MEDICAL POLICY – 1.04.502
Myoelectric Prosthetic Components for the Upper Limb

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 prostheses and</td>
<td>Myoelectric upper limb prostheses and conventional grip myoelectric prosthetic hands may be considered medically</td>
</tr>
<tr>
<td>Device</td>
<td>Medical Necessity</td>
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</tbody>
</table>
| **conventional grip myoelectric prosthetic hands** | 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 member’s functional needs when 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 neurological 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 patient (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. |

| 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>
</table>
| **Prosthetic hand attachment with mechanical fingers (that uses full or partial myoelectric power)** | A prosthetic hand attachment with mechanical fingers (digits) that uses full or partial myoelectric power for independent movement of individual joints is considered investigational.  
**Note:** Advanced technology full or partial myoelectric prosthetic hand attachment with mechanical fingers (digits) that uses full or partial myoelectric power for independent movement of individual joints is considered investigational. |
Device
Investigational 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.

## Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HCPCS</strong></td>
<td></td>
</tr>
<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>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>
<tr>
<td>Code</td>
<td>Description</td>
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<tr>
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<tr>
<td>L6975</td>
<td>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</td>
</tr>
<tr>
<td>L7007</td>
<td>Electric hand, switch or myoelectric controlled, adult</td>
</tr>
<tr>
<td>L7008</td>
<td>Electric hand, switch or myoelectric controlled, pediatric</td>
</tr>
<tr>
<td>L7009</td>
<td>Electric hook, switch or myoelectric controlled, adult</td>
</tr>
<tr>
<td>L7045</td>
<td>Electric hook, switch or myoelectric controlled, pediatric</td>
</tr>
<tr>
<td>L7181</td>
<td>Electronic elbow, microprocessor simultaneous control of elbow and terminal device</td>
</tr>
<tr>
<td>L7190</td>
<td>Electronic elbow, adolescent, Variety Village or equal, myoelectronically controlled</td>
</tr>
<tr>
<td>L7191</td>
<td>Electronic elbow, child, Variety Village or equal, myoelectronically controlled</td>
</tr>
<tr>
<td>L7259</td>
<td>Electronic wrist rotator, any type.</td>
</tr>
</tbody>
</table>

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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 (e.g., 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.
Background

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. 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.

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.

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, including heat generated by wearing the prosthesis, wire failure, and the unattractive appearance.

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 DEKA Arm System, developed in a joint effort with DARPA and approved by the Food and Drug Administration in May 2014, 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 EMG electrodes, the DEKA Arm System contains a combination of mechanisms, including switches, movement sensors, and force sensors.

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 cohort studies and survey data. 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 reasons for disuse. Detailed data on function and functional status, and direct comparisons between body-powered and newer model myoelectric prostheses are limited or lacking. The limited evidence suggests that, compared with body-powered prostheses, myoelectric components may improve range of motion to some extent, have similar capability for light work, but may have reduced performance under heavy working conditions. The literature also indicates 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 at least in part 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. Nonuse of any prosthesis is associated with lack of functional need, discomfort (excessive weight and heat), and impediment to sensory feedback. 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 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.

Ongoing and Unpublished Clinical Trials

Some current trials 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><strong>Ongoing</strong></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>54</td>
<td>Sep 2016 (ongoing)</td>
</tr>
<tr>
<td>NCT01551420</td>
<td>Home Study of an Advanced Upper Limb Prosthesis</td>
<td>75</td>
<td>Dec 2017</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><strong>Unpublished</strong></td>
<td></td>
<td></td>
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<tr>
<td>NCT01967004a</td>
<td>Validation of a Control Method for Upper Limb Myoelectric Prostheses Using Radio Frequency Identification (RFID)</td>
<td>10</td>
<td>Jun 2014 (unknown)</td>
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<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
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</tr>
<tr>
<td>NCT01901081</td>
<td>A Feasibility Study to Assess Safety and Functionality of Implantable Myoelectric Sensors for Upper Extremity Prosthetic Control in Transradial Amputees</td>
<td>10</td>
<td>May 2016 (unknown)</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 provide appropriate reviewers who collaborate with and make recommendations during this process, 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. The 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 (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Regulatory Status

Manufacturers must register prostheses with the restorative 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, now called the LUKE™ arm (DEKA Integrated Solutions, now DEKA Research & Development) 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.

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

• Deka Arm System (DEKA Integrated Solutions)
• Dynamic Arm (Advanced Arm Dynamics)
• Dynamic Mode Control hand
• Electrohand 2000 for children (Otto Bock)
• ErgoArm hybrid system (Otto Bock)
• i-LIMB™ (Touch Bionics)
• LTI Boston Digital™ Arm Systems-various upper limb devices and components (Liberating Technologies Inc.)
• Michelangelo® Hand (Otto Bock)
- Otto Bock has a number of myoelectric prosthesis, that may not be in this list (Otto Bock)
- ProDigits™ (Touch Bionics)
- SensorHand™ (Advanced Arm Dynamics)
- Utah Arm Systems (Motion Control)

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,</td>
</tr>
</tbody>
</table>
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.

01/05/15 Coding update. New HCPCS codes L6026 (replaces L6025 deleted 12/31/14) and L7259 added to the policy.


01/28/16 Minor update. Added HCPCS L7181 to coding table.

05/01/16 Annual Review, approved April 12, 2016. Policy statements unchanged. No references added.

03/01/17 Annual review, approved February 14, 2017. Policy updated with literature review through November 21, 2016; no references added. Policy statements unchanged.

04/11/17 Coding update; removed HCPCS code L6025 as it was terminated on 12/31/2014.

04/14/17 Coding update; added HCPCS code L6925.

09/22/17 Policy moved into new format; no change to policy statements.

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