Medicare Medical Policy

Myoelectric Upper Limb Prosthesis

MEDICARE MEDICAL POLICY NUMBER: 374

Effective Date: 3/1/2024

Last Review Date: 12/2023

Next Annual Review: 12/2024

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
General	**NOTE:** While there are no specific CMS coverage criteria specifically for myoelectric upper limb prosthetic components, CMS does address coverage requirements for prosthetics in general.[1] According to the *Social Security Act §1861(s)(9)*, prostheses are covered under the Medicare Artificial Legs, Arms and Eyes benefit.[2] See *Policy Guidelines* below for more information regarding Medicare and medical necessity.
Replacement or Repairs	Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §120 - Prosthetic Devices, Subsections A and D **NOTE:** I. Replacement of medically necessary **non**-functioning myoelectric prosthetics may be **medically necessary** when Medicare's prosthetic replacement requirements in the above manual are met (e.g., irreparable change in condition of device or component, etc.) and the device or required component are not under manufacturer warranty. II. Replacement or upgrades of medically necessary **functioning** myoelectric prosthetics may be **medically necessary** if the device is no longer providing therapeutic benefit due to a change in the physiological condition of the member. III. Replacement or upgrades of **functioning** myoelectric prosthetics are **not medically necessary** when Medicare's replacement criteria are not met **OR** when the initial device didn't meet coverage criteria. This includes upgrading to newer models when existing devices are still functioning and still providing therapeutic benefit. These replacement or upgrade situations would be considered a "convenience."

	See *Policy Guidelines* below for more information regarding Medicare and replacement of prosthetics.
Myoelectric Upper Limb Prosthetics – Initial Provision	Company medical policy for Myoelectric Upper Limb Prosthesis I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met. II. These services are considered **not medically necessary** for Medicare Plan members either when the Company medical policy criteria are **not** met ***or*** when a service is deemed "not medically necessary" by the Company policy. See *Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

Upper extremity (limb) prosthetics are generally categorized and described by the level of amputation and the type of power source utilized to operate the limb. There are three types of upper extremity prostheses that reference the power source:[3]

- Body power - This type relies on a system of mechanisms such as cable(s)/linkage(s)/anchor point(s) and upon the coordination of contracting muscles create motion of the prosthetic limb's joints via the control mechanism.
- External (i.e., electrical) power – This type is controlled by the use of electric signals from the body's muscles which are translated and amplified via battery power to eventual control of the prosthetic components.
- Passive/restorative – This type does not have active motion within the prosthesis. Passive prostheses may allow motion of the next proximal joint; without controlling a motion within the prosthesis. Motion of the passive prosthesis is not described as external or body power.

Description

Myoelectric Prosthesis

Myoelectric prostheses are powered by electric motors with an external power source, utilizing muscle activity from the residual limb for control of joint movement. Surface electrodes placed on the limb stump detect electromyographic signals. A controller then amplifies and processes these signals to drive battery-powered motors that move the hand, wrist and elbow.

LUKE Arm

The LUKE/DEKA prosthetic arm, developed by DEKA Integrations Corp, is a prosthetic arm developed for individuals who have lost all or part of their upper limb. The prosthesis is primarily controlled by a micro-electromechanical system operated through an inertial measurement unit located in a sensor device attached to the top of the shoe. The prosthesis also utilizes signals from myoelectric technology, using EMG electrodes from muscles in the shoulder/upper arm to control movement.[1]

Partial-Hand Myoelectric Prostheses (e.g., i-digit quantum [formerly, ProDigits])

Partial-hand myoelectric prostheses are designed to replace the function of digits in individuals missing 1 or more fingers. This type of prosthetic device requires the level of loss or deficiency be distal to the wrist and proximal to the metacarpophalangeal joint.

MEDICARE AND MEDICAL NECESSITY

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*.

While prosthetics are eligible for coverage, Medicare requires that all durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) are **both** medically reasonable **and** necessary to meet the functional needs of the individual patient.[4] This includes determining if there is a "less costly alternative" which can provide the needed and appropriate therapeutic benefit for the individual.[5] 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 functional medical needs of the member to complete their activities of daily living (ADLs). Items which provide features beyond what is medically reasonable and necessary to support the body member would fall under the category of an "upgrade." Upgraded items include "excess components" to a prosthetic device (e.g., a feature, an accessory, or a service) that are in addition to, or more extensive than, the item that is reasonable and necessary under Medicare's coverage requirements.[6] For individuals for whom myoelectric prosthetics are being considered, the health plan's policy criteria will apply.

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations. During the MAO review, an evidence-based process must be used. This includes using authoritative evidence, such as studies performed by government agencies (i.e., the FDA), well-designed clinical studies that appeared in peer

reviewed journals, and evaluations performed by independent technology assessment groups. *(Medicare Managed Care Manual, Ch. 4, §90.5)***Replacement of Prostheses**

Replacement of medically necessary prosthetics are subject to Medicare rules for prosthetic device replacement. Specifically, documentation must demonstrate the following:

1. There is no warranty provision provided by the manufacturer to either replace or repair the current device[7]; **and**
2. The initial provision of the device met coverage criteria; **and**
3. Either a or b below:
    a. A change in physiological condition of the member and their current device does not adequately provide the necessary therapeutic benefit; **or**
    b. There is an irreparable change in the condition of the device or part of the device.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

While not directly related to medical necessity, CMS provides billing and coding guidance for the reporting of powered L-coded items. Specifically, Medicare doesn't allow additional coding for extra components for use with prostheses reported with HCPCS code L6880 because this code is considered "all-inclusive."[8-10] Effective January 1, 2022, only products which have received code verification review by the PDAC Contractor are eligible to be reported or billed using HCPCS codes L6715 or L6880.[11] The PDAC Product Classification List (PCL) search tool can be used to determine which products have received this review.

Computerized or microprocessor limbs are based on a patient's current functional capabilities and expected functional rehabilitation potential. If more than one prosthetic limb meets a patient's prosthetic rehabilitation needs, the least costly prosthetic will be approved.

The following codes may be used, depending on what prosthesis was ordered. There may also be supplies/components that could be used in conjunction with of these devices.

HCPCS Code L9900

HCPCS code L9900 is never allowed separate reimbursement because Medicare considers this code to be a bundled item or service, no matter what it is used to represent, and even if billed alone. While

several LCAs and LCDs specifically call out this code as non-covered when used for specific types of devices, not all possible scenarios where this code may be used are addressed in LCDs or LCAs; however, the Noridian webpage for *Two New Codes Established for Miscellaneous Supplies* provides general noncoverage information, for any use not found in an LCD or LCA.

CODES*		
CPT	None	
HCPCS	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)
	L6628	Upper extremity addition, quick disconnect hook adapter, otto bock or equal
	L6629	Upper extremity addition, quick disconnect lamination collar with coupling piece, otto bock or equal
	L6632	Upper extremity addition, latex suspension sleeve, each
	L6680	Upper extremity addition, test socket, wrist disarticulation or below elbow
	L6687	Upper extremity addition, frame type socket, below elbow or wrist disarticulation
	L6715	Terminal device, multiple articulating digit, includes motor(s), initial issue or replacement
	L6810	Addition to terminal device, precision pinch device
	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
	L6890	Addition to upper extremity prosthesis, glove for terminal device, any material, prefabricated, includes fitting and adjustment
	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
	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
	L7368	Lithium ion battery charger, replacement only
	L7400	Addition to upper extremity prosthesis, below elbow/wrist disarticulation, ultralight material (titanium, carbon fiber or equal)
	L7403	Addition to upper extremity prosthesis, below elbow/wrist disarticulation, acrylic material
	L9900	Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS "L" code
	L8465	Prosthetic shrinker, upper limb, each

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Centers for Medicare & Medicaid Services. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §120 – Prosthetic Devices. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Accessed 11/23/2022.
2. Centers for Medicare & Medicaid Services. 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. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf. Accessed 11/23/2022.
3. Palmetto GBA. Upper Limb Prostheses - Correct Coding. https://dmepdac.com/palmetto/pdacv2.nsf/DIDC/6P053RAIDE~Articles%20and%20Publications~Advisory%20Articles. Accessed 11/23/2022.
4. Centers for Medicare & Medicaid Services. Medicare Benefit Policy Manual, Chapter 15– Covered Medical and Other Health Services, §110.1 - Definition of Durable Medical Equipment,

C. Necessary and Reasonable. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf#page=120. Accessed 11/23/2022.
5. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §90 - Payment for Additional Expenses for Deluxe Features. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf. Accessed 11/23/2022.
6. Centers for Medicare & Medicaid Services. 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. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf. Accessed 11/23/2022.
7. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §40.4 – Items Covered Under Warranty. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf. Accessed 11/16/2023.
8. Noridian Healthcare Solutions, Inc.. Billing of Powered L-Coded Items - Correct Coding – Revised; Updated 07/14/2021. https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/2020/billing-of-powered-l-coded-items-correct-coding-revised. Accessed 11/23/2022.
9. Palmetto GBA. PDAC Billing of Powered L-Coded Items - Correct Coding – Revised. https://dmepdac.com/palmetto/PDACv2.nsf/DIDC/JY6L23LIQN~Articles%20and%20Publications~Advisory%20Articles. Accessed 11/23/2022.
10. Palmetto GBA. PDAC Articulating Digit(s) and Prosthetic Hands - Correct Coding – Revised. Updated 11/17/2021. https://dmepdac.com/palmetto/PDACv2.nsf/DIDC/U2FF8051ZN~Articles%20and%20Publications~Advisory%20Articles. Accessed 11/23/2022.
11. Palmetto GBA. PDAC Code Verification Review Requirement for Articulating Digit(s) and Prosthetic Hands – Revised. Updated 06/15/2021. https://dmepdac.com/palmetto/PDACv2.nsf/DIDC/C53ST779DX~Articles%20and%20Publications~Advisory%20Articles. Accessed 11/23/2022.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
3/2023	New Medicare Advantage medical policy
3/2024	Annual review; Add replacement and repair criteria; Language revision due to Company policy change from “investigational” to “not medically necessary”, added code