Introduction

After a person has had a hand or arm amputated, an artificial limb (prosthesis) may be used. Myoelectric prostheses have been developed that give much better control of the arm than other types of prostheses. These devices take electrical signals generated by the muscles in the remaining part of the arm, amplify them, and then use those signals to move the joints in the arm. These myoelectric prostheses give the person more natural and better control of their limb. This policy describes when a myoelectric prosthetic hand or arm may be medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Device</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myoelectric upper limb</td>
<td>Myoelectric upper limb prostheses with conventional grip</td>
</tr>
</tbody>
</table>
### Device | Medical Necessity
--- | ---
prostheses and conventional grip myoelectric prosthetic hands | myoelectric prosthetic hands (see Figure 1 below) may be considered medically necessary when ALL of the following criteria are met:
- The patient 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 patient has demonstrated sufficient neurologic and cognitive function to operate the prosthesis safely and effectively

AND
- The patient is free of comorbidities that could interfere with function of the prosthesis (neuromuscular disease, etc.)

AND
- The results of a functional evaluation indicate that with training, use of a myoelectric prosthesis is likely to meet the functional needs of the individual (eg, gripping, releasing, holding, and coordinating movement of the prosthesis) when performing activities of daily living. This evaluation should consider the patient’s needs for control, durability (maintenance), function (speed, work capability), and usability.

Gloves for an upper extremity prosthesis | Gloves for an upper extremity prosthesis are considered not medically necessary because they are not primarily medical in nature

Myoelectric upper limb prosthetic devices | Myoelectric upper limb prosthetic devices are considered not medically necessary when the criteria in this policy are not met.
<table>
<thead>
<tr>
<th>Device</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prosthetic hand attachment with mechanical fingers (that uses full or partial myoelectric power)</td>
<td>A prosthetic hand attachment with individually powered (multiarticulating) fingers (digits)(see image below) that uses full or partial myoelectric power for independent movement of individual joints is considered investigational.</td>
</tr>
<tr>
<td></td>
<td>Note: Advanced technology full or partial myoelectric prosthetic hand attachments with individually powered digits are designed to replace the finer control of missing fingers either in their entirety or in part (e.g., i-limb digits, ProDigits™, and others). Articulation (independent movement) of the prosthetic finger joints involves sophisticated biomechanical technology; in contrast to the conventional grip myoelectric prosthetic hand that is an alternative to a hook-type hand attachment. As yet, the value of a myoelectric prosthetic hand with jointed, individually powered fingers over a conventional myoelectric hand has not been proven.</td>
</tr>
<tr>
<td>Upper-limb prosthetic components with sensor and myoelectric controls</td>
<td>Upper-limb prosthetic components with sensor and myoelectric controlled are considered investigational</td>
</tr>
<tr>
<td>Myoelectric controlled upper limb orthoses</td>
<td>Myoelectric controlled upper limb orthoses are considered investigational</td>
</tr>
</tbody>
</table>

**Documentation Requirements**

The patient’s medical records submitted for review should document that medical necessity criteria are met. The record should include detailed history and physical documenting ALL of following criteria are met:

- The member has an amputation or missing limb at the wrist or above (that is, forearm, elbow, etc.)
- Standard body-powered prosthetic devices cannot be used or is insufficient to meet the functional needs of the member in performing activities of daily living
- The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device
- The member has demonstrated sufficient neurological and cognitive function to operate the prosthesis safely and effectively
- Absence of a comorbidity that could interfere with function of the prosthesis (e.g,
**Documentation Requirements**

- Result of the functional evaluation indicating that with training, use of a myoelectric prosthesis is likely to meet the functional needs of the member

---

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L6026</td>
<td>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(s)</td>
</tr>
<tr>
<td>L6715</td>
<td>Terminal device, multiple articulating digit, includes motor(s), initial issue or replacement</td>
</tr>
<tr>
<td>L6880</td>
<td>Electric hand, switch or myoelectric controlled, independently articulating digits, any grasp pattern or combination of grasp patterns, includes motor(s)</td>
</tr>
<tr>
<td>L6890</td>
<td>Addition to upper extremity prosthesis, glove for terminal device, any material, prefabricated, includes fitting and adjustment</td>
</tr>
<tr>
<td>L6895</td>
<td>Addition to upper extremity prosthesis, glove for terminal device, any material, custom fabricated</td>
</tr>
<tr>
<td>L6925</td>
<td>Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal electrodes, cables, 2 batteries and one charger, myoelectronic control of terminal device</td>
</tr>
<tr>
<td>L6935</td>
<td>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</td>
</tr>
<tr>
<td>L6945</td>
<td>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</td>
</tr>
<tr>
<td>L6955</td>
<td>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</td>
</tr>
<tr>
<td>L6965</td>
<td>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</td>
</tr>
</tbody>
</table>
### Code | Description
--- | ---
 | 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
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.

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### Related Information

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.
Benefit Application

In this policy, procedures are considered reconstructive when intended to address a significant variation from normal related to accidental injury, disease, trauma, treatment of a disease, or congenital defect, irrespective of whether a functional impairment is present.

This reconstructive benefit may be applied in cases in which the myoelectric prosthesis is requested based on appearance. Not all benefit contracts include benefits for reconstructive services as defined by this policy. Benefit language supersedes this document.

Description

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

Background

Upper-Limb Amputation

Upper-limb prostheses are used for amputations at any level, from the hand to the shoulder. 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 prosthesis relies on manual repositioning, typically by moving with the opposite arm and cannot restore function. It is the lightest of the 3 prosthetic types and is thus generally the most comfortable.
**Body-Powered Prostheses**

The body-powered prosthesis uses 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 (heat generated by wearing the prosthesis), wire failure, and the unattractive appearance.

**Myoelectric Prostheses**

Myoelectric prostheses use muscle activity from the remaining limb for control of joint movement. Electromyographic (EMG) 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 Regulatory Status 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 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 (DARPA), 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.
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 (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 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/orthotist 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.

**Summary of Evidence**

For individuals who have a missing limb at the wrist or above who receive myoelectric upper limb prosthesis components at the wrist 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, 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 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 differing 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 a meaningful 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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1 below.
Table 1. Summary of Key Clinical Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01551420</td>
<td>Home Study of an Advanced Upper Limb Prosthesis</td>
<td>100</td>
<td>Feb 2018 (ongoing)</td>
</tr>
<tr>
<td>NCT03215771a</td>
<td>Longitudinal Observation of Myoelectric Upper Limb Orthosis Use Among Veterans With Upper Limb Impairment</td>
<td>15</td>
<td>Sep 2019</td>
</tr>
<tr>
<td>NCT03178890a</td>
<td>The Osseointegrated Human-machine Gateway</td>
<td>18</td>
<td>Feb 2020</td>
</tr>
<tr>
<td>NCT02349035</td>
<td>Application of Targeted Reinnervation for People With Transradial Amputation</td>
<td>12</td>
<td>Jan 2021</td>
</tr>
<tr>
<td>NCT03401762</td>
<td>Wearable MCI [myoelectric computer interface] to Reduce Muscle Co-activation in Acute and Chronic Stroke</td>
<td>96</td>
<td>Aug 2021</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02274532</td>
<td>Myoelectric SoftHand Pro to Improve Prosthetic Function for People With Below-elbow Amputations: A Feasibility Study</td>
<td>18 54</td>
<td>May 2016 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial
a Denotes industry-sponsored or co-sponsored trial

Clinical Input Received 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**

No guidelines or statements were identified.

**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.

**Regulatory Status**

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.

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 some 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.
Available myoelectric devices include, but are not limited to, the following:

- **ProDigits™** (Touch Bionics)
- **i-limb™** (Touch Bionics)
- **SensorHand™ Speed** (Otto Bock)
- **Michelangelo® Hand** (Otto Bock)
- **LTI Boston Digital Arm™ System** (Liberating Technologies)
- **Utah Arm Systems** (Motion Control)
- **bebionic** (steeper)

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/10/14</td>
<td>New PR (PREMERA) policy to replace 1.04.04. Myoelectric upper limb prostheses and conventional grip myoelectric prosthetic hands may be considered medically necessary when criteria are met. Myoelectric prosthetic hand attachments with mechanical fingers that have independently powered joints are considered investigational.</td>
</tr>
<tr>
<td>09/03/14</td>
<td>Interim Update. Policy Guidelines added with details about when orthotics, prosthetics, or prosthetic components added to a conventional prosthesis are not covered. Added The Deka Arm System to the Regulatory Status section. No new references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>01/05/15</td>
<td>Coding update. New HCPCS codes L6026 (replaces L6025 deleted 12/31/14) and L7259 added to the policy.</td>
</tr>
<tr>
<td>01/28/16</td>
<td>Minor update. Added HCPCS L7181 to coding table.</td>
</tr>
<tr>
<td>05/01/16</td>
<td>Annual Review, approved April 12, 2016. Policy statements unchanged. No references added.</td>
</tr>
<tr>
<td>03/01/17</td>
<td>Annual review, approved February 14, 2017. Policy updated with literature review through November 21, 2016; no references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>04/11/17</td>
<td>Coding update; removed HCPCS code L6025 as it was terminated on 12/31/2014.</td>
</tr>
<tr>
<td>04/14/17</td>
<td>Coding update; added HCPCS code L6925.</td>
</tr>
<tr>
<td>09/22/17</td>
<td>Policy moved into new format; no change to policy statements.</td>
</tr>
<tr>
<td>05/01/18</td>
<td>Annual Review, approved April 10, 2018. Policy updated with literature review through January 2018; references 5 and 7-13 added. Investigational statements added for myoelectric orthoses and prostheses with both sensor and myoelectric control. Added statement that gloves for upper extremity prostheses are not medically necessary. Title changed from &quot;Myoelectric Prosthetic Components for the Upper Limb&quot; to &quot;Myoelectric Prosthetic and Orthotic Components for the Upper Limb&quot;. Added HCPCS codes L6890 and L6895.</td>
</tr>
</tbody>
</table>
Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

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Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filling a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at

https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD) Complaint forms are available at


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العامة التي تشير إلى الحفاظ على عناوين ملاحظات طبية أو

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Kreyòl ayisyen (Creole):


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Oromo (Cushite):


Italiano (Italian):

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