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Medicare Advantage Policy Manual **Policy ID:** M-DME81

Powered and Microprocessor-Controlled Knee and Ankle-Foot Prostheses and Microprocessor-Controlled Knee-Ankle-Foot Orthoses

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Several microprocessor-controlled prosthetic knees have been developed, equipped with a sensor that detects when the knee is in full extension and adjusts the swing phase automatically, permitting a more natural walking pattern of varying speeds. In addition to knee prosthetics, microprocessor-controlled ankle-foot prostheses have been developed for transtibial amputees. These prosthetics are built with sensors in the feet that determine the direction and speed of the foot's movement, which controls the flexion angle of the ankle, allowing the foot to lift during the swing phase and potentially adjust to changes in force, speed, and terrain during the step phase. The intent of the technology is to make ambulation more efficient and prevent falls in patients ranging from the young active amputee to the elderly diabetic patient. Finally, there are also in development lower-limb prostheses designed to replace muscle activity in order to bend and straighten the prosthetic joint, some of which

are designed with the potential to reduce hip and back problems arising from an unnatural gait than can occur with the use of passive prosthesis.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	For replacement or repair of prosthetics, LCD criteria is applied; however, general Medicare coverage rules for prosthetic replacements and repairs also found in the *Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §120 - Prosthetic Devices, Subsections A* and *D* also remain applicable also (see Cross-References section).
National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	To be considered for coverage, Medicare requires the requested item to be **both** medically necessary **and** reasonable. This includes determining if there is a "less costly alternative" which can provide the needed and appropriate therapeutic benefit for the individual.[1] There must be a medically reasonable and necessary need for a higher-level prosthetic item documented within the clinical record. For ***general coverage criteria for L5856-L5859, L5969 and L5973 (note, not all devices are covered) and replacement/repair requests of these items***: ✓ Lower Limb Prostheses (L33787) *(Companion article is A52496, which can be accessed directly from the LCD, addresses coding and replacement requests)* *According to LCA A52496, "The only products which may be billed using the following list of HCPCS codes are those for which a written coding verification review (CVR) has been made by the Pricing, Data Analysis, and Coding (PDAC) contractor and subsequently published on the appropriate Product Classification List…* *Effective for claims with dates of service on or after January 1, 2014:* *L5969* *Effective for claims with dates of service on or after January 1, 2021:* *L5856, L5857, L5858, L5973, L5980, L5987"* For ***HCPCS code L2006, as well as replacement/repair requests of this item***:

- ✓ Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686) *(HCPCS code L2006 is used for a custom-fabricated KAFO, thus, both basic coverage criteria and custom fabricated coverage criteria must be met.) (Companion article is A52457, which can be accessed directly from the LCD, addresses coding and replacement/repair requests)*

According to LCA A52457, "Effective for claims with dates of service on or after January 1, 2020, the only products which may be billed to Medicare using code L2006 are those for which a written coding verification has been made by the Pricing, Data Analysis, and Coding (PDAC) contractor and that are listed in the Product Classification List."

**Scroll to the "Public Version(s)" section at the bottom of the LCD for links to prior versions if necessary.

POLICY GUIDELINES

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:

For initial provision:

- Past medical history, including prior prosthetic use, if applicable;
- Current functional level and expected functional potential, including an explanation for the difference, if one exists (note, an exception to this requirement may be made for bilateral amputees as they often cannot be bound by functional level classifications);
- For requests for HCPCS code L5859, the medical records should also describe the nature and extent of the comorbidity of the spine or the sound limb which is what is limiting this beneficiary to a household ambulator, and clearly document how this feature will enable the beneficiary to function as a community ambulator. Also include documentation that supports the clinical criteria from LCD L33787 specific to HCPCS code L5859.
- For custom fabricated orthoses (HCPCS L2006), there must also be detailed documentation in the treating practitioner's records to support the medical necessity of custom fabricated rather than a prefabricated orthosis as described in the related LCD.

For replacement:

- Documentation that the device still fills a medical need for the individual;
- Reason for replacement (e.g., change in physiologic condition of the member, irreparable wear, etc.);
- Confirmation the device is no longer under manufacturer warranty.

For repair:

- Date the item was initially provided (delivered) to the member;
- Documentation that the cost to repair the item does not exceed the expense of a replacement item (estimates are acceptable).

Additional standard documentation requirements for DMEPOS items can be found in the LCA for Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426) *(this LCA can be accessed directly from the Medicare Coverage Database website).*

REGULATORY STATUS

Microprocessor-controlled prostheses are categorized as class I, exempt devices. Manufacturers must register prostheses with the restorative devices branch of FDA and keep a record of any complaints but are not required to undergo a full review by the U.S. Food and Drug Administration (FDA). Some examples include, but are not limited to, the following devices:

- Intelligent Prosthesis (IP) (Blatchford, England);
- The Adaptive (Endolite, England);
- Rheo Knee® (Össur, Iceland);
- C-Leg®, the Genium™ Bionic Prosthetic System, and the X2 and X3 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN);
- Seattle Power Knees (3 models include Single Axis, 4-bar and Fusion, from Seattle Systems).
- Proprio Foot® (Össur)
- iPED (developed by Martin Bionics and licensed to College Park Industries),
- Elan Foot (Endolite);
- PowerFoot BiOM®, developed at the Massachusetts Institute of Technology and licensed to iWall)
- The Power Knee™, by Össur.
- ALLUX MPK knee by Proteor USA
- C-Brace® (Otto Bock)

CROSS REFERENCES

Definitive Lower Limb Prostheses, DME, Policy No. M-18

Durable Medical Equipment, Prosthetic and Orthotic Replacements, Duplicates, Repairs, and Upgrades to Existing Equipment, DME, Policy No. M-75

Myoelectric Prosthetic and Orthotic Components for the Upper Limb, DME, Policy No. M-80

REFERENCES

1. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.1 - Definition of Durable Medical Equipment, C. Necessary and Reasonable, 2. Reasonableness of the Equipment

2. Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §10.1.3 – Prosthetics and Orthotics (Leg, Arm, Back, and Neck Braces, Trusses, and Artificial Legs, Arms, and Eyes) - Coverage Definition

CODING

NOTE: As with all services and items, providers and suppliers are expected to report all items with the appropriate Healthcare Common Procedure Coding System (HCPCS) code. Most prosthetics described in this policy will **not** use the miscellaneous code L5999. If there is uncertainty regarding what code is appropriate, see the Medicare Pricing, Data Analysis and Coding (PDAC) Contractor's (Palmetto GBA) Product Classification List (select the "Product Classification List" button if not already selected) to determine appropriate HCPCS coding for a specific prosthetic.

Codes	Number	Description
CPT	None	
HCPCS	K1014	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control
	L2006	Knee ankle foot device, any material, single or double upright, swing and/or stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated
	L5615	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control
	L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control 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 sensor(s), any type
	L5859	Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered
	L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)
	L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, include power source
	L5999	Lower extremity prosthesis, not otherwise specified

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*