

1.04.04 Myoelectric Prosthetic and Orthotic Components for the Upper Limb

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Policy Statement

- I. Myoelectric upper-limb prosthetic components may be considered **medically necessary** when all of the following conditions are met:
 - A. The individual has an amputation or missing limb at the wrist or above (e.g., forearm, elbow)
 - 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 (ADLs)
 - C. The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device
 - D. The individual has demonstrated sufficient neurologic and cognitive function to operate the prosthesis effectively
 - E. The individual is free of comorbidities that could interfere with function of the prosthesis (e.g., neuromuscular disease)
 - F. 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, 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.
- II. Advanced upper-limb prosthetic components with both sensor and myoelectric control (e.g., LUKE Arm) are considered **investigational**.
- III. A prosthesis with individually powered digits, including but not limited to a partial hand prosthesis, is considered **investigational**.
- IV. Myoelectric controlled upper-limb orthoses are considered **investigational**.
- V. Myoelectric upper-limb prosthetic components are considered **investigational** under all other conditions, and are subject to individual review.

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

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.

Codes

See the [Codes table](#) for details.

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.

Related Policies

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

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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

Background

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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms. To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Prospective comparative studies with objective and subjective outcome measures would provide the most informative data on which to compare different prostheses, but little evidence was identified that directly addresses whether standard myoelectric prostheses improve function and health-related quality of life.

The available indirect evidence is based on 2 assumptions: (1) use of any prosthesis confers a clinical benefit, and (2) self-selected use is an acceptable measure of the perceived benefit (combination of utility, comfort, appearance) of a particular prosthesis for that person. Most studies identified have described amputees' self-selected use or rejection rates. The results are usually presented as hours worn at work, hours worn at home, and hours worn in social situations. Amputees' self-reported reasons for use and abandonment are also frequently reported. Upper-limb amputee's needs may depend on the particular situation; e.g., the increased functional capability may be needed with heavy work or domestic duties, while a more naturally appearing prosthesis with reduced functional capability may be acceptable for an office, school, or other social environment.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Myoelectric Proximal Upper-Limb Prosthesis

Clinical Context and Therapy Purpose

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.

The following PICO was used to select literature to inform this review.

Population

Individuals with a missing limb at the wrist or higher.

Intervention

Myoelectric upper-limb prosthesis components at or proximal to the wrist.

Comparator(s)

The body-powered prosthesis.

Outcomes

Relevant outcomes include: Functional outcomes in the use of the Myoelectric upper limb prosthesis and impact on quality of life.

Follow-up ranged on average between 2 years and 4 years.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

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 one of the 2 types of prostheses; after a 3-month period, the terminal devices were switched, and the children selected one 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 (eg, the weight of the device), and lack of functionality.

Table 1. Summary of Key Study Characteristics

Author	Study Type	N	Dates	Participants	Intervention	FU
Rejection rates						
Biddiss et al (2007) ¹	Systematic review	40 articles	1983-2004	Pediatric and adult		25 y
Silcox et al (1993) ³	Within-subject comparison	44		Adult	All fitted with a myoelectric prosthesis	
Sjoberg et al (2017) ⁵	Prospective case-control	9 children <2.5 y 27 children >2.5 to 4 y	1994-2002	Pediatric	Training with a myoelectric prosthesis	Until 12 years of age
Acceptance rates						
Kruger and Fishman (1993) ²	Randomized within-subject comparison	78		Pediatric	Trial period for both myoelectric and body-powered	2 y
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 y)	Training with a myoelectric prosthesis	2 y (range, 0.7-5)

FU: follow-up.

Table 2. Summary of Key Study Outcomes

Author	Outcomes	Adult or Pediatric	Myoelectric	Body-Powered	Passive None
Rejection rates					
Biddiss et al (2007) ¹	Mean rejection rates	Pediatric	32%	45%	38%
Silcox et al (1993) ³	Rejection of own prosthesis	Adult	23%	26%	39%
Sjoberg et al (2017) ⁵	Rejection of a myoelectric prosthesis	<2.5 y	3 (33%)		
		2.5 to 4 y	4 (15%)		
Acceptance and preference rates					

Author	Outcomes	Adult or Pediatric	Myoelectric	Body-Powered	Passive None
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 one 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 (e.g., 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

Clinical Context and Therapy Purpose

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.

The following PICO was used to select literature to inform this review.

Population

Individuals with a missing limb at the wrist or higher who receive sensor and myoelectric controlled upper-limb prosthetic components.

Intervention

Implantation of sensor and myoelectric controlled upper-limb prosthetic components.

Comparator(s)

Use of a conventional prosthesis.

Outcomes

Relevant outcomes include: Functional outcomes in the use of the Myoelectric upper limb prosthesis and impact on quality of life. Outcomes were both performance-based and self-reported measures. Follow-up ranged on average between 2 years and 4 years.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

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.^{7,8,9,10,11,12} 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 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).

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 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 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

Clinical Context and Therapy Purpose

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.

The following PICO was used to select literature to inform this review.

Population

Individuals with a missing hand distal to the wrist.

Intervention

A myoelectric upper-limb prosthesis with individually powered digits.

Comparator

Body-powered prosthesis.

Outcome(s)

Generally, the outcomes were functional status and quality of life.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

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

Clinical Context and Therapy Purpose

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.

The following PICO was used to select literature to inform this review.

Population

Individuals who are stable post-stroke, who have upper-limb weakness or paresis.

Intervention

A myoelectric powered upper-limb orthotic device.

Comparator

Usual care post-stroke.

Outcomes

The functional status and movement of the upper-limb with and without the orthotic in stable post-stroke participants who had no prior experience with the device. Impact on quality of life was also measured.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

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 one 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.

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. Studies are needed that show consistent improvements in relevant outcome measures. Results should also be replicated in a larger number of patients.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2012 Input

In response to requests, input on partial hand prostheses was received from 1 physician specialty society and 2 academic medical centers while this policy was under review in 2012. Input was mixed. Reviewers agreed that there was a lack of evidence and experience with individual digit control, although some thought that these devices might provide functional gains for selected patients.

2008 Input

In response to requests, input was received from 1 physician specialty society and 4 academic medical centers while this policy was under review in 2008. The American Academy of Physical Medicine & Rehabilitation and all 4 reviewers from academic medical centers supported the use of

electrically powered upper-extremity prosthetic components. Reviewers also supported evaluation of the efficacy and tolerability of the prosthesis in a real-life setting, commenting that outcomes are dependent on the personality and functional demands of the individual patient.

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.

Ongoing and Unpublished Clinical Trials

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

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date (Status)
<i>Ongoing</i>			
NCT03401762	Wearable MCI [myoelectric computer interface] to Reduce Muscle Co-activation in Acute and Chronic Stroke	96	Aug 2024
NCT05768802	Evaluation of Myoelectric Implantable Recording Array (MIRA) in Participants With Transradial Amputation (MIRA)	5	Dec 2029
NCT03178890 ^a	The Osseointegrated Human-machine Gateway	18	May 2024
<i>Unpublished</i>			
NCT02274532	Myoelectric SoftHand Pro to Improve Prosthetic Function for People With Below-elbow Amputations: A Feasibility Study	18	May 2016 (completed)

NCT: national clinical trial.

^aDenotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
 - Date of amputation
 - Current physical and cognitive status including any comorbidities or other conditions that might limit the utility of the device
- Prescription for the prosthesis from referring provider (Physiatrist or Orthopedist)
- Name of ordering prosthetist, fax and phone number
- All prosthetists clinical/office notes including:
 - Current make, model, components in use if applicable
 - Describe daily activities and needs related to daily activities
 - Describe malfunction of current myoelectric upper limb device if applicable
 - History of current or past prosthesis use
 - Rationale for a new myoelectric upper limb prosthesis or orthosis
 - Issue date, repair cost and warranty expiration for current device if applicable
 - Any rehabilitation the patient has received
 - Previous repairs that have been provided by manufacturer of myoelectric limb/device
 - Rationale why a body-powered prosthesis is not appropriate or cannot be used
- Clearly list all HCPCS codes with descriptions of generic codes

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for

clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	None	
HCPCS	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)
	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
	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
	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
	L7190	Electronic elbow, adolescent, Variety Village or equal, myoelectronically controlled
	L7191	Electronic elbow, child, Variety Village or equal, myoelectronically controlled
	L7499	Upper extremity prosthesis, not otherwise specified
	L8701	Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated
L8702	Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
04/02/2010	BCBSA Medical Policy adoption
03/13/2012	Coding Update
03/13/2013	Policy revision without position change
03/29/2013	Policy revision with position change
01/30/2015	Coding update
05/29/2015	Coding update
01/01/2017	Policy title change from Myoelectric Upper Limb Prostheses Policy revision without position change
06/01/2017	Policy revision without position change
11/01/2017	Policy revision without position change
05/01/2018	Policy title change from Myoelectric Prosthetic Components for the Upper Limb Policy revision without position change
02/01/2019	Coding update
06/01/2019	Policy revision without position change
05/01/2020	Annual review. Policy statement and literature review updated.
12/01/2020	Coding update.
05/01/2021	Annual review. Policy guidelines and literature review updated.
06/01/2022	Annual review. Policy statement, guidelines and literature review updated.
05/01/2023	Annual review. No change to policy statement. Literature review updated.
05/01/2024	Annual review. Policy statement, guidelines and literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	AFTER Blue font: Verbiage Changes/Additions
<p>Myoelectric Prosthetic and Orthotic Components for the Upper Limb 1.04.04</p> <p>Policy Statement:</p> <ol style="list-style-type: none"> I. Myoelectric upper-limb prosthetic components may be considered medically necessary when all of the following conditions are met: <ol style="list-style-type: none"> A. The patient has an amputation or missing limb at the wrist or above (e.g., forearm, elbow) 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 (ADLs) C. The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device D. The patient has demonstrated sufficient neurologic and cognitive function to operate the prosthesis effectively E. The patient is free of comorbidities that could interfere with function of the prosthesis (e.g., neuromuscular disease) F. 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, 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 II. Replacement or repair of a myoelectric upper-limb prosthesis may be considered medically necessary when both of the following criteria are met: <ol style="list-style-type: none"> A. The current prosthetic componentry is out of warranty B. The current prosthesis requires repairs and the cost of such repairs would be more than 60% of the cost of a new prosthesis 	<p>Myoelectric Prosthetic and Orthotic Components for the Upper Limb 1.04.04</p> <p>Policy Statement:</p> <ol style="list-style-type: none"> I. Myoelectric upper-limb prosthetic components may be considered medically necessary when all of the following conditions are met: <ol style="list-style-type: none"> A. The individual has an amputation or missing limb at the wrist or above (e.g., forearm, elbow) 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 (ADLs) C. The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device D. The individual has demonstrated sufficient neurologic and cognitive function to operate the prosthesis effectively E. The individual is free of comorbidities that could interfere with function of the prosthesis (e.g., neuromuscular disease) F. 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, 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.

POLICY STATEMENT

BEFORE <u>Red font: Verbiage removed</u>	AFTER <u>Blue font: Verbiage Changes/Additions</u>
<p>III. The following myoelectric upper-limb prosthetic components are considered not medically necessary:</p> <ul style="list-style-type: none"> A. Custom high-definition cover or glove B. High fidelity radial interface componentry <p>IV. Advanced upper-limb prosthetic components with both sensor and myoelectric control (e.g., LUKE Arm) are considered investigational.</p> <p>V. A prosthesis with individually powered digits, including but not limited to a partial hand prosthesis, is considered investigational.</p> <p>VI. Myoelectric controlled upper-limb orthoses are considered investigational.</p> <p>VII. Myoelectric upper-limb prosthetic components are considered investigational under all other conditions, and are subject to individual review.</p>	<p>II. Advanced upper-limb prosthetic components with both sensor and myoelectric control (e.g., LUKE Arm) are considered investigational.</p> <p>III. A prosthesis with individually powered digits, including but not limited to a partial hand prosthesis, is considered investigational.</p> <p>IV. Myoelectric controlled upper-limb orthoses are considered investigational.</p> <p>V. Myoelectric upper-limb prosthetic components are considered investigational under all other conditions ,and are subject to individual review.</p>