BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 1.04.04 Myoelectric Prosthetic and Orthotic Components for the Upper Limb

Annual Effective Policy Date: July 1, 2024

Original Policy Date: December 2011

Related Policies:

1.04.05 - Microprocessor-Controlled Prostheses for the Lower Limb
8.03.01 - Functional Neuromuscular Electrical Stimulation

Myoelectric Prosthetic and Orthotic Components for the Upper Limb

Description

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

OBJECTIVE

The objective of this evidence review is to determine whether myoelectric upper-limb prostheses and orthoses improve the net health outcome in individuals with upper-limb amputations, weakness, or paresis.

POLICY STATEMENT

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

- The individual has an amputation or missing limb at the wrist or above (eg, 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 individual has demonstrated sufficient neurologic and cognitive function to operate the prosthesis effectively; and
- The individual is free of comorbidities that could interfere with function of the prosthesis (eg, neuromuscular disease); and
- Functional evaluation indicates that with training, use of a myoelectric prosthesis is likely to meet the functional needs of the individual (eg, gripping, releasing, holding, coordinating movement of the prosthesis) when performing activities of daily living. This evaluation should consider the individual needs for control, durability (maintenance), function (speed, work capability), and usability.

Advanced upper-limb prosthetic components with both sensor and myoelectric control (e.g., LUKE Arm) 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**.

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 (eg, 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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

In this policy, procedures are considered reconstructive when intended to address a significant variation from normal related to accidental injury, disease, trauma, treatment of a disease, or congenital defect, irrespective of whether a functional impairment is present. This reconstructive benefit may be applied in cases in which the myoelectric prosthesis is requested based on appearance. Not all benefit contracts include benefits for reconstructive services as defined by this policy. Benefit language supersedes this document.

FDA REGULATORY STATUS

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, but are not limited to, 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 (Ottobock).

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.

FDA product codes: GXY, IQZ.

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

RATIONALE

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 prosthesis with 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
September 2013	Replace policy	Policy updated with literature review. Reference 4 added; title changed to "Myoelectric Prosthetic Components for the Upper Limb€š; policy statements unchanged
June 2015	Replace policy	Policy updated with literature review, no references added; policy statement added on powered digits, included but not limited to a partial hand prosthesis added as not medically necessary.
March 2017	Replace policy	Policy updated with literature review; no references added. Policy statements unchanged.
December 2017	Replace policy	Policy updated with literature review through July 21, 2017; no references added. Policy statements unchanged except "Prosthesis with individually powered digits€š was corrected from not medically necessary to investigational.
June 2018	Replace policy	Policy updated with literature review through January 25, 2018;references 5 and 7-13 added. Investigational statements added for myoelectric orthoses and prostheses with both sensor and myoelectric control. Title changed to "Myoelectric Prosthetic and Orthotic Components for the Upper Limb".
June 2019	Replace policy	Policy updated with literature review through January 6, 2019; no references added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through February 20, 2020; no references added. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through December 13, 2020; no references added. Policy statements unchanged.
June 2022	Replace policy	Policy updated with literature review through December 20, 2021; no references added. 'Not medically necessary' policy statement updated to 'Investigational' per current policy language standards and clarification added that second policy statement pertains to second PICO involving advanced prosthetic components with both sensor and myoelectric control (e.g., LUKE Arm), intent unchanged.
June 2023	Replace policy	Policy updated with literature review through December 19, 2022; no references added. Policy statements unchanged.
June 2024	Replace policy	Policy updated with literature review through January 29, 2024; no references added. Minor editorial refinements to policy statements; intent unchanged.