



**Kaiser Foundation Health Plan  
of Washington**

**Clinical Review Criteria  
Myoelectric Upper Limb Prosthesis**

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**Criteria**

**For Medicare Members**

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
KPWA Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, "Myoelectric Upper Limb Prosthesis," for medical necessity determinations. Use the Non-Medicare criteria below.

**For Non-Medicare Members**

1. Myoelectric upper limb prosthetic components may be medically necessary when **ALL of the following** criteria are met:
  - A. The patient has an amputation or missing limb at the wrist or above (forearm, elbow, etc.); AND
  - B. 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. The inadequacies of a standard device must be documented in detail by a physical or occupational or physiatrist therapist who is not employed by the vendor or prosthetist; AND
  - C. The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device, as demonstrated by functional testing using a physical or computer model prosthesis; AND
  - D. The patient has demonstrated sufficient neurological and cognitive function to operate the prosthesis effectively; AND
  - E. The patient is free of comorbidities that could interfere with function of the prosthesis (neuromuscular disease, etc.); AND
  - F. Functional evaluation by a qualified professional (e.g., prosthetist) indicates that with training, use of a myoelectric prosthesis is likely to meet the functional needs of the individual (e.g., 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. **Both of the following** criteria must be met:
    - i. The device is necessary for the patient to perform instrumental activities of daily (see B above)
    - ii. The device is not primarily for the purpose of allowing the patient to perform vocational, leisure or recreational activities.
  - G. Patient must be at least 1 year old.

investigational.

Repair and/or replacement of an external prosthetic device, including an upper limb myoelectric prosthetic device, is covered as follows:

- Repair is covered only when anatomical change or reasonable wear and tear renders the item nonfunctional and the repair will make the equipment usable.
- Replacement is covered only when anatomical change or reasonable wear and tear renders the item nonfunctional and non-repairable.

Repair or replacement of an external prosthetic device, including an upper limb myoelectric prosthetic device, made unusable or nonfunctioning because of individual misuse, abuse or neglect is not covered

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

## Background

External prosthetic appliances, often referred to as prosthetic devices or prostheses, are devices used to replace the functions of missing body parts. A passive prosthesis is a type of device that must be moved manually, typically by the opposite arm. The standard prosthetic appliance for replacement of an upper extremity, either below or above the elbow, is a body-powered prosthesis with a terminal hook device. This type of prosthetic device is the most durable and requires gross body movement and sufficient strength for adequate use. It is attached to the user's body through a system of harnesses. The patient controls the hand, forearm and elbow by movement of the harness system. Gross body motion is required to pull the harness and thereby move the prosthesis. Usage of a body-powered prosthesis requires adequate space for compensation of movement; the user must be able to place his/her body in front of the object to be manipulated. This type of device allows voluntary closing or opening of the hand, but not both.

The myoelectric device functions by means of electrical impulses. It is a prosthetic device used as an alternative to a passive or conventional body-powered device which enables a patient to adjust the force of his/her grip and both open and closes the hand voluntarily. Myoelectric devices may be recommended for amputees who are unable to use body-powered devices or who require improved grip function/motion for performance of daily activities. Adults or children with above- or below-the-elbow amputations may use the device effectively, although for children there is some controversy regarding use because due to normal growth patterns the prosthesis may require multiple socket replacements over time.

Unlike body-powered prosthetic devices, myoelectric devices move the prosthetic limbs with small, electric, motorized controls, which allow more precise movement. Small electrodes are installed in the socket of the prosthesis. The electrodes sense electrical activity of the muscles, called electromyographic (EMG) signals. When amplified, the EMG signal stimulates the motors in the device to perform a function. The signal is very weak (i.e., 5–200 microvolts); an individual must be able to produce a strong enough EMG signal for the device to record and amplify; that is, the person must possess a minimum microvolt threshold in the remaining musculature of the arm. The user must also be able to isolate muscle contraction, so that if one muscle is contracted (e.g., flexion), the opposing muscle is relaxed (e.g., extension). Contraction of both muscles (co-contraction) would result in signals turning the motor on and off at the same time, causing the device not to function and eliminating its myoelectric capability.

Myoelectric devices operate on rechargeable batteries and require no external cables or harnesses. The myoelectric prosthetic device does not require gross body movements or added space for compensation of movement to provide adequate functional movement; it can be operated in any user position that allows muscle contraction. Instead of a suspension harness, the devices use one of two suspension techniques: skeletal/soft tissue lock or suction.

Proponents suggest that myoelectric devices have many advantages over conventional ones. When designing prostheses to replace a hand, manufacturers attempt to replicate the grip function, the hand's major function. Other functions that are often replicated are pinch force, wrist rotation and elbow function. Investigators assert that a myoelectric device offers greater grip capabilities and more improved rotational function than conventional devices. Furthermore, because no control cable or harness is associated with the myoelectric device, cosmetic skin can be applied to the device to enhance cosmetic appearance. More recent control systems incorporate programmable

microprocessors allowing various ranges of adjustment, performance of multiple functions and sequential operation of elbow, wrist and hand motions. In some cases, a combination of myoelectric and body- powered technology (i.e., hybrid prosthesis) is used to enhance the amputee's overall functionality, depending on the level and location of amputation. Patients with amputations above the transhumeral level may elect a body- powered device to control shoulder and elbow movement and a myoelectric device to control hand and wrist motion, allowing control of two joints at once. There are also devices that are similar to the normal wrist, enabling the terminal device to be rotated, thus allowing more natural movement or placement. More recently, hand devices have become available with five individual powered digits and separately powered prosthetic digits are available for individuals who have lost a part of the hand or finger.

## Medical Technology Assessment Committee(MTAC)

### Controlled Upper Limb Prosthesis

#### 08/11/2004: MTAC REVIEW

**Evidence Conclusion:** There is minimal published data on the microprocessor- controlled upper limb prosthesis. These data do not provide evidence on the benefit of using these more sophisticated prostheses in improving health outcomes of the amputees, their impact on their physical and social activities, or to suggest which patients will benefit more with using them.

**Articles:** The search yielded 35 articles. The majority dealt with the technical aspects and mechanisms of action of the prostheses. The search did not reveal any randomized controlled trials. Only one case series (N=18) that investigated the satisfaction level of young users of myoelectric prosthesis was identified. This was a small case series, and did not involve a microprocessor.

Controlled upper limb prosthesis in the treatment of members with missing or amputated upper limb does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Date Created	Dates Reviewed	Date Last Revised
08/11/2004	04/04/2011 <sup>MDCRPC</sup> , 02/07/2012 <sup>MDCRPC</sup> , 12/04/2012 <sup>MDCRPC</sup> , 10/01/2013 <sup>MPC</sup> , 08/05/2014 <sup>MPC</sup> , 06/02/2015 <sup>MPC</sup> , 04/05/2016 <sup>MPC</sup> , 02/07/2017 <sup>MPC</sup> , 12/05/2017 <sup>MPC</sup> , 10/02/2018 <sup>MPC</sup>	02/07/2017

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee

<sup>MPC</sup> Medical Policy Committee

Revision History	Description
04/05/2016	Developed criteria to expand coverage for service
02/07/2017	Medicare is silent; MPC approved to adopt GHC criteria for Medicare members

## Codes

HCPCS: L6025, L6935, L6945, L6955, L6965, L6975, L6611, L6677, L6715, L6880, L6881, L6882, L7007, L7008, L7009, L7045, L7180, L7181, L7190, L7191