The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

### Preauthorization

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

### Protocol

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### Description

Myoelectric prostheses are powered by electric motors with an external power source. The joint movement of an 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.

### 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.

**Policy**

Myoelectric upper limb prosthetic components may be considered medically necessary when the following conditions are met:

- The patient has an amputation or missing limb at the wrist or above (e.g., forearm, elbow); 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 effectively; AND
- The patient is free of comorbidities that could interfere with function of the prosthesis (neuromuscular disease, etc.); AND
- Functional evaluation indicates that with training, use of a myoelectric prosthesis is likely to meet the functional needs of the individual (e.g., gripping, releasing, holding, 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.

A prosthesis with individually powered digits, including but not limited to a partial hand prosthesis, is considered investigational.

Myoelectric upper limb prosthetic components are considered not medically necessary under all other conditions.

**Policy Guidelines**

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.

**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 three categories depending on the means of generating movement at the joints: passive, body-powered, and electrically powered movement. All three 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 three 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, particularly the wear temperature, 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 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. 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 two joints at once (i.e., one body-powered, one 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 (e.g., 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.

**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.
Available myoelectric devices include ProDigits™ and i-limb™ (Touch Bionics), the SensorHand™ Speed and Michelangelo® Hand (Otto Bock), the LTI Boston Digital Arm™ System (Liberating Technologies), the Utah Arm Systems (Motion Control), and bebionic (steeper).

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.

Related Protocols

Functional Neuromuscular Electrical Stimulation

Microprocessor-Controlled Prostheses for the Lower Limb

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.