BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Myoelectric Prosthetic and Orthotic Components for the Upper Limb

Policy #: 124
Category: DME

Latest Review Date: March 2021
Policy Grade: B

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after March 13, 2018:

Blue Advantage will treat **myoelectric prostheses** as a **covered benefit** for patients with upper limb amputations:

- 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 arms(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 (e.g. neuromuscular disease); 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 coordination 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.
- Children age 2 years or older who have shown at least 6 months successful use of a passive prosthetic device and have a minimum EMG signal of 6μV threshold.

Blue Advantage will cover one myoelectric prosthesis per limb **per five years when medically indicated.** Coverage will not be provided if the prosthesis is functioning properly and in good general condition.

Blue Advantage will treat **a prosthesis with individually powered digits, including but not limited to a partial hand prosthesis,** as a **non-covered benefit** and as **investigational.**

Blue Advantage will treat **high-definition silicone** used to make a prosthesis **resemble a patient's skin** as a **non-covered benefit** and as **cosmetic**.

Blue Advantage will treat **myoelectric prostheses** as **contraindicated** and as a non-covered benefit for patients with upper limb amputations:

- Whose ADLs require frequent lifting of heavy objects (16lbs or greater);
- Whose environments involve frequent contact with dirt, dust, grease, water, and solvent;
- Whose neuromas and/or phantom limb pain are exacerbated with the use of the prosthesis.

Blue Advantage will treat **myoelectric controlled upper-limb orthoses** as a **non-covered benefit** and as **investigational.**

Blue Advantage will treat **upper-limb prosthetic components with both sensor and myoelectric controls (LUKE/DEKA),** as a **non-covered benefit** and as **investigational.**

Blue Advantage will treat **additions or upgrades to the prosthetic for convenience, sports or recreational activities** as a **non-covered benefit** and as **investigational.**

Effective for dates of service June 25, 2012 through March 12, 2018:
Blue Advantage will treat **myoelectric prostheses** as a **covered benefit** for patients with upper limb amputations:

- 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 arms(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 coordination 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.
- Children age 2 years or older who have shown at least 6 months successful use of a passive prosthetic device and have a minimum EMG signal of 6μV threshold.

Blue Advantage will cover one myoelectric prosthesis per limb **per five years when medically indicated.** Coverage will not be provided if the prosthesis is functioning properly and in good general condition.

Blue Advantage will treat **a prosthesis with individually powered digits, including but not limited to a partial hand prosthesis,** as a **non-covered benefit** and as **investigational.**

Blue Advantage will treat **high-definition silicone** used to make a prosthesis **resemble a patient's skin** as a **non-covered benefit** and as **cosmetic**.

Blue Advantage will treat **myoelectric prostheses** as **contraindicated** and as a non-covered benefit for patients with upper limb amputations:

- Whose ADLs require frequent lifting of heavy objects (16lbs or greater);
- Whose environments involve frequent contact with dirt, dust, grease, water, and solvent;
- Whose neuromas and/or phantom limb pain are exacerbated with the use of the prosthesis.

Blue Advantage will treat **myoelectric orthoses for upper extremities** as a **non-covered benefit** and as **investigational.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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 Amputation
The need for a prosthesis can occur for a number of reasons, including trauma, surgery, or congenital anomalies.

Treatment
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 (digits, hand, wrist, elbow, and shoulder), and thus the complexity of joint movement increases.

Upper limb prostheses are classified into 3 categories depending on the means of generating movement at the joints: passive, body-powered, and electrically powered movement. All 3 types of prostheses have been in use for more than 30 years; each possesses unique advantages and disadvantages.

Passive Prostheses
The passive prostheses rely on manual repositioning, typically using the opposite arm and cannot restore function. This unit is the lightest of the 3 prosthetic types and is thus generally the most comfortable.

Body-Powered Prostheses
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
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.

Myoelectric hand attachments are similar in form to those offered with the body-powered prosthesis, but are battery-powered. Commercially available examples include:

- The Michelangelo Hand (Advanced Arm Dynamics)
- i-limb (Touch Bionics)
- benionic (steeper)

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 2 joints at once (i.e., 1 body-powered and 1 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 & Development and the U.S. Department of Defense Advanced Research Projects Agency program. It 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 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/orthoptist 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.

KEY POINTS:

The most recent literature update was performed through December 13, 2020.

Summary of Evidence:

For individuals who have a missing limb at the wrist or higher who receive myoelectric upper-limb prosthesis components at 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 rejection; data are limited or lacking in the areas of function and functional status. The limited evidence suggests that, when compared with body-powered prostheses, myoelectric components possess the similar capability to perform light work; however, myoelectric components could also suffer a reduction in performance when operating under heavy working conditions. The literature has also indicated that the percentage of amputees who accept the 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 partly 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 prosthesiswith equivalent function to a body-powered prosthesis for light work. Because of the different 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 an 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 that the technology results in an 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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements:
No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Myoelectric hand, myoelectric arm, myoelectric elbow, electric prosthesis, electronic prosthesis, Utah Arm and Hand System, Otto Bock myoelectric prosthesis, LTI Boston Digital arm System, SensorHand™, ProDigits™ and i-LIMB™, LIVINGSKIN™, MyoPro™, MyoMo, Inc., LUKE™ arm, The Michelangelo Hand (Advanced Arm Dynamics), DEKA Gen 2 and DEKA Gen 3

APPROVED BY GOVERNING BODIES:

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 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 (DEKA Integrated Solutions, now DEKA Research & Development), now called the LUKE™ Arm (Mobius Bionics), was cleared for marketing by FDA through the de novo 513(f)(2) classification process for novel low- to moderate-risk medical devices that are first-of-a-kind.
The MyoPro® (Myomo) is registered with the FDA as a Class 1 limb orthosis.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

HCPCS codes:

L3999	Upper limb orthosis, not otherwise specified
L6026	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, excludes terminal device(s)
L6621	Upper extremity prosthesis addition, flexion/extension wrist with or without friction, for use with external powered terminal device
L6629	Upper extremity addition, quick disconnect lamination collar with coupling piece, otto bock or equal
L6672	Upper extremity addition, harness, chest or shoulder, saddle type
L6680	Upper extremity addition, test socket, wrist disarticulation or below elbow
L6682	Upper extremity addition, test socket, elbow disarticulation or above elbow
L6684	Upper extremity addition, test socket, shoulder disarticulation or interscapular thoracic
L6686	Upper extremity addition, suction socket
L6687	Upper extremity addition, frame type socket, below elbow or wrist disarticulation

L6688	Upper extremity addition, frame type socket, above elbow or elbow disarticulation
L6689	Upper extremity addition, frame type socket, shoulder disarticulation
L6690	Upper extremity addition, frame type socket, interscapular-thoracic
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
L6890	Terminal device, glove for above hands, production glove
L6895	Terminal device, glove for above hands, custom glove
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
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
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, Boston, Utah or equal, myoelectronically controlled
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
L7259	Electronic wrist rotator, any type
L7261	Electronic wrist rotator, for Utah arm
L7360	Six volt battery, otto bock or equal, each
L7362	Battery charger, six volt, otto bock or equal
L7364	Twelve volt battery, Utah or equal, each
L7366	Battery charger, twelve volt, Utah or equal
L7499	Upper extremity prosthesis, not otherwise specified
L8465	Prosthetic shrinker, upper limb, each
L8701	Elbow, wrist, hand device, powered, with single or double upright(s), any type joint(s), includes microprocessor, sensors, all components and accessories Revised 10/1/2020
L8702	Elbow, wrist, hand, finger device, powered, with single or double upright(s), includes microprocessor, sensors, all components and accessories Revised 10/1/2020)

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, April 2006
Medical Policy Group, April 2007
Medical Policy Group, April 2009
Medical Policy Group, March 2010
Available for comment April 7-May 21, 2010
Medical Policy Group, June 2011
Medical Policy Group, December 2011
Medical Policy Panel, June 2012
Medical Policy Group, June 2012
Available for comment June 29, 2012 through August 12, 2012
Medical Policy Group, September 2013
Medical Policy Group, June 2014
Medical Policy Group, November 2014
Medical Policy Group, June 2015
Medical Policy Group, August 2015
Medical Policy Group, December 2016
Medical Policy Group, September 2017
Medical Policy Group, April 2018
Medical Policy Group, December 2018: 2019 CPT Coding Update
Medical Policy Group, April 2019
Medical Policy Group, March 2020
Medical Policy Group, October 2020: Coding Update
Medical Policy Group, March 2021
Medical Policy Group, January 2022: Updates to Current Coding (added L6621, L6881-L6882, L7181)

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.