction knee, shin, SACH foot
	L5270	Hip disarticulation, tilt table type; molded socket, locking hip joint, single axis constant friction knee, shin, SACH foot
	L5280	Hemipelvectomy, Canadian type; molded socket, hip joint, single axis constant friction knee, shin, SACH foot
	L5301	Below knee (BK), molded socket, shin, SACH foot, endoskeletal system
	L5312	Knee disarticulation (or through knee), molded socket, single axis knee, pylon, SACH foot, endoskeletal system
	L5321	Above knee (AK), molded socket, open end, SACH foot, endoskeletal system, single axis knee
	L5331	Hip disarticulation, Canadian type, molded socket, endoskeletal system, hip joint, single axis knee, SACH foot
	L5341	Hemipelvectomy, Canadian type, molded socket, endoskeletal system, hip joint, single axis knee, SACH foot
	L5610	Addition to lower extremity, endoskeletal system, above knee (AK), hydracadence system
	L5611	Addition to lower extremity, endoskeletal system, above knee (AK), knee disarticulation, four-bar linkage, with friction swing phase control
	L5613	Addition to lower extremity, endoskeletal system, above knee (AK), knee disarticulation, four-bar linkage, with hydraulic swing phase control
	L5614	Addition to lower extremity, exoskeletal system, above knee (AK), knee disarticulation, four-bar linkage, with pneumatic swing phase control
	L5616	Addition to lower extremity, endoskeletal system, above knee (AK), universal multiplex system, friction swing phase control
	L5700	Replacement, socket, below knee (BK), molded to patient model
	L5701	Replacement, socket, above knee (AK)/knee disarticulation, including attachment plate, molded to patient model
	L5702	Replacement, socket, hip disarticulation, including hip joint, molded to patient model
	L5703	Ankle, Symes, molded to patient model, socket without solid ankle cushion heel (SACH) foot, replacement only

Codes	Number	Description
	L5710	Addition, exoskeletal knee-shin system, single axis, manual lock
	L5711	Additions exoskeletal knee-shin system, single axis, manual lock, ultra-light material
	L5712	Addition, exoskeletal knee-shin system, single axis, friction swing and stance phase control (safety knee)
	L5714	Addition, exoskeletal knee-shin system, single axis, variable friction swing phase control
	L5716	Addition, exoskeletal knee-shin system, polycentric, mechanical stance phase lock
	L5718	Addition, exoskeletal knee-shin system, polycentric, friction swing and stance phase control
	L5722	Addition, exoskeletal knee-shin system, single axis, pneumatic swing, friction stance phase control
	L5724	Addition, exoskeletal knee-shin system, single axis, fluid swing phase control
	L5726	Addition, exoskeletal knee-shin system, single axis, external joints, fluid swing phase control
	L5728	Addition, exoskeletal knee-shin system, single axis, fluid swing and stance phase control
	L5780	Addition, exoskeletal knee-shin system, single axis, pneumatic/hydra pneumatic swing phase control
	L5783	Addition to lower extremity, user adjustable, mechanical, residual limb volume management system
	L5810	Addition, endoskeletal knee-shin system, single axis, manual lock
	L5811	Addition, endoskeletal knee-shin system, single axis, manual lock, ultra-light material
	L5812	Addition, endoskeletal knee-shin system, single axis, friction swing and stance phase control (safety knee)
	L5814	Addition, endoskeletal knee-shin system, polycentric, hydraulic swing phase control, mechanical stance phase lock
	L5816	Addition, endoskeletal knee-shin system, polycentric, mechanical stance phase lock
	L5818	Addition, endoskeletal knee-shin system, polycentric, friction swing and stance phase control
	L5822	Addition, endoskeletal knee-shin system, single axis, pneumatic swing, friction stance phase control
	L5824	Addition, endoskeletal knee-shin system, single axis, fluid swing phase control
	L5826	Addition, endoskeletal knee-shin system, single axis, hydraulic swing phase control, with miniature high activity frame
	L5828	Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control
	L5830	Addition, endoskeletal knee-shin system, single axis, pneumatic/swing phase control
	L5840	Addition, endoskeletal knee-shin system, four-bar linkage or multiaxial, pneumatic swing phase control
	L5841	Addition, endoskeletal knee-shin system, polycentric, pneumatic swing, and stance phase control
	L5848	Addition to endoskeletal knee-shin system, fluid stance extension, dampening feature, with or without adjustability
	L5926	Addition to lower extremity prosthesis, endoskeletal, knee disarticulation, above knee, hip disarticulation, positional rotation unit, any type
	L5930	Addition, endoskeletal system, high activity knee control frame

Codes	Number	Description
	L5968	Addition to lower limb prosthesis, multiaxial ankle with swing phase active dorsiflexion feature
	L5970	All lower extremity prostheses, foot, external keel, SACH foot
	L5972	All lower extremity prostheses, foot, flexible keel
	L5974	All lower extremity prostheses, foot, single axis ankle/foot
	L5976	All lower extremity prostheses, energy storing foot (Seattle Carbon Copy II or equal)
	L5978	All lower extremity prostheses, foot, multiaxial ankle/foot
	L5979	All lower extremity prostheses, multiaxial ankle, dynamic response foot, one-piece system
	L5980	All lower extremity prostheses, flex-foot system
	L5981	All lower extremity prostheses, flex-walk system or equal
	L5982	All exoskeletal lower extremity prostheses, axial rotation unit
	L5984	All endoskeletal lower extremity prostheses, axial rotation unit, with or without adjustability
	L5985	All endoskeletal lower extremity prostheses, dynamic prosthetic pylon
	L5986	All lower extremity prostheses, multiaxial rotation unit (MCP or equal)
	L5987	All lower extremity prostheses, shank foot system with vertical loading pylon

Date of Origin: *July 2022*