

Corporate Medical Policy

Myoelectric Prosthetic Components for the Upper Limb

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Description of Procedure or Service

Description

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

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 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 (e.g., digits, hand, wrist, elbow, and 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 over 30 years; each possesses unique advantages and disadvantages.

- The passive prosthesis relies on manual repositioning, typically by moving it 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 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.

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- Myoelectric hand attachments have traditionally been similar in form to those offered with the body-powered prosthesis, but with battery power. An example of recent technology is the SensorHand™ from 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 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. These may be covered by livingskin™, a high-definition silicone prosthesis created to resemble a patient's natural skin.
- A hybrid system, a combination of body-powered and myoelectric components, may be used for high-level amputations (i.e., at or above the elbow). Hybrid systems allow control of two joints at once (i.e., one body-powered and 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 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.

The LUKE Arm (previously known as the DEKA Arm System) was developed in a joint effort between DEKA Research and Development and DARPA. 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 LUKE Arm System contains a combination of mechanisms including switches, movement sensors, and force sensors. The primary control resides with inertial measurement sensors on top of the feet. The prosthesis includes vibration pressure and grip sensors.

Myoelectric Orthoses

The MyoPro (Myomo) is a myoelectric powered upper-extremity orthotic. This orthotic device weighs about 1.8 kilograms (4 pounds), has manual wrist articulation, and myoelectric initiated bi-directional elbow movement. The MyoPro detects weak muscle activity from the affected muscle groups. A therapist or prosthetist/orthotist can adjust the gain (amount of assistance), signal boost, thresholds, and range of motion. Potential users include patients with traumatic brain injury, spinal cord injury, brachial plexus injury, amyotrophic lateral sclerosis, and multiple sclerosis. Use of robotic devices for therapy has been reported. The MyoPro is the first myoelectric orthotic available for home use.

REGULATORY STATUS

Manufacturers must register prostheses with the Restorative and Repair 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 the Michaelangelo® Hand (Otto Bock), the LTI Boston Digital Arm™ System (Liberating Technologies Inc.) the Utah Arm Systems (Motion Control), and bebioinic (steeper).

The MyoPro® (Myomo) is registered with the FDA as a class 1 limb orthosis.

Related Policies

Microprocessor-Controlled Prostheses for the Lower Limb

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Neurostimulation, Electrical

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for myoelectric prosthetic components for the upper limb when it is determined to be medically necessary because the criteria and guidelines shown below have been met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Myoelectric Prosthetic Components for the Upper Limb are covered

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 (forearm, elbow, etc.); 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 neurological 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, 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.

When Myoelectric Prosthetic Components for the Upper Limb are not covered

Upper-limb prosthetic components with both sensor and myoelectric control are considered **investigational**.

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

Myoelectric controlled upper-limb orthoses are considered **investigational**.

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Myoelectric prosthetic components for the upper limb are considered **not medically necessary** in individuals who do not meet the criteria listed above.

Policy Guidelines

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 a systematic review and comparative studies. 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; data are limited or lacking in the areas of function and functional status. 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 indicates that the percentage of amputees who accept use of a myoelectric prosthesis is about 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. Because of the differing advantages and disadvantages of the 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 at the wrist or higher who receive sensor and myoelectric controlled upper-limb prosthetic components, the evidence includes a series of publications from a 12-week home study. Relevant outcomes are functional outcomes and quality of life. The prototypes for the advanced prosthesis were evaluated by the U.S. military and Veterans Administration. Demonstration of improvement in function has been mixed. After several months of home use, activity speed was shown to be similar to the conventional prosthesis, and there were improvements in the performance of some activities, but not all. There were no differences between the prototype and the participants' prostheses for outcomes of dexterity, prosthetic skill, spontaneity, pain, community integration, or quality of life. Study of the current generation of the sensor and myoelectric controlled prosthesis is needed to determine whether newer models of this advanced prosthesis lead to consistent improvements in function and quality of life. The evidence is insufficient to determine the effects of the technology on health outcomes.

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.

For individuals with upper-extremity weakness or paresis who receive a myoelectric powered upper-limb orthosis, the evidence includes a small within-subject study. Relevant outcomes are functional outcomes and quality of life. The largest study (N=18) identified tested participants with and without the orthosis but did not provide any training with the device. Performance on the tests was inconsistent. Studies are needed that show consistent improvements in relevant outcome measures. Results should also be replicated in a larger number of patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: L6026 , L6715, L6880, L6925, L6935, L6945, L6955, L6965, L6975, L7007, L7008, L7009, L7045, L7180, L7181, L7190, L7191, L7259, L8701, L8702

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Reference Manual [Electronic Version]. 1.04.04, 1/14/10

Defense Advanced Research Projects Agency (DARPA). Fact Sheet: Revolutionary Prosthetic Program. February, 2008. Retrieved from http://www.darpa.mil/Our_Work/DSO/Programs/Revolutionizing_Prosthetics.aspx

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Dosen S, Cipriani C, Kostić M, Controzzi M, Carrozza MC, Popović DB. Cognitive vision system for control of dexterous prosthetic hands: experimental evaluation. J Neuroeng Rehabil. 2010 Aug 23;7:42. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2940869/?tool=pubmed>

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BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.04, 6/14/12

Specialty Matched Consultant Advisory Panel review 2/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.04, 6/13/13

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BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.04, 9/14/17

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.04, 3/8/2018

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BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.04, 3/14/2019

Specialty Matched Consultant Advisory Panel 7/2019

Policy Implementation/Update Information

- 08/17/10 New policy implemented. Myoelectric prosthetic components for the upper limb may be considered medically necessary in amputees who meet the criteria and guidelines outlined in the policy.(mco)
- 3/15/11 Specialty Matched Consultant Advisory Panel review 2/2011. Added L7180, L7181, L7190, L7191 to “Billing /Coding” section. References updated. (mco)
- 5/24/11 References updated. No changes to policy statement or coverage criteria. (mco)
- 12/30/11 Added new codes L6715 and L6880 to “Billing/Coding” section. Effective date 1/1/2012. (mco)
- 3/20/12 Specialty Matched Consultant Advisory Panel review 2/2012. References updated. No changes to policy statements. (mco)
- 3/12/13 Specialty Matched Consultant Advisory Panel review 2/2013. References updated. Added “Related Policy” to Description section. (mco)
- 8/13/13 Specialty Matched Consultant Advisory Panel review 7/2013. References updated. Medical Director review 7/2013. No changes to Policy Statements. (mco)
- 8/12/14 Specialty Matched Consultant Advisory Panel review 7/2014. Description section updated. References updated. Medical Director review 7/2014.
- 12/30/14 Codes L6026 and L7259 added to Billing/Coding section for effective date 1/1/2015. Code L6025 deleted. (sk)
- 7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. Reference added. Investigational statement “A prosthesis with individually powered digits, including but not limited to a partial hand prosthesis, is considered **investigational**” added to policy. Policy guidelines updated. Notification given 7/28/15 for policy effective date 10/1/15. (sk)
- 7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. (sk)

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- 1/27/17 Reference added. Policy Guidelines updated. (sk)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. (sk)
- 10/27/17 Reference added. (sk)
- 4/13/18 Reference added. Investigational statements added for myoelectric orthoses and for prostheses with both sensor and myoelectric control. (sk)
- 7/13/18 Specialty Matched Consultant Advisory Panel review 6/27/2018. (sk)
- 12/31/18 Codes L8701 and L8702 added to the Billing/Coding section. (sk)
- 5/14/19 Reference added. (sk)
- 9/10/19 Specialty Matched Consultant Advisory Panel review 7/30/2019. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.