Myoelectric Prosthetic and Orthotic Components for the Upper Limb

Medicare Advantage Medical Policy #MA-118
Original Effective Date: 08/01/2025
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Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider myoelectric upper-limb prosthetic components to be **eligible for coverage.****

Patient Selection Criteria for Initial Prosthesis

Coverage eligibility for myoelectric upper-limb prosthetic components will be considered when **ALL** of the following criteria are met:

- The individual has an amputation or missing limb at the wrist or above (forearm, elbow, etc.); **AND**
- Standard body-powered prosthetic devices cannot be used or are insufficient to meet the functional needs of the individual in performing activities of daily living; **AND**
- The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device; **AND**
- The individual has demonstrated sufficient neurologic and cognitive function to operate the prosthesis effectively; **AND**
- The individual is free of comorbidities that could interfere with function of the prosthesis (neuromuscular disease, cardiovascular disease, infection, etc.); **AND**
- Functional evaluation indicates that with training, use of a myoelectric prosthesis is likely to meet the functional needs of the individual (e.g., gripping, releasing, holding, coordinating movement of the prosthesis) when performing activities of daily living. This evaluation should consider the individual's needs for control, durability (maintenance), function (speed, work capability), and usability.

Note: See Policy Guidelines section for required documentation for clinical review and expanded description on ADLs.

Based on review of available data, the Company may consider replacement or repair of a myoelectric upper limb prosthesis to be **eligible for coverage.****

Patient Selection Criteria for Replacement Prosthesis

Coverage eligibility for medically necessary replacement of a myoelectric upper-limb prosthetic components will be considered when **ALL** of the following criteria are met:

- Patient selection criteria for initial prosthesis are met; **AND**
- The current prosthetic components are out of warranty; **AND**
- The current prosthesis requires repairs and the cost of such repairs would be more than 60% of the cost of a new prosthesis.

Note: Labor costs for a new prosthesis are not separately reimbursable. Labor costs are reimbursable for medically necessary repairs after the prosthesis' warranty has expired.

When Services Are Considered Not Medically Necessary

The use of myoelectric upper-limb prosthetic components when patient selection criteria are not met is considered to be **not medically necessary.****

Custom fabricated gloves for an upper extremity prosthesis are considered **not medically necessary**** because they are not primarily medical in nature.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers advanced upper-limb prosthetic components with both sensor and myoelectric control [e.g., LUKE Arm System (DEKA Gen 2 and DEKA Gen 3), SensorHand™‡ Speed, COAPT Complete Control Gen2] to be **investigational.***

Based on review of available data, the Company considers a prosthesis with individually powered digits, including but not limited to a partial hand prosthesis (e.g., i-Limb Hand™‡,ProDigits™‡, i-Digits™‡ Quantum), to be **investigational.***

Based on review of available data, the Company considers myoelectric controlled upper-limb orthoses (e.g., MyoPro®‡) to be **investigational.***

Policy Guidelines

Documentation required for clinical review should include all of the following:

- Detailed history and physical exam including, date of amputation, current physical and cognitive status, and support for patient selection criteria
- Prescription for the prosthesis from referring physician (Physiatrist or Orthopedist)
- Name of ordering Prosthetist, fax and phone number
- All prosthetist's clinical notes including:
    - Has a prosthesis been previously worn
    - If a prosthesis is currently used, include make, model, and components in use
    - When was current myoelectric limb issued and when does warranty expire

  - Describe malfunction of current myoelectric upper limb prosthesis
  - What repairs have been provided by manufacturer of myoelectric limb
  - What is the repair cost for current prosthesis
  - Medical reasoning or rationale for a new myoelectric upper limb prosthesis
  - Describe functional needs related to daily activities
  - Result of the functional evaluation and documentation if with training, use of a myoelectric prosthesis will meet the functional needs of the member, i.e. provide detailed explanation of what functional needs and activities of daily living can be only met with myoelectric prosthesis and why, which features of the myoelectric prosthesis meet specific functional needs related to activities of daily living
  - Why is a body-powered prosthesis not appropriate; i.e. provide detailed explanation why standard body-powered prosthetic devices cannot be used, or which functional needs and activities of daily living cannot be met and why
- Clearly stated make, model and components of the requested prosthesis, and all pertinent HCPCS codes with descriptions of generic or unlisted codes. For all additional unlisted codes (e.g. L7499), documentation needs to include detailed description of the feature, and medical justification of functional need and activity of daily living it will support.

Activities of Daily Living (ADLs) – These activities are the basic functions required for self-care of every-day life.

- Eating
- Bathing
- Grooming
- Dressing
- Transferring
- Toileting

Amputees should be evaluated by an independent qualified professional to determine the most appropriate prosthetic components and control mechanism (eg, body-powered, myoelectric, or combination of body-powered and myoelectric). A trial period may be indicated to evaluate the tolerability and efficacy of the prosthesis in a real-life setting.

Background/Overview

Upper-Limb Amputation

The need for a prosthesis can occur for a number of reasons, including trauma, surgery, or congenital anomalies.

Treatment

The primary goals of the upper-limb prostheses are to restore function and natural appearance. Achieving these goals also requires sufficient comfort and ease of use for continued acceptance by the wearer. The difficulty of achieving these diverse goals with an upper-limb prosthesis increases

with the level of amputation (digits, hand, wrist, elbow, shoulder), and thus the complexity of joint movement increases.

Upper-limb prostheses are classified into 3 categories depending on the means of generating movement at the joints: passive, body-powered, and electrically powered movement. All 3 types of prostheses have been in use for more than 30 years; each possesses unique advantages and disadvantages.

Passive Prostheses

- The passive prostheses rely on manual repositioning, typically using the opposite arm and cannot restore function. This unit is the lightest of the 3 prosthetic types and is thus generally the most comfortable.

Body-Powered Prostheses

- The body-powered prostheses use a body harness and cable system to provide functional manipulation of the elbow and hand. Voluntary movement of the shoulder and/or limb stump extends the cable and transmits the force to the terminal device. Prosthetic hand attachments, which may be claw-like devices that allow good grip strength and visual control of objects or latex-gloved devices that provide a more natural appearance at the expense of control, can be opened and closed by the cable system. Patient complaints with body-powered prostheses include harness discomfort, particularly the wear temperature, wire failure, and the unattractive appearance.

Myoelectric Prostheses

- Myoelectric prostheses use muscle activity from the remaining limb for control of joint movement. Electromyographic signals from the limb stump are detected by surface electrodes, amplified, and then processed by a controller to drive battery-powered motors that move the hand, wrist, or elbow. Although upper-arm movement may be slow and limited to 1 joint at a time, myoelectric control of movement may be considered the most physiologically natural.
- Myoelectric hand attachments are similar in form to those offered with the body-powered prosthesis but are battery-powered. Commercially available examples are listed in the FDA or Other Governmental Regulatory Approval section.
- A hybrid system, a combination of body-powered and myoelectric components, may be used for high-level amputations (at or above the elbow). Hybrid systems allow for control of 2 joints at once (ie, 1 body-powered, 1 myoelectric) and are generally lighter and less expensive than a prosthesis composed entirely of myoelectric components.

Technology in this area is rapidly changing, driven by advances in biomedical engineering and by the U.S. Department of Defense Advanced Research Projects Agency, which is funding a public and private collaborative effort on prosthetic research and development. Areas of development include the use of skin-like silicone elastomer gloves, “artificial muscles,” and sensory feedback. Smaller

motors, microcontrollers, implantable myoelectric sensors, and reinnervation of remaining muscle fibers are being developed to allow fine movement control. Lighter batteries and newer materials are being incorporated into myoelectric prostheses to improve comfort.

Partial-hand myoelectric prostheses, for example, ProDigits, or i-Digits Quantum (Össur, Reykjavik, Iceland), are designed to replace the function of digits in individuals missing one or more of their fingers as a result of a partial-hand amputation. This type of prosthetic device requires a very specific range of amputation such as amputation level through, or just proximal to, the metacarpal phalangeal level of one or more digits.

The LUKE Arm (previously known as the DEKA Arm System) was developed in a joint effort between DEKA Research & Development and the U.S. Department of Defense Advanced Research Projects Agency program. It is the first commercially available myoelectric upper-limb that can perform complex tasks with multiple simultaneous powered movements (eg, movement of the elbow, wrist, and hand at the same time). In addition to the electromyographic electrodes, the LUKE Arm contains a combination of mechanisms, including switches, movement sensors, and force sensors. The primary control resides with inertial measurement sensors on top of the feet. The prosthesis includes vibration pressure and grip sensors.

Myoelectric Orthoses
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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Manufacturers must register prostheses with the Restorative and Repair Devices Branch of the U.S. Food and Drug Administration (FDA) and keep a record of any complaints, but do not have to undergo a full FDA review.

Available myoelectric devices include ProDigits™‡ and i-Limb™‡ (Touch Bionics), the SensorHand™‡ Speed and Michelangelo®‡ Hand (Otto Bock), the LTI Boston Digital Arm™‡ System (Liberating Technologies), the Utah Arm Systems (Motion Control), and bebionic (Ottobock).
In 2014, the DEKA Arm System (DEKA Integrated Solutions, now DEKA Research & Development), now called the LUKE™‡ Arm (Mobius Bionics), was cleared for marketing by FDA through the de novo 513(f)(2) classification process for novel low- to moderate-risk medical devices that are first-of-a-kind.

FDA product codes: GXY, IQZ.
The MyoPro®‡ (Myomo) is registered with the FDA as a class 1 limb orthosis.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

Myoelectric prostheses are powered by electric motors with an external power source. The joint movement of an upper-limb prosthesis or orthosis (eg, hand, wrist, and/or elbow) is driven by microchip-processed electrical activity in the muscles of the remaining limb or limb stump.

Summary of Evidence

For individuals who have a missing limb at the wrist or higher who receive myoelectric upper-limb prosthesis components at or proximal to the wrist, the evidence includes a systematic review and comparative studies. Relevant outcomes are functional outcomes and quality of life. The goals of upper-limb prostheses relate to restoration of both appearance and function while maintaining sufficient comfort for continued use. The identified literature focuses primarily on patient acceptance and rejection; data are limited or lacking in the areas of function and functional status. The limited evidence suggests that, when compared with body-powered prostheses, myoelectric components possess the similar capability to perform light work; however, myoelectric components could also suffer a reduction in performance when operating under heavy working conditions. The literature has also indicated that the percentage of amputees who accept the use of a myoelectric prosthesis is approximately the same as those who prefer to use a body-powered prosthesis, and that self-selected use depends partly on the individual's activities of daily living. Appearance is most frequently cited as an advantage of myoelectric prostheses, and for patients who desire a restorative appearance, the myoelectric prosthesis can provide greater function than a passive prosthesis with equivalent function to a body-powered prosthesis for light work. Because of the different advantages and disadvantages of currently available prostheses, myoelectric components for persons with an amputation at the wrist or above may be considered when passive, or body-powered prostheses cannot be used or are insufficient to meet the functional needs of the patient in activities of daily living. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a missing limb at the wrist or higher who receive sensor and myoelectric controlled upper-limb prosthetic components, the evidence includes a series of publications from a 12-week home study. Relevant outcomes are functional outcomes and quality of life. The prototypes for the advanced prosthesis were evaluated by the U.S. military and Veterans Administration. Demonstration of improvement in function has been mixed. After several months of home use,

activity speed was shown to be similar to the conventional prosthesis, and there were improvements in the performance of some activities, but not all. There were no differences between the prototype and the participants' prostheses for outcomes of dexterity, prosthetic skill, spontaneity, pain, community integration, or quality of life. Study of the current generation of the sensor and myoelectric controlled prosthesis is needed to determine whether newer models of this advanced prosthesis lead to consistent improvements in function and quality of life. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
For individuals who have a missing limb distal to the wrist who receive a myoelectric prosthesis with individually powered digits, no peer-reviewed publications evaluating functional outcomes in amputees were identified. Relevant outcomes are functional outcomes and quality of life. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with upper-extremity weakness or paresis who receive a myoelectric powered upper-limb orthosis, the evidence includes a small within-subject study. Relevant outcomes are functional outcomes and quality of life. The largest study (N=18) identified tested participants with and without the orthosis but did not provide any training with the device. Performance on the tests was inconsistent. Studies are needed that show consistent improvements in relevant outcome measures. Results should also be replicated in a larger number of patients. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2012 Input

In response to requests, input on partial hand prostheses was received from 1 physician specialty society and 2 academic medical centers while this policy was under review in 2012. Input was mixed. Reviewers agreed that there was a lack of evidence and experience with individual digit control, although some thought that these devices might provide functional gains for selected patients.

2008 Input

In response to requests, input was received from 1 physician specialty society and 4 academic medical centers while this policy was under review in 2008. The American Academy of Physical Medicine & Rehabilitation and all 4 reviewers from academic medical centers supported the use of electrically powered upper-extremity prosthetic components. Reviewers also supported evaluation of the efficacy and tolerability of the prosthesis in a real-life setting, commenting that outcomes are dependent on the personality and functional demands of the individual patient.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date (Status)
Ongoing			
NCT03401762	Wearable MCI [myoelectric computer interface] to Reduce Muscle Co-activation in Acute and Chronic Stroke	96	Aug 2024
NCT05768802	Evaluation of Myoelectric Implantable Recording Array (MIRA) in Participants With Transradial Amputation (MIRA)	5	Dec 2029
NCT03178890[a]	The Osseointegrated Human-machine Gateway	18	May 2024
Unpublished			
NCT02274532	Myoelectric SoftHand Pro to Improve Prosthetic Function for People With Below-elbow Amputations: A Feasibility Study	18	May 2016 (completed)

NCT: national clinical trial.
[a]Denotes industry-sponsored or cosponsored trial.

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Policy History

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Current Effective Date: 08/01/2025
05/20/2025 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 05/2026

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	L6026, L6700, L6715, L6880, L6881, L6882, L6925, L6935, L6945, L6955, L6965, L6975, L7007, L7008, L7009, L7045, L7180, L7190, L7191, L8701, L8702
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or

diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage

Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.