Cigna Medical Coverage Policy

Subject **Prosthetic Devices: Upper Limb Myoelectric**

Effective Date **11/15/2013**
Next Review Date **11/15/2014**
Coverage Policy Number **0233**

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Hyperlink to Related Coverage Policies

Lower Limb Prosthetic Devices (Including Vacuum-Assisted Socket System and Microprocessor/Computer-Controlled Lower Limb Prostheses)

INSTRUCTIONS FOR USE

*The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supersedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2013 Cigna*

Coverage Policy

Coverage for limb prosthetic devices may be subject to the terms, conditions and limitations of the applicable benefit plan's External Prosthetic Appliances and Devices (EPA) or Durable Medical Equipment (DME) benefit and schedule of copayments. In addition, some benefit plans may specifically exclude or limit coverage for certain prosthetic devices. Replacement and/or repair may be limited in some benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for EPA and DME is limited to the lowest-cost alternative.

Additionally, power enhancements and/or power controls are specifically excluded under many benefit plans. Microprocessor-controlled/computer-controlled devices, including myoelectric devices, are considered a type of power enhancement/controlled device, and therefore are not covered under many benefit plans.

If coverage for a myoelectric prosthetic device is available, the following conditions of coverage apply.

Cigna covers an upper limb myoelectric prosthetic device as medically necessary for an individual with an amputation or congenital absence of a portion of an arm (e.g., hand, forearm, elbow) when ALL of the following criteria are met:

- The individual has sufficient cognitive ability to successfully utilize a myoelectric prosthetic device.
- The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device.
- A standard body-powered prosthetic device cannot be used or is insufficient to meet the functional needs of the individual in performing activities of daily living.

Cigna covers repair and/or replacement of an external prosthetic device, including an upper limb myoelectric prosthetic device, 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 nonrepairable.

Cigna does not cover repair or replacement of an external prosthetic device, including an upper limb myoelectric prosthetic device, becomes unusable or nonfunctioning because of individual misuse, abuse or neglect.

General 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 may consist of a hand, wrist or elbow that 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 used for amputees who are unable to use body-powered devices or require improved grip function/motion for daily activities. The device may be recommended for adults or children with above- or below-the-elbow amputations, although for children there is some controversy as the prosthesis may require multiple socket replacements over time due to normal growth patterns.

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 (Lake and Miguelez, 2003). 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 transhumoral 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.

U.S Food and Drug Administration (FDA)
Device classification for an external assembled upper limb prosthetic device could not be found on the FDA site. External limb prosthetic components, however, are regulated by the FDA as Class I devices and are exempt from premarket notification procedures.

Several myoelectric devices are currently available, including but not limited to the Otto Bock myoelectric prosthesis (Otto Bock, Minneapolis, MN), the LTI Boston Digital Arm™ System, (Liberating Technologies Inc., Holliston, MA), and the Utah Arm Systems (Motion Control, Salt Lake City, UT).

Literature Review
Results of studies published in the peer-reviewed scientific literature evaluating the impact of these devices on clinical outcomes are mixed (Egermann, et al., 2009; Pylatiuk, et al., 2007; Biddess and Chau, 2007; Crandall and Tomhave, 2002; Edelstein and Berger, 1993; Stein and Walley, 1983). Evidence is primarily in the form of small case series and does not provide strong conclusions to support the use of these devices for improving quality of life, although some authors have reported greater function and range of motion (Crandall, Tomhave, 2002; Stein and Walley, 1983). Edelstein and Berger (1993) reported that activities such as donning socks, cutting paper and applying bandages were performed more rapidly with a myoelectric device when compared to a body-powered device, although performance with both devices was rated poorer than normal quality. In general, the reported outcomes are subjective and include patient acceptance and reasons for disuse; little data regarding functional status and direct comparisons to body-powered devices or passive devices are available. In addition, patient selection criteria are not clearly defined. Despite these and other confounding variables, however, the published literature tends to support some clinical benefit from the use of a myoelectric prosthesis when compared to a conventional passive or body-powered device.

Use Outside of the US: No relevant information found.

Summary
Evidence in the published, peer-reviewed, scientific literature is mixed in regard to demonstrating the superiority of myoelectric prostheses compared to standard devices, although authors report improved function and range of motion. Additional well-designed, controlled clinical trials would be helpful to determine the overall benefit of these devices compared to standard devices. However, myoelectric prosthetic devices may be indicated for a subset of patients who cannot use body-powered devices or when a standard prosthetic device is insufficient to meet the functional needs of the patient.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Covered when medically necessary, only when coverage is available under the plan for the specific device/component/item. Benefit exclusions and limitations may apply. The devices listed below are specifically excluded under many plans and therefore may not be covered:

HCPCS Codes	Description
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
L6611	Addition to upper extremity prosthesis, external powered, additional switch, any type
L6646	Upper extremity addition, shoulder joint, multipositional locking, flexion, adjustable abduction friction control, for use with body powered or external powered system
L6648	Upper extremity addition, shoulder lock mechanism, external powered actuator
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)
L6881	Automatic grasp feature, addition to upper limb electric prosthetic terminal device
L6882	Microprocessor control feature, addition to upper limb prosthetic terminal device
L6920	Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal switch, cables, two batteries and one charger, switch control of terminal device
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
L6930	Below elbow, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal switch, cables, two batteries and one charger, switch 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
L6940	Elbow disarticulation, external power, molded inner socket, removable humeral shell, outside locking hinges, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch 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
L6950	Above elbow, external power, molded inner socket, removable humeral shell, internal locking elbow, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch 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
L6960	Shoulder disarticulation, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch 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
L6970	Interscapular-thoracic, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch 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
L7040	Prehensile actuator, switch controlled
L7045	Electric hook, switch or myoelectric controlled, pediatric
L7170	Electronic elbow, Hosmer or equal, switch controlled
L7180	Electronic elbow, microprocessor sequential control of elbow and terminal device
L7181	Electronic elbow, microprocessor simultaneous control of elbow and terminal device
L7185	Electronic elbow, adolescent, Variety Village or equal, switch controlled
L7186	Electronic elbow, child, Variety Village or equal, switch controlled
L7190	Electronic elbow, adolescent, Variety Village or equal, myoelectronically controlled
L7191	Electronic elbow, child, Variety Village or equal, myoelectronically controlled
L7260	Electronic wrist rotator, Otto Bock or equal
L7261	Electronic wrist rotator, for Utah arm

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