Myoelectric Prosthetic and Orthotic Components for the Upper Limb

Effective: October 1, 2018

Next Review: June 2019
Last Review: June 2018

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

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

MEDICAL POLICY CRITERIA

Note: The plan provides coverage for either an upper limb prosthesis with myoelectric components if criteria are met or for a mechanical prosthesis without myoelectric function, but not for both for a single limb.

I. Myoelectric upper limb prostheses may be medically necessary when all of the following criteria are met (A - F):

A. The patient has an amputation or missing limb at the wrist or above (forearm, elbow, etc.); and
B. 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

C. The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device, as demonstrated by functional testing using a physical or computer model prosthesis; and

D. The patient has demonstrated sufficient neurological and cognitive function to operate the prosthesis effectively; and

E. The patient is free of comorbidities that could interfere with function of the prosthesis (neuromuscular disease, etc.); and

F. Functional evaluation by a qualified professional (e.g., prosthetist) indicates that with training, use of a myoelectric prosthesis and associated components is necessary to meet the functional needs of the individual (e.g., automatic grasp features, microprocessor control features, or other components to aid 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. Both of the following criteria must be met (1 and 2):

1. The device is necessary for the patient to perform instrumental activities of daily living including job functioning; and

2. The device is not primarily for the purpose of allowing the patient to perform leisure or recreational activities.

II. Myoelectric upper limb prosthetic components are considered not medically necessary under all other conditions including but not limited to replacement of an existing, functioning prostheses (e.g., as an "upgrade" for a prosthesis that still works and fits).

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

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

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Documentation of amputation or missing limb at the wrist or above
- Documentation that standard body-powered devices can’t be used or are not efficient including the ADLs that cannot be accomplished currently
- Documentation that the remaining musculature in the limb contains the minimum microvolt threshold to allow operation of the device including a functional test using a physical or computer model prosthesis
• Documentation the patient is cognitively and neurologically able to operate the prosthetic
• Documentation the patient doesn’t have any comorbidities that might interfere with the use of the prosthetic
• An evaluation by a qualified professional such as a prosthetist that show the patient will be able to use the prosthetic for ADLs including the patient’s ability to control, maintain, function, and use the prosthetic including why it is necessary for the patient to perform ADLs or job functions and evidence it is not being requested only for leisure or recreational activities
• Documentation that the prosthetic is not being requested to replace a functioning prosthetic

CROSS REFERENCES

1. Powered Knee Prosthesis, or Powered Ankle-Foot Prosthesis, and Microprocessor-Controlled Ankle-Foot Prosthesis, DME, Policy No. 81

BACKGROUND

Upper limb prostheses are used following amputation 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 prosthesis 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 based on the means of generating movement at the joints as follows:

PASSIVE PROSTHESIS:

• The lightest weight upper extremity prosthesis
• Patients generally describe this as the most comfortable of the three types
• Must be repositioned manually, typically by moving it with the opposite arm
• Cannot restore function.

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 PROSTHESIS

Uses 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.

Implantable EMG sensors with wireless signal transmission (e.g., Implantable Myoelectric Sensors [IMES®]) are being studied as alternatives to surface electrodes to improve prosthetic hand function. These implantable sensors may eliminate the limitations inherent in surface electrodes such as issues related to poor skin contact (e.g., skin sweating) and the ability to detect signals only from superficial muscles.

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.

Patient dissatisfaction with myoelectric prostheses includes the increased cost, maintenance (particularly for the glove), and weight.

Examples of available technologies:

- The SensorHand™ by 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 Utah Arm 3 by Motion Control has a microprocessor interface that allows individualized adjustments to achieve maximum performance.
- 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.
- Otto Bock has a number of myoelectric hand and elbow prostheses including the AutoGrasp feature, the Michelangelo® Hand, and the Electrohand 2000 designed for children.
- LTI Boston Digital Arm™ System by Liberating Technologies Inc. is marketed as having greater torque than any other powered prosthetic elbows.
- These devices may be covered by LIVINGSKIN™, a high-definition silicone prosthesis created to resemble a patient’s natural skin.

SENSOR AND MYOELECTRIC PROSTHESIS

The LUKE Arm (previously known as the DEKA Arm System) 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 Luke Arm is the same shape and weight as an adult arm.

HYBRID SYSTEM, A COMBINATION OF BODY-POWERED AND MYOELECTRIC COMPONENTS

- May be used for high-level amputations (at or above the elbow).
- Allows control of two joints at once (i.e., one body-powered and one myoelectric)
- Generally lighter weight and less expensive than a prosthesis composed entirely of myoelectric components.
• An example of a hybrid system is the ErgoArm by Otto Bock which has a myoelectric hand and a cable-controlled elbow joint.

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.

**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.

**Regulatory Status**

Prostheses are class I devices that are exempt from U.S. Food and Drug Administration (FDA) marketing clearance, but manufacturers must register prostheses with the restorative devices branch of the FDA and keep a record of any complaints.

Examples of available myoelectric devices are listed above.

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

**EVIDENCE SUMMARY**

In evaluating the effects of the increased sophistication of myoelectric upper limb prostheses compared with body-powered prostheses, passive prostheses, or no prosthesis, the most informative data are from prospective comparative studies with objective and subjective measures that directly address function and health-related quality of life.

In light of the magnitude of functional loss in upper extremity amputation, evaluation of the evidence is based on two assumptions:

1. Use of any prosthesis confers clinical benefit, and
2. Self-selected use is an acceptable measure of the perceived benefit (combination of utility, comfort, and appearance) of a prosthesis for that individual.

It should be considered that the upper limb amputee’s needs may depend on their situation. For example, increased functional capability may be needed with heavy work or domestic duties, while a more natural appearing prosthesis with reduced functional capability may be acceptable for an office, school, or another social environment.
MYOELECTRIC UPPER LIMB PROSTHESIS

Systematic Reviews

A 2015 systematic review (SR) by Carey evaluated differences between myoelectric and body-powered prostheses. The SR included 31 studies.[1] The evidence was conflicting for functional performance between the two prostheses. The authors concluded that there is insufficient evidence to show that one system provides a significant advantage over the other and that prosthetic selection should be based on patient preference and functional needs.

A 2007 SR by Biddis of 40 articles published over the previous 25 years assessed upper limb prosthesis acceptance and abandonment.[2] For pediatric patients the mean rejection rate was 38% for passive prostheses (one study), 45% for body-powered prostheses (three studies), and 32% for myoelectric prostheses (12 studies). For adults there was considerable variation between studies, with mean rejection rates of 39% (six studies), 26% (eight studies), and 23% (10 studies) for passive, body-powered and myoelectric prostheses, respectively. The authors found no evidence that the acceptability of passive prostheses had declined over the period from 1983 to 2004, “despite the advent of myoelectric devices with functional as well as cosmetic appeal.” Body-powered prostheses were also found to have remained a popular choice, with the type of hand-attachment being the major factor in acceptance. Body-powered hooks were considered acceptable by many users, but body-powered hands were frequently rejected (80%–87% rejection rates) due to slowness in movement, awkward use, maintenance issues, excessive weight, insufficient grip strength, and the energy needed to operate. Rejection rates of myoelectric prostheses tended to increase with longer follow-up. There was no evidence of a change in rejection rates over the 25 years of study, but the results are limited by sampling bias from isolated populations and the generally poor quality of the studies included.

Randomized Controlled Trials

In comparative studies of prostheses, subjects served as their own control. Since these studies included use by all subjects of both a myoelectric and a body-powered prosthesis, randomization was directed at the order in which each amputee used the prostheses. Two trials were found in which a total of 196 children used both a myoelectric and a body-powered hand prosthesis, in randomized order, for a period of three months each.[3,4] No clinically relevant objective or subjective difference was found between the two types of prostheses.

Nonrandomized Studies

A number of small (n<50) non-randomized case series[5-7] and online or mailed surveys[8-11] were found, but few studies directly addressed whether myoelectric prostheses improved function and health-related quality of life. Most of the studies identified described amputees’ self-selected use or rejection rates. The results were usually presented as hours worn at work or school, hours worn at home, and hours worn in social situations. Amputees’ self-reported reasons for use and abandonment were also frequently reported. 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 indicated that the percentage of amputees who accepted use of a myoelectric prosthesis was about the same as those who prefer to use a body-powered prosthesis, and that self-selected use depended at least in part on the individual’s activities of daily living. Appearance was most
frequently cited as an advantage of myoelectric prostheses. Nonuse of any prosthesis was associated with lack of functional need, discomfort (excessive weight and heat), and impediment to sensory feedback.

Section Summary: Myoelectric Upper-Limb Prosthesis

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 the percentage of amputees who accept 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. When compared with body-powered prostheses, myoelectric components possess similar capability to perform light work, and myoelectric components may improve range of motion. The literature has also indicated that 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.

SENSOR AND MYOELECTRIC UPPER LIMB COMPONENTS

Investigators from three Veterans Administration medical centers and the Center for the Intrepid at Brooke Army Medical Center published a series of reports on home use of the LUKE prototype (DEKA Gen 2 and DEKA Gen 3) in 2017 and 2018.[12-16] Participants were included in the in-laboratory training if they met criteria and had sufficient control options (e.g., myoelectric and/or active control over one or both feet) to operate the device. In-lab training included a virtual reality training component. At the completion of the in-lab training, the investigators determined, using a priori criteria, which participants were eligible to continue to the 12-week home trial. The criteria included the independent use of the prosthesis in the laboratory and community setting, fair, functional performance, and sound judgment when operating or troubleshooting minor technical issues. On ClinicalTrials.gov, the total enrollment target is listed as 100 patients with study completion by February 2018 (NCT01551420).

One of the publications (Resnick, 2017) reported on the acceptance of the LUKE prototype before and after a 12-week trial of home use.[14] Of 42 participants enrolled at the time, 32 (76%) participants completed the in-laboratory training, 22 (52%) wanted to receive a LUKE Arm and proceeded to the home trial, 18 (43%) completed the home trial, and 14 (33%) expressed a desire to receive the prototype at the end of the home trial. Over 80% of those who completed the home trial preferred the prototype arm for hand and wrist function, but as many preferred the weight and look of their own prosthesis. One-third of those who completed the home training thought that the arm was not ready for commercialization. Participants who completed the trial were more likely to be prosthesis users at study onset (p=0.03), and less likely to have musculoskeletal problems (p=0.047).[12] Reasons for attrition during the in-laboratory training were reported in a separate publication by Resnik and Klinger (2017).[15] Attrition was related to the prosthesis entirely or in part by 67% of the participants, leading to a recommendation to provide patients with an opportunity to train with the prosthesis before a final decision about the appropriateness of the device.

Functional outcomes of the Gen 2 and Gen 3 arms, as compared with participants’ prostheses, were reported by Resnick et al (2018).[13] At the time of the report, 23 regular prosthesis users had completed the in-lab training, and 15 had gone on to complete the home use portion of the study. Outcomes were both performance-based and self-reported measures. At the end of the
lab training, dexterity was similar, but performance was slower with the LUKE prototype than
with their conventional prosthesis. At the end of the home study, activity speed was similar to
the conventional prostheses, and one of the performance measures (Activities Measure for
Upper-Limb Amputees) was improved. Participants also reported that they were able to
perform more activities, had less perceived disability, and less difficulty in activities, but there
were no differences between the two prostheses on many of the outcome measures including
dexterity, prosthetic skill, spontaneity, pain, community integration, or quality of life. Post hoc
power analysis suggested that evaluation of some outcomes might not have been sufficiently
powered to detect a difference.

In a separate publication, Resnick et al (2017) reported that participants continued to use their
prosthesis (average, 2.7 h/d) in addition to the LUKE prototype, concluding that availability of
both prostheses would have the greatest utility.[16] This conclusion is similar to those from
earlier prosthesis surveys, which found that the selection of a specific prosthesis type
(myoelectric, powered, or passive) could differ depending on the specific activity during the
day. In the DEKA Gen 2 and Gen 3 study reported here, 29% of participants had a body-
powered device, and 71% had a conventional myoelectric prosthesis.

Section Summary: Sensor and Myoelectric Upper-Limb Components

The LUKE Arm was cleared for marketing in 2014 and is now commercially available. The
prototypes for the LUKE Arm, the DEKA Gen 2 and Gen 3, were evaluated by the U.S. military
and Veteran’s Administration in a 12-week home study, with study results reported in a series
of publications. Acceptance of the advanced prosthesis in this trial was mixed, with one-third of
enrolled participants desiring to receive the prototype at the end of the trial. Demonstration of
improvement in function has also been mixed. After several months of home use, activity
speed was shown to be similar to the conventional prosthesis. There was an improvement in
the performance of some, but not all, activities. Participants continued to use their prosthesis
for part of the day, and some commented that the prosthesis was not ready for
commercialization. There were no differences between the LUKE Arm prototype and the
participants’ prostheses for many outcome measures. Study of the current generation of the
LUKE Arm is needed to determine whether the newer models of this advanced prosthesis lead
to consistent improvements in function and quality of life.

MYOELECTRIC ORTHOTIC

Peters (2017) evaluated the immediate effect (no training) of a myoelectric elbow-wrist-hand
orthosis on paretic upper-extremity impairment.[17] Participants (n=18) were stable and
moderately impaired with a single stroke 12 months or later before study enrollment. They
were tested using a battery of measures without, and then with the device; the order of testing
was not counterbalanced. The primary measure was the upper-extremity section of the Fugl-
Meyer Assessment, a validated scale that determines active movement. Upper-extremity
movement on the Fugl-Meyer Assessment was significantly improved while wearing the
orthotic (a clinically significant increase of 8.71 points, p<0.001). The most commonly observed
gains were in elbow extension, finger extension, grasping a tennis ball, and grasping a pencil.
The Box and Block test (moving blocks from one side of a box to another) also improved
(p<0.001). Clinically significant improvements were observed for raising a spoon and cup, and
there were significant decreases in the time taken to grasp a cup and gross manual dexterity.
Performance on these tests changed from unable to able to complete. The functional outcome
measures (raising a spoon and cup, turning on a light switch, and picking up a laundry basket
with two hands) were developed by the investigators to assess these moderately impaired participants. The authors noted that performance on these tasks was inconsistent, and proposed a future study that would include training with the myoelectric orthosis before testing.

Page (2013) compared the efficacy of a myoelectric orthosis combined with repetitive task-specific practice to repetitive task-specific practice alone in improving performance following stroke.[18] Sixteen subjects at a mean of 75 months post-stroke were divided into two groups. Both groups received therapist-supervised repetitive task-specific practice for three days a week for eight weeks. One group used the orthotic during practice. After intervention, there was no significant difference between groups in Fugl-Meyer score increases, six measures of the Stroke Impact Scale, or Canadian Occupational Performance Measure Performance. There was a significant difference in the Stroke Impact Scale Total (p=0.027).

Section Summary: Myoelectric Orthotic

The largest study identified tested participants with and without the orthosis. This study evaluated the function with and without the orthotic in stable poststroke participants who had no prior experience with the device. Outcomes were inconsistent. Studies are needed that show consistent improvements in relevant outcome measures. Results should also be replicated in a larger number of patients.

PRACTICE GUIDELINE SUMMARY

No practice guidelines identified.

SUMMARY

There is enough research to show that myoelectric upper limb prostheses improve health outcomes for people with an amputation or missing limb at the wrist or above when the medical policy criteria are met. Therefore, myoelectric upper limb prostheses may be considered medically necessary when policy criteria are met. Myoelectric upper limb prostheses, under all other conditions including but not limited to replacement of an existing functioning prostheses are considered not medically necessary when policy criteria are not met.

There is not enough research to show that upper-limb prosthetic components with both sensor and myoelectric control improve health outcomes compared with conventional prostheses. Therefore, upper-limb prosthetic components with both sensor and myoelectric control are considered investigational.

There is not enough research to show that myoelectric controlled upper-limb orthoses improve health outcomes for people with upper limb weakness or paresis. Only two comparative studies have been published examining myoelectric orthoses. They had small sample sizes and demonstrated inconsistent performance. Therefore, myoelectric controlled upper-limb orthoses are considered investigational.

REFERENCES


### CODES

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*Date of Origin: June 2010*