

Medical Policy Manual

Topic: Myoelectric Prosthetic Components for the Upper Limb

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Section: Durable Medical Equipment

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION^[1]

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

Upper limb prostheses are used following amputation 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 prosthesis are to restore natural appearance and function. 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 as the level of amputation (digits, hand, wrist, elbow, and shoulder), and thus the complexity of joint movement, increases.

Upper limb prostheses are classified based on the means of generating movement at the joints as follows:

1. The passive prosthesis:

- The lightest weight upper extremity prosthesis
- Patients generally describe this as the most comfortable of the three types
- Must be repositioned manually, typically by moving it with the opposite arm
- Cannot restore function.

2. 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, wire failure, and the unattractive appearance.

3. The myoelectric prosthesis

- Uses muscle activity from the remaining limb for the 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 one 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.
- Patient dissatisfaction with myoelectric prostheses includes the increased cost, maintenance (particularly for the glove), and weight.
- Examples of available technologies:
 - The SensorHand™ by Advanced Arm Dynamics, which is described as having an AutoGrasp feature, an opening/closing speed of up to 300 mm/second, and advanced EMG signal processing.
 - The Utah Arm 3 by Motion Control has a microprocessor interface that allows individualized adjustments to achieve maximum performance.
 - The i-LIMB™ hand (Touch Bionics), sometimes referred to as the bionic hand, is the first commercially available myoelectric hand prosthesis with individually powered digits.
 - ProDigits™, also from Touch Bionics, are prosthetic digits for one or more fingers in patients with amputation at a transmetacarpal level or higher.
 - Otto Bock has a number of myoelectric hand and elbow prostheses including the Electrohand 2000 designed for children.
 - LTI Boston Digital Arm™ System by Liberating Technologies Inc. is marketed as having greater torque than any other powered prosthetic elbows
 - These devices may be covered by LIVINGSKIN™, a high-definition silicone prosthesis created to resemble a patient's natural skin.

4. A hybrid system, a combination of body-powered and myoelectric components
 - May be used for high-level amputations (at or above the elbow).
 - Allows control of two joints at once (i.e., one body-powered and one myoelectric)
 - Generally lighter weight and less expensive than a prosthesis composed entirely of myoelectric components.
 - An example of a hybrid system is the ErgoArm by Otto Bock which has a myoelectric hand and a cable-controlled elbow joint

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 re-innervation 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.

Regulatory Status

Prostheses are class I devices that are exempt from U.S. Food and Drug Administration (FDA) marketing clearance, but manufacturers must register prostheses with the restorative devices branch of the FDA and keep a record of any complaints.

Examples of available myoelectric devices are listed above.

MEDICAL POLICY CRITERIA

- I. 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; 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.

- II. Medical necessity may be established for *either* an upper limb prosthesis with myoelectric components if criteria are met or for a mechanical prosthesis without myoelectric function, but not for both
- III. A prosthesis with individually powered digits, including but not limited to a partial hand prosthesis, is considered **investigational**.
- IV. Myoelectric upper limb prosthetic components are considered **not medically necessary** under all other conditions including but not limited to replacement of an existing, functioning prostheses (e.g., as an "upgrade" for a prosthesis that still works and fits)

SCIENTIFIC EVIDENCE^[1]

Background

In evaluating the effects of the increased sophistication of myoelectric upper limb prostheses compared with body-powered prostheses, passive prostheses, or no prosthesis, the most informative data are prospective comparative studies with objective and subjective measures that directly address function and health-related quality of life.

In light of the magnitude of functional loss in upper extremity amputation, evaluation of the evidence is based on two assumptions:

1. Use of any prosthesis confers clinical benefit, and
2. Self-selected use is an acceptable measure of the perceived benefit (combination of utility, comfort, and appearance) of a particular prosthesis for that individual.

It should be considered that the upper limb amputee's needs may depend on their particular situation. For example, increased functional capability may be needed with heavy work or domestic duties, while a more natural appearing prosthesis with reduced functional capability may be acceptable for an office, school, or other social environment.

Literature Appraisal

Amputation at Wrist or Above

Systematic Reviews

A systematic review of 40 articles published over the previous 25 years assessed upper limb prosthesis acceptance and abandonment.^[2] For pediatric patients the mean rejection rate was 38% for passive prostheses (1 study), 45% for body-powered prostheses (3 studies), and 32% for myoelectric prostheses (12 studies). For adults there was considerable variation between studies, with mean rejection rates of 39% (6 studies), 26% (8 studies), and 23% (10 studies) for passive, body-powered and myoelectric prostheses, respectively. The authors found no evidence that the acceptability of passive prostheses had declined over the period from 1983 to 2004, "despite the advent of myoelectric devices with functional

as well as cosmetic appeal.” Body-powered prostheses were also found to have remained a popular choice, with the type of hand-attachment being the major factor in acceptance. Body-powered hooks were considered acceptable by many users, but body-powered hands were frequently rejected (80%–87% rejection rates) due to slowness in movement, awkward use, maintenance issues, excessive weight, insufficient grip strength, and the energy needed to operate. Rejection rates of myoelectric prostheses tended to increase with longer follow-up. There was no evidence of a change in rejection rates over the 25 years of study, but the results are limited by sampling bias from isolated populations and the generally poor quality of the studies included.

Randomized Controlled Trials

In comparative studies of prostheses, subjects served as their own control. Since these studies included use by all subjects of both a myoelectric and a body-powered prosthesis, randomization was directed at the order in which each amputee used the prostheses. Two trials were found in which a total of 196 children used both a myoelectric and a body-powered hand prosthesis, in randomized order, for a period of 3 months each.^[3,4] No clinically relevant objective or subjective difference was found between the two types of prostheses.

Non-randomized Trials

A number of small ($n < 50$) non-randomized case series^[5-7] and online or mailed surveys^[8-11] were found, but few studies directly addressed whether myoelectric prostheses improved function and health-related quality of life. Most of the studies identified described amputees’ self-selected use or rejection rates. The results were usually presented as hours worn at work or school, hours worn at home, and hours worn in social situations. Amputees’ self-reported reasons for use and abandonment were also frequently reported. The limited evidence available suggests that, in comparison 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 indicated that the percentage of amputees who accepted use of a myoelectric prosthesis was about the same as those who prefer to use a body-powered prosthesis, and that self-selected use depended at least in part on the individual’s activities of daily living. Appearance was most frequently cited as an advantage of myoelectric prostheses. Nonuse of any prosthesis was associated with lack of functional need, discomfort (excessive weight and heat), and impediment to sensory feedback.

Amputation Below the Wrist (Hand or Digits)

A myoelectric hand with individual control of digits has been widely reported in lay technology reports, video clips and basic science reports. No peer-reviewed publications were found to evaluate functional outcomes of individual digit control in amputees.

Summary

The goals of upper limb prostheses relate to restoration of both appearance and function while maintaining sufficient comfort for continued use. The identified literature focused primarily on patient acceptance and reasons for disuse; detailed data on function and functional status, and direct comparisons of body-powered and newer model myoelectric prostheses are limited. The evidence has consistently reported that the type of prosthesis used by amputees was determined by functional need, amputation level, appearance, and comfort. Therefore, a myoelectric upper limb prosthesis may be considered medically necessary for patients with an amputation or missing limb at the level of the wrist

or above when a functional evaluation has found the patient to have adequate physical and cognitive function to operate the prosthesis, and a standard body-powered prosthesis is insufficient to meet the functional needs of the individual in performing activities of daily living.

Due to the lack of peer-reviewed publications evaluating the functional outcomes of individual digit control in amputees, myoelectric hand prostheses with individual control of digits are considered investigational.

REFERENCES

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CROSS REFERENCES

[Powered Knee Prosthesis, or Powered Ankle-Foot Prosthesis, and Microprocessor-Controlled Ankle-Foot Prosthesis](#), DME, Policy No. 81

CODES	NUMBER	DESCRIPTION
CPT	None	

CODES	NUMBER	DESCRIPTION
HCPCS	L6025	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
	L6715	Terminal device, multiple articulating digit, includes motor(s), initial issue or replacement
	L6880	Electric hand, switch or myoelectric controlled, independently articulating digits, any grasp pattern or combination of grasp patterns, includes motor(s)
	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

CODES	NUMBER	DESCRIPTION
	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