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# Myoelectric Prosthetic and Orthotic Components for Upper Limb

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<b>Related Policies (if applicable)</b>
None

## Disclaimer

**Carefully check state regulations and/or the member contract.** Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

## Legislative Mandates

**EXCEPTION:** For members **residing in the state of Arkansas**, § 23-99-417 relating to orthotic devices, orthotic services, prosthetic devices, and prosthetic services, requires coverage for an orthotic device or service, a prosthetic device or service, prosthetic device for athletics or recreation, or a prosthetic device for showering or bathing. "Prosthetic device for athletics or recreation" means a device that provides an individual with the ability or potential for prosthesis ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels including the use of a blade-type foot designed for running and other high activity or high-impact endeavors. A candidate for a recreational prosthesis shall qualify in the Medicare functional level status as a K-3 or K-4

functional level as a user who: 1) Can achieve any high-level activity pursuits; and 2) Exhibits an ability to perform above and beyond normal ambulation. Coverage is not required for a device or service more than once every three [3] years unless medically necessary. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

**EXCEPTION:** For members **residing in the state of Arkansas**, § 23-99-405 related to coverage of mastectomy and reconstruction services, should an enrollee elect reconstruction after a mastectomy, requires coverage for surgery and reconstruction of the breast on which the mastectomy has been performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, and prostheses and coverage for physical complications at all stages of a mastectomy, including lymphedema. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

**EXCEPTION:** For members **residing in the state of Maine**, 24-A s 4315 requires a carrier shall provide coverage for prosthetic devices in all health plans that, at a minimum equals the coverage and payment for prosthetic devices provided under federal laws and regulations for the aged and disabled pursuant to 42 United States Code, Sections 1395k, 1395l and 1395m and 42 Code of Federal Regulations, Sections 414.202, 414.210, 414.228 and 410.100. Covered benefits must be provided for: (1) A prosthetic device determined by the enrollee's provider to be the most appropriate model that adequately meets the medical needs of the enrollee; and (2) With respect to an enrollee under 18 years of age, in addition to coverage of a prosthetic device required by paragraph (2), a prosthetic device determined by the enrollee's provider to be the most appropriate model that meets the medical needs of the enrollee for recreational purposes, as applicable, to maximize the enrollee's ability to ambulate, run, bike and swim and to maximize upper limb function. A carrier may require prior authorization for prosthetic devices in the same manner as prior authorization is required for any other covered benefit. Coverage under this section must also be provided for repair or replacement of a prosthetic device if repair or replacement is determined appropriate by the enrollee's provider. For an enrollee under 18 years of age, coverage is not required pursuant to this section for a prosthetic device that is designed exclusively for an athletic purpose. "Prosthetic device" means an artificial device to replace, in whole or in part, an arm or a leg. This applies to Fully Insured Small Group, Mid-Market, Large Group, Student PPO, HMO, POS, EPO.

**EXCEPTION: Illinois:** 215 ILCS 5/356z.18 Prosthetic and Customized Orthotic Devices (SB 2195) requires that with respect to any an enrollee at any age, in addition to coverage of a prosthetic or custom orthotic device, benefits shall be provided for a prosthetic or custom orthotic device determined by the enrollee's provider to be the most appropriate model that is medically necessary for the enrollee to perform physical activities, as applicable,

such as running, biking, swimming, and lifting weights, and to maximize the enrollee's whole body health and strengthen the lower and upper limb function. Repairs and replacements of prosthetic and orthotic devices are also covered, subject to the co-payments and deductibles, unless necessitated by misuse or loss. For the purposes of this section, customized orthotic device means a supportive device for the body or a part of the body, the head, neck, or extremities, and includes the replacement or repair of the device based on the patient's physical condition as medically necessary, excluding foot orthotics defined as an in-shoe device designed to support the structural components of the foot during weight-bearing activities. Licensed provider means a prosthetist, orthotist, or pedorthist licensed to practice in this State. Prosthetic device means an artificial device to replace, in whole or in part, an arm or leg and includes accessories essential to the effective use of the device and the replacement or repair of the device based on the patient's physical condition as medically necessary. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

## Coverage

### **Myoelectric Upper-Limb Prosthetic Components**

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

- The individual has an amputation or missing limb at the wrist or above (e.g., 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 individual has demonstrated sufficient neurological and cognitive function to operate the prosthesis effectively; **and**
- The individual is free of comorbidities that could interfere with function of the prosthesis (e.g., 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 individual's 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 experimental, investigational and/or unproven.**

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

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

### **Myoelectric Upper-Limb Orthoses**

Myoelectric controlled upper-limb orthoses **are considered experimental, investigational and/or unproven.**

## **Policy Guidelines**

Upper-limb 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.

## **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., hand, wrist, and/or elbow) is driven by microchip-processed electrical activity in the muscles of the remaining limb or 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 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 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 prostheses use 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 control of joint movement. Electromyographic 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 1 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 for control of 2 joints at once (i.e., 1 body-powered, 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, 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 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 electromyographic 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/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, but are not limited to, i-Digits®Quantum and i-limb™ (Touch Bionics [now part of Össur]), the SensorHand™ Speed and Michelangelo® Hand (Otto Bock), the LTI Boston Digital Arm™ System (Liberating Technologies [now Coapt]), the Utah Arm Series 3 (Fillauer 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

### **Myoelectric Proximal Upper-Limb Prosthesis**

The purpose of myoelectric upper-limb prosthesis components at or proximal to the wrist is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with a missing limb at the wrist or higher.

### **Review of Evidence**

#### Systematic Reviews

A 2007 systematic review of 40 articles published over the previous 25 years assessed upper-limb prosthesis acceptance and abandonment (see Table 1). (1) For pediatric patients, the mean rejection rate was 38% for passive prostheses (1 study), 45% for body-powered prostheses (3 studies), and 32% for myoelectric prostheses (12 studies) (see Table 2). For adults, there was considerable variation between studies, with mean rejection rates of 39% for passive (6 studies), 26% for body-powered (8 studies), and 23% for myoelectric (10 studies) prostheses. Reviewers 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 were limited by sampling bias from isolated populations and the generally poor quality of studies selected.

#### *Within-Subject Comparisons*

One prospective controlled study (1993) compared preferences for body-powered with myoelectric hands in children. (2) Juvenile amputees (toddlers to teenagers) were fitted in a randomized order with 1 of the 2 types of prostheses; after a 3-month period, the terminal devices were switched, and the children selected 1 of the prostheses to use. At the time of follow-up, more than a third of children were wearing the myoelectric prosthesis, a third were wearing a body-powered prosthesis, and 22% were not using a prosthesis (see Table 2). There was no difference in the children’s ratings of the myoelectric and body-powered devices.

Silcox et al. (1993) conducted a within-subject comparison of preference for body-powered or myoelectric prostheses in adults. (3) Of 44 patients fitted with a myoelectric prosthesis, 91% also owned a body-powered prosthesis, and 20% owned a passive prosthesis. Rejection rates of these prostheses are shown in Table 2. Use of a body-powered prosthesis was unaffected by the type of work; good-to-excellent use was reported in 35%

of patients with heavy work demands and 39% of patients with light work demands. In contrast, the proportion of patients using a myoelectric prosthesis was higher in the group with light work demands (44%) than in those with heavy work demands (26%). There was also a trend toward the higher use of the myoelectric prosthesis compared with a body-powered prosthesis in social situations. Appearance was cited more frequently as a reason for using a myoelectric prosthesis than any other factor. Weight and speed were more frequently cited than any other factors as reasons for nonuse of the myoelectric prosthesis.

McFarland et al. (2010) conducted a cross-sectional survey of major combat-related upper-limb loss in veterans and service members from Vietnam (n=47) and Iraq (n=50) recruited through a national survey. (4) In the first year of limb loss, the Vietnam group received a mean of 1.2 devices (usually body-powered), while the Iraq group received a mean of 3.0 devices (typically 1 myoelectric/hybrid, 1 body-powered, 1 cosmetic). Preferences in the Iraq group are shown in Table 2. At the time of the survey, upper-limb prosthetic devices were used by 70% of the Vietnam group and 76% of the Iraq group. The most common reasons for rejection included short residual limbs, pain, poor comfort (e.g., the weight of the device), and lack of functionality.

**Table 1. Summary of Key Study Characteristics**

Author	Study Type	N	Dates	Participants	Intervention	Follow-up
<i>Rejection rates</i>						
Biddiss et al. (2007) (1)	Systematic review	40 articles	1983-2004	Pediatric and adult		25 years
Silcox et al. (1993) (3)	Within-subject comparison	44		Adult	All fitted with a myoelectric prosthesis	
Sjoberg et al. (2017) (5)	Prospective case-controlled	9 children <2.5 years; 27 children >2.5 to 4 years	1994-2002	Pediatric	Training with a myoelectric prosthesis	Until 12 years of age
<i>Acceptance rates</i>						
Kruger and Fishman (1993) (2)	Randomized within-subject comparison	78		Pediatric	Trial period for both myoelectric and body-powered	2 years

McFarland et al. (2010) (4)	Cross-sectional survey	50		Veterans and service members	Provided with all 3 device types	
Egermann et al. (2009) (6)	Parental questionnaire	41		Pediatric (2-5 years)	Training with a myoelectric prosthesis	2 years (range 0.8-5)

**Table 2. summary of Key Study Outcomes**

Author	Outcomes	Adult or Pediatric	Myoelectric	Body-Powered	Passive	None
<i>Rejection rates</i>						
Biddiss et al. (2007) (1)	Mean rejection rates	Pediatric	32%	45%	38%	
		Adult	23%	26%	39%	
Silcox et al. (1993) (3)	Rejection of own prosthesis	Adult	22 (50%)	13 (32%)	5 (55%)	
Sjoberg et al. (2017) (5)	Rejection of a myoelectric prosthesis	<2.5years	3 (33%)			
		2.5 to y years	4 (15%)			
<i>Acceptance and preference rates</i>						
Kruger and Fishman (1993) (2)	Preference rates		34(44%)	26 (34%)		18 (22%)
McFarland et al. (2010) (4)	Preference rates	Iraq veterans	18 (36%)	15 (30%)		11 (22%)
Egermann et al. (2009) (6)	Acceptance	Pediatric	31 (76%)			

Values are percent or n (%).

#### *Acceptance Rates in Children*

Sjoberg et al. (2017) conducted a prospective long-term case-control study to determine whether fitting a myoelectric prosthesis before 2.5 years of age improved prosthesis acceptance rates compared with the current Scandinavian standard of fitting between 2.5 and 4 years old. (5) All children had a congenital amputation and had used a passive hand

prosthesis from 6 months of age, and both groups (case, n=9; control, n=27) were fitted with the same type of prosthetic hand and received structured training beginning at 3 years of age. They were followed every 6 months between 3 and 6 years of age and then as needed for service or training for a total of 17 years. Prosthetic skill measured by the Skills Index Ranking Scale (SIRS) increased over time, however, there were no statistically significant differences between groups. By 12 years of age, all but 1 child in the case group and all but 2 children in the control group achieved maximum performance on the SIRS (level 14, the ability to throw objects from above the shoulder). To note, 3 (33%) children in the case group and 4 (15%) in the control group were lost to follow-up at after 9 years of age due to prosthetic rejection. This difference was not statistically significant in this small study. Overall, study results did not favor earlier intervention with a myoelectric prosthesis.

Egermann et al. (2009) evaluated the acceptance rate of a myoelectric prosthesis in 41 children between 2 and 5 years of age. (6) To be fitted with a myoelectric prosthesis, the children had to communicate well and follow instructions from strangers, have interest in an artificial limb, have bimanual handling (use of both limbs in handling objects), and have a supportive family setting. A 1- to 2-week interdisciplinary training program (inpatient or outpatient) was provided for the child and parents. At a mean 2-year follow-up (range, 0.7-5.1 years), a questionnaire was distributed to evaluate acceptance and use during daily life (100% return rate). Successful use, defined as a mean daily wearing time of more than 2 hours, was achieved in 76% of the study group. The average daily use was 5.8 hours per day (range, 0-14 h/d). The level of amputation significantly influenced the daily wearing time, with above elbow amputees wearing the prosthesis for longer periods than children with below-elbow amputations. Three (60%) of 5 children with amputations at or below the wrist refused use of any prosthetic device. There were statistically nonsignificant trends for increased use in younger children, in those who had inpatient occupational training, and in children who had a previous passive (vs body-powered) prosthesis. During the follow-up period, maintenance averaged 1.9 times per year (range, 0-8 repairs); this was correlated with the daily wearing time. The authors noted that more important selection criteria than age were the activity and temperament of the child (eg, a myoelectric prosthesis would more likely be used in a calm child interested in quiet bimanual play, whereas a body-powered prosthesis would be more durable for outdoor sports, and in sand or water).

#### Section Summary: Myoelectric Proximal 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**

The purpose of implantation of sensor and myoelectric controlled upper-limb prosthetic components is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with a missing limb at the wrist or higher who receive sensor and myoelectric controlled upper-limb prosthetic components.

#### Review of Evidence

Investigators from 3 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. (7-12) 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 1 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.

Resnick et al. (2017) reported on the acceptance of the LUKE prototype before and after a 12-week trial of home use. (7) 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 ( $p=.03$ ), and less likely to have musculoskeletal problems ( $p=.047$ ). (8) Reasons for attrition during the in-laboratory training were reported in a separate publication by Resnik and Klinger (2017). (9) 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). (10) 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 1 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 2 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. (11) 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 Hand with Individual Digit Control**

The purpose of a myoelectric upper-limb prosthesis with individually powered digits is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with a missing hand distal to the wrist.

#### Review of Evidence

Although the availability of a myoelectric hand with individual control of digits has been widely reported in lay technology reports, video clips, and basic science reports, no peer-reviewed publications were found to evaluate functional outcomes of individual digit control in amputees.

## **Myoelectric Orthotic**

The purpose of a myoelectric powered upper-limb orthotic device is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals who are stable post-stroke, who have upper-limb weakness or paresis.

### Review of Evidence

Peters et al. (2017) evaluated the immediate effect (no training) of a myoelectric elbow-wrist-hand orthosis on paretic upper-extremity impairment. (13) 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,  $p < .001$ ). 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 1 side of a box to another) also improved ( $p < .001$ ). 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 2 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.

Androwis et al. (2025) published a pilot study (N=10) evaluating myoelectric-powered wearable orthosis (MPWO) in patients with chronic incomplete spinal cord injury. (14) Patients were randomly assigned to clinic-only MPWO (n=3), the MPWO worn both at home and in the clinic (n=4), or to traditional occupational therapy (n=3). All patients received 18 training sessions over 6 weeks. The device was applied to the patients more impaired side when possible. On the MPWO-trained side, average increases of about 30% to 37% were observed in maximum handgrip active range of motion and about 28% to 30% in maximum grip force after training amongst all patients with MPWO (n=7). The clinic plus home MPWO group tended to exhibit the greatest gains. The non-MPWO trained side in the MPWO groups also showed indirect improvements, with modest increases of about 7% to 12% in active range of motion and grip force measures (suggesting a possible cross-education effect). In contrast, the occupational therapy control group showed minimal changes (<10% on average).

### 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 post-stroke participants who had no prior experience with the device. Outcomes were inconsistent. A more recent pilot

study with orthosis in patients with spinal cord injury indicated benefit with orthosis compared with occupational therapy, but the sample size was too small to draw any conclusions. Studies are needed that show consistent improvements in relevant outcome measures. Results should also be replicated in a larger number of patients.

### **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 and a randomized pilot 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.

### Professional Guidelines and Position Statements

There are no professional guidelines and position statements that would likely influence this policy.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 3.

**Table 3. Summary of Key Trials**

<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date (Status)</b>
<i>Ongoing</i>			
NCT07347561	Myoelectric and Bionic Hands in Upper Limb Amputations: A Comparison of Body Image, Function and User Satisfaction	20	Mar 2026
NCT06684730	Comparison of Standard Myoelectric Hand and Bionic Hand Use in Individuals With Upper Limb Amputation	22	Jan 2026
NCT05768802	Evaluation of Myoelectric Implantable Recording Array (MIRA) in Participants With Transradial Amputation (MIRA)	5	Dec 2029
NCT03178890 <sup>a</sup>	The Osseointegrated Human-machine Gateway	18	May 2024 (unknown status)

## Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

<b>CPT Codes</b>	None
<b>HCPCS Codes</b>	A8005, A8006, L6026, L6611, L6621, L6646, L6648, L6700, L6715, L6880, L6881, L6882, L6883, L6884, L6885, L6920, L6925, L6935, L6940, L6945, L6950, L6955, L6960, L6965, L6970, L6975, L7007, L7008, L7009, L7040, L7045, L7170, L7180, L7181, L7185, L7186, L7190, L7191, L7259, L7360, L7362, L7364, L7366, L7367, L7368, L7499, L8701, L8702

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## Centers for Medicare and Medicaid Services

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at [cms.hhs.gov](https://www.cms.hhs.gov).

### Policy History/Revision

Date	Description of Change
5/7/2026	New policy document. Myoelectric upper-limb prosthetic components may be considered medically necessary when all criteria listed in Coverage are met. Advanced upper-limb prosthetic components with both sensor and myoelectric control (e.g., LUKE Arm) are considered

	<p>experimental, investigational and/or unproven. A prosthesis with individually powered digits, including but not limited to a partial hand prosthesis, is considered experimental, investigational and/or unproven. Myoelectric upper-limb prosthetic components are considered not medically necessary under all other conditions. Myoelectric controlled upper-limb orthoses are considered experimental, investigational and/or unproven.</p>
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