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Medicare Advantage Policy Manual **Policy ID:** M-DME80

Myoelectric Prosthetic and Orthotic Components for the Upper Limb

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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, including care that may be both medically reasonable and necessary.

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 Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. 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 a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). 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. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Myoelectric prostheses and orthotics are powered by electric motors with an external power source, and the joint movement of these prostheses or orthoses is driven by microchip-processed electrical activity in the muscles of the remaining limb or limb stump. Upper limb prostheses or orthoses (e.g., hand, wrist, and/or elbow) are used following amputation at any level from the hand to the shoulder, and the need for a prosthesis or orthotic can occur for a number of reasons, such as trauma, surgery, or congenital anomalies. The primary goals of the upper limb prosthesis/orthotics are to restore natural appearance and function, but achieving these goals also requires sufficient comfort and ease of use for continued acceptance by the wearer.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	See References and "Policy Guidelines" below[1,2] For ***replacement or repairs***: Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services *See Section 120 in the following link:* §120 - Prosthetic Devices, Subsections A and D
National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None **Note:** According to the Medicare Pricing, Data Analysis and Coding (PDAC) Contractor (Palmetto GBA), effective January 1, 2022, only products which have received code verification review by the Medicare PDAC are eligible to be reported or billed using HCPCS codes L6715 or L6880. The PDAC Product Classification 8 List search tool can be used to determine which products have received this review.
Medical Policy Manual	*Specific Medicare coverage guidance is not available for myoelectric prostheses or orthoses for upper limbs or their components. Therefore, the health plan's medical policy is applicable.* **Note:** While orthotics and prosthetics are a covered benefit under Medicare, the item in question needs to be both *medically reasonable* **and** *medically necessary* to meet the functional needs of the individual patient. For myoelectric ***prosthetic*** coverage, documentation must include, but is not limited to, rationale for why a body powered device is not sufficient to meet the medical needs of the member to complete their activities of daily living (ADLs). For myoelectric controlled upper-limb ***orthotics***, the available literature does not support that these orthoses improve health outcomes for people with upper limb weakness or paresis. See the health plan's policy for the literature research and evidence summary for more information. For ***initial provision***: ✓ Myoelectric Prosthetic and Orthotic Components for the Upper Limb, Durable Medical Equipment, Policy No. 80 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or

injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

According to *Social Security Act §1861(s)(9)*, prostheses are covered under the Medicare Artificial Legs, Arms and Eyes benefit and orthoses are covered under the Medicare Braces Benefit.

Items that provide features **beyond** what is necessary to support the body member would fall under the category of an "upgrade." Upgrades include "excess components" to a prosthetic or orthotic device (e.g., a feature, an accessory, or a service) that are in addition to, or more extensive and/or more expensive than, the item that is reasonable and necessary under Medicare's coverage requirements.[3] In addition, in order 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.[4] See the "Medical Policy Manual" row above for more details.

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:

- Documentation in chart notes and medical records of amputation or missing limb, as well as where the amputation is (above the wrist or below, etc.);
- Documentation regarding how standard body-powered prosthetic devices either cannot be used or are insufficient to meet the member's function needs in performing activities of daily living (ADLs);
- Results of functional testing (physical or computer model prosthesis) demonstrating the remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of the myoelectric prosthetic device;
- Demonstrated sufficient neurological and cognitive function to effectively operate the prosthesis;

- Documented co-morbidities that could interfere with function of the prosthesis (e.g., neuromuscular disease, etc), if any exist;
- Functional evaluation by a qualified professional (e.g., prosthetist) indicating use of a myoelectric prosthesis and the associated components are necessary to meet the functional needs of the individual.
    - This includes consideration of the patient's need for control, durability, function, usability, and that the device is necessary to perform instrumental activities of daily living, including job function, and that the device is *not* primarily for the purpose of leisure or recreational activities.

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.);
- Current functionality of the current device and 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).

REGULATORY STATUS

Examples of available myoelectric prostheses and orthoses include, but may not be limited to, the following:

- The SensorHand™ by Advanced Arm Dynamics, which is described as having an AutoGrasp feature, an opening/closing speed of up to 300 mm/second, and advanced EMG signal processing.
- The Utah Arm 3 by Motion Control has a microprocessor interface that allows individualized adjustments to achieve maximum performance.
- The i-LIMB™ hand (Touch Bionics), sometimes referred to as the bionic hand, is the first commercially available myoelectric hand prosthesis with individually powered digits.
- ProDigits™, also from Touch Bionics, are prosthetic digits for one or more fingers in patients with amputation at a transmetacarpal level or higher.
- Otto Bock has a number of myoelectric hand and elbow prostheses including the AutoGrasp feature, the Michelangelo® Hand, and the Electrohand 2000 designed for children.
- LTI Boston Digital Arm™ System by Liberating Technologies Inc. is marketed as having greater torque than any other powered prosthetic elbows
- The LUKE Arm (previously known as the DEKA Arm System) can perform complex tasks with multiple simultaneous powered movements (e.g., movement of the elbow, wrist, and hand at the same time). In addition to the EMG electrodes, the LUKE Arm

contains a combination of mechanisms including switches, movement sensors, and force sensors. The Luke Arm is the same shape and weight as an adult arm.

- These devices may be covered by LIVINGSKIN™, a high-definition silicone prosthesis created to resemble a patient's natural skin.
- An example of a hybrid system is the ErgoArm (Otto Bock) which has a myoelectric hand and a cable-controlled elbow joint.
- The MyoPro (Myomo) is a myoelectric powered upper-extremity orthotic. This orthotic device weighs about 1.8 kilograms (4 pounds), has manual wrist articulation, and myoelectric initiated bi-directional elbow movement. The MyoPro detects weak muscle activity from the affected muscle groups. A therapist or prosthetist/orthoptist can adjust the gain (amount of assistance), signal boost, thresholds, and range of motion. Potential users include patients with traumatic brain injury, spinal cord injury, brachial plexus injury, amyotrophic lateral sclerosis, and multiple sclerosis. Use of robotic devices for therapy has been reported. The MyoPro is the first myoelectric orthotic available for home use.

CROSS REFERENCES

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

Powered and Microprocessor-Controlled Knee and Ankle-Foot Prostheses and Microprocessor-Controlled Knee-Ankle-Foot Orthoses, DME, Policy No. M-81

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

REFERENCES

1. Medicare Benefit Policy Manual, Pub. #100-02, Chapter 15 – Covered Medical and Other Health Services, §120 – Prosthetic Devices
2. Medicare Claims Processing Manual, Pub. #100-04, 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
3. Medicare Claims Processing Manual, Chapter 20, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §120 - DME MACs - Billing Procedures Related To Advanced Beneficiary Notice (ABN) Upgrades
4. 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
5. Noridian web page for *Billing of Powered L-Coded Items - Correct Coding - Revised [Last Cited 06/19/2024]*

6. Palmetto GBA PDAC web page for *Billing of Powered L-Coded Items - Correct Coding - Revised (Doesn't allow additional coding for extra components for prostheses reported with L6880 as it is considered all-inclusive.) [Last Cited 06/19/2023]*
7. Noridian web page for MyoPro® (Myomo, Inc.) Assist Device - Correct Coding - R*etired [Last Cited 06/17/2021]*
8. *Noridian web page for Powered Upper Extremity Exoskeleton - Correct Coding – updated 12/28/2023 [Last Cited 06/19/2024]*

CODING

NOTE: For dates of service on or after January 1, 2019, specific HCPCS codes (L8701 or L8702) are available and should be used when reporting for the MyoPro® upper extremity assist device. [6,7,8] The MyoPro was reported with HCPCS code E1399 for services prior to January 1, 2019.[7]

Unlisted codes should not be used when a specific code exists. If there is uncertainty regarding what code is appropriate, see the *PDAC* Product Classification List to determine what HCPCS coding should be used for a specific prosthetic or orthotic. According to the PDAC, the following are additional products and their assigned codes:

- The Touch Bionics i-LIMB™ hand - HCPCS code L6880.
- The Touch Bionics Prodigits - HCPCS code L6715.
- The Otto Bock ErgoArm and DynamicArm elbow - HCPCS code L6693.

Codes	Number	Description
CPT	None	
HCPCS	E1399	Durable medical equipment, miscellaneous
	L6026	Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes and cables, two batteries, charger, myoelectric control of terminal device, excludes terminal device(s)
	L6693	Upper extremity addition, locking elbow, forearm counterbalance
	L6700	Upper extremity addition, external powered feature, myoelectronic control module, additional emg inputs, pattern-recognition decoding intent movement
	L6715	Terminal device, multiple articulating digit, includes motor(s), initial issue or replacement
	L6880	Electric hand, switch or myoelectric controlled, independently articulating digits, any grasp pattern or combination of grasp patterns, includes motor(s)
	L6881	Automatic grasp feature, addition to upper limb electric prosthetic terminal device
	L6882	Microprocessor control feature, addition to upper limb prosthetic terminal device
	L6925	Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device

Codes	Number	Description
	L6935	Below elbow, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L6945	Elbow disarticulation, external power, molded inner socket, removable humeral shell, outside locking hinges, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L6955	Above elbow, external power, molded inner socket, removable humeral shell, internal locking elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L6965	Shoulder disarticulation, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L6975	Interscapular-thoracic, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L7007	Electric hand, switch or myoelectric controlled, adult
	L7008	Electric hand, switch or myoelectric controlled, pediatric
	L7009	Electric hook, switch or myoelectric controlled, adult
	L7045	Electric hook, switch or myoelectric controlled, pediatric
	L7180	Electronic elbow, microprocessor sequential control of elbow and terminal device
	L7181	Electronic elbow, microprocessor simultaneous control of elbow and terminal device
	L7190	Electronic elbow, adolescent, Variety Village or equal, myoelectronically controlled
	L7191	Electronic elbow, child, Variety Village or equal, myoelectronically controlled
	L7259	Electronic wrist rotator, any type
	L7499	Upper extremity prosthesis, not otherwise specified
	L8701	Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated
	L8702	Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated

***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.*