Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Myoelectric Prosthetic and Orthotic Components for the Upper Limb

Description/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/orthoptist can adjust the gain (amount of assistance), signal boost, thresholds, and range of motion. Potential users include patients with traumatic brain injury, spinal cord injury, brachial plexus injury, amyotrophic lateral sclerosis, and multiple sclerosis. Use of robotic devices for therapy has been reported. The MyoPro is the first myoelectric orthotic available for home use.

Regulatory Status

Manufacturers must register prostheses with the restorative devices branch of 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 Otto Bock myoelectric prosthesis and the Michelangelo® Hand (Otto Bock), the LTI Boston Digital Arm™ System (LiberatingTechnologies), and the Utah Arm Systems (Motion Control).

In 2014, FDA cleared the DEKA Arm System (DEKA Integrated Solutions) for marketing. FDA reviewed the DEKA Arm System through its de novo classification process, a regulatory pathway for some 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.

Medical Policy Statement

The safety and effectiveness of myoelectronic prostheses have been established. They may be considered useful therapeutic options for carefully selected candidates.

The safety and effectiveness of myoelectronic prosthesis with whole hand individually powered digits have been established. They may be considered useful therapeutic options for carefully selected candidates.

A partial hand prosthesis with individually powered digits is considered experimental/investigational.

Myoelectric controlled upper-limb orthoses (e.g., MyoPro) are considered experimental/investigational.

Inclusionary and Exclusionary Guidelines

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

- The individual has an amputation or missing limb at the wrist or above (forearm, elbow, etc.); **AND**
- Standard body-powered prosthetic devices cannot be used or are insufficient to meet the functional needs of the individual in performing activities of daily living; **AND**
- The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device; **AND**
- The individual has demonstrated sufficient neurologic and cognitive function to operate the prosthesis effectively; **AND**

- The individual is free of comorbidities that could interfere with function of the prosthesis (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, 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.
- Children age 2 years or older who have shown at least 6 months successful use of a passive prosthetic device and have a minimum EMG signal of 6μV threshold.

Myoelectric upper-limb whole prosthetic hands with independent articulating digits (L6880) may be considered **established** when the following conditions are met:

- Must meet the above criteria for a myoelectric upper limb prosthetic; **And**
- The patient has an amputation or missing limb at the wrist or above (forearm, elbow, etc.); **And**
- A standard myoelectric prosthesis has been used for one year or more and found insufficient to meet the functional needs of the individual in performing activities of daily living.

Exclusions:

- In patients with a partial hand prosthesis with independent articulating digits
- In patients whose ADLs require frequent lifting of heavy objects (12 lbs or greater);
- In patients whose environments involve frequent contact with dirt, dust, grease, water, and solvent;
- In patients whose neuromas and/or phantom limb pain are exacerbated with the use of the prosthesis.
- Myoelectric controlled upper-limb orthoses for individuals with upper-extremity weakness or paresis

Myoelectric upper-limb prosthetic components are considered not established under all other conditions.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

L6026	L6880	L6881	L6882	L6920	L6925
L6930	L6935	L6940	L6945	L6950	L6955
L6965	L6975	L7007	L7008	L7009	L7045
L7170	L7180	L7181	L7185	L7186	L7190
L7191	L7259				

*L6715 covered only as replacement of digit(s) when whole hand prosthesis was originally approved.

Other codes (investigational, not medically necessary, etc.):

L8701 L8702

Note: Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

Rationale

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 measures would provide the most informative data on which to compare different prostheses, but little evidence was identified that directly addressed whether 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 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 of the studies identified describe 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. It should be considered that upper-limb amputee's needs might depend on the particular situation. For example, 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 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 patients 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.[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). 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. The study authors found no evidence that the acceptability of passive prostheses had declined over the period from 1983 to 2004, “despite the advent of myoelectric devices with functional as well as

cosmetic appeal." Body-powered prostheses were also found to have remained a popular choice, with the type of hand-attachment being the major factor in acceptance. Body-powered hooks were considered acceptable by many users, but body-powered hands were frequently rejected (80%-87% rejection rates) due to slowness in movement, awkward use, maintenance issues, excessive weight, insufficient grip strength, and the energy needed to operate. Rejection rates of myoelectric prostheses tended to increase with longer follow-up. There was no evidence of a change in rejection rates over the 25 years of study, but the results are limited by sampling bias from isolated populations and the generally poor quality of the studies included.

Within-Subject Comparisons

One prospective controlled study (1993) compared preferences for body-powered and myoelectric hands in children.[2] Juvenile amputees (toddlers to teenagers, n=120) 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 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 who had been fitted with a myoelectric prosthesis, 40 (91%) also owned a body-powered prosthesis and 9 (20%) owned a passive prosthesis. 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 in 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%) in comparison with those with heavy work demands (26%). There was also a trend toward higher use of the myoelectric prosthesis (n=16) in comparison with a body-powered prosthesis (n=10) in social situations. Appearance was cited more frequently (19 patients) as a reason for using a myoelectric prosthesis than any other factor. Weight (16 patients) and speed (10 patients) were more frequently cited than any other factor as reasons for nonuse of the myoelectric prosthesis.

McFarland et al (2010) conducted a cross-sectional survey of upper-limb loss in veterans and service members from Vietnam (n=47) and Iraq (n=50) who were recruited through a national survey of veterans and service members who experienced combat-related major limb loss.[5] 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). At the time of the survey, upper-limb prosthetic devices were used by 70% of the Vietnam group and 76% of the Iraq group. Body-powered devices were favored by the Vietnam group (78%), while a combination of myoelectric/hybrid (46%) and body-powered (38%) devices were favored by the Iraq group. Replacement of myoelectric/hybrid devices was 3 years or longer in the Vietnam group while 89% of the Iraq group replaced myoelectric/hybrid devices in under 2 years. All types of upper-limb prostheses were abandoned in 30% of the Vietnam group and 22% of the Iraq group; the most common reasons for rejection included short residual limbs, pain, poor comfort (e.g., 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 & 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%	
		Adult	23%	26%	39%	
Silcox et al (1993)[3]	Rejection of own prosthesis	Adult	11 (50%)	13 (32%)	5 (55%)	
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						
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 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. By 12 years of age both groups achieved maximum performance on the Skills Index Ranking Scale, although 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 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

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 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.

One of the publications (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 ($p=0.03$), and less likely to have musculoskeletal problems ($p=0.047$).[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

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

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, $p<0.001$). The most commonly observed gains were in elbow extension, finger extension, grasping a tennis ball, and grasping a pencil. The Box and Block test (moving blocks from one side of a box to another) also improved ($p<0.001$). Clinically significant improvements were observed for raising a spoon and cup, and there were significant decreases in the time taken to grasp a cup and gross manual dexterity. Performance on these tests changed from unable to able to complete. The functional outcome measures (raising a spoon and cup, turning on a light switch, and picking up a laundry basket with 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. Although the performance on these tasks were inconsistent, for selected individuals such a prosthesis may be beneficial.

SUMMARY OF EVIDENCE

For individuals who have a missing a missing limb at the wrist or above who receive myoelectric upper limb prosthesis components at the wrist or proximal to the wrist, the evidence includes cohort studies and survey data. 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 reasons for disuse; detailed data on function and functional status, and direct comparisons between body-powered and newer model myoelectric prostheses are limited or lacking. The limited evidence available suggests that in comparison with body-powered prostheses, myoelectric components may improve range of motion to some extent, have similar capability for light work but may have reduced performance under heavy working conditions. The literature also indicates that the percentage of amputees who accept 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 at least in part 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. Nonuse of any prosthesis is associated with lack of functional need, discomfort (excessive weight and heat), and impediment to sensory feedback. Because of the differing advantages and disadvantages of the 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 a meaningful 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 may be helpful in determining whether newer models of this advanced prosthesis lead to consistent improvements in function and quality of life. The evidence is sufficient to determine the effects of the technology on health outcomes.

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 sufficient to determine the effects of the technology on health outcomes.

For individuals with upper-extremity weakness or paresis who receive a myoelectric powered upper-limb orthosis, the evidence includes a small within-subject study. Relevant outcomes are functional outcomes and quality of life. The largest study (N=18) identified tested participants with and without the orthosis but did not provide any training with the device. Performance on

the tests was inconsistent. Studies are needed that show consistent improvements in relevant outcome measures. Results should also be replicated in a larger number of patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03401762	Wearable MCI [myoelectric computer interface] to reduce muscle co-activation in acute and chronic stroke	96	Aug 2024
NCT03178890[a]	The Osseointegrated Human-machine Gateway	18	May 2024
NCT05768802	Evaluation of Myoelectric Implantable Recording Array (MIRA) in Participants With Transradial Amputation (MIRA)	5	Dec 2029
Unpublished			
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. [a] Denotes industry-sponsored or cosponsored trial.

CLINICAL INPUT RECEIVED FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

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 and Rehabilitation and all 4 reviewers from academic medical centers supported 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.

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. The 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.

PRACTICE GUIDELINES AND POSITION STATEMENTS

No guidelines or statement were identified.

Government Regulations
National:
Medicare Benefit Policy Manual. Prosthetic Devices chapter 15(120), Medicare Claims Processing Manual chapter 20. Rev. 12557; issued: 03/28/24.

For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary," based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

HCPCS code L6715 describes multiple articulating digit(s) (fingers and/or thumb) which are used on initial issue when paired with a partial hand base procedure code (L6000, L6010, L6020). The articulating digit(s) can also be used as a "replacement digit(s)" with the use of the RB modifier as part of a prosthetic repair. The following base procedure codes include a custom fabricated socket:

- L6000 Partial hand, thumb remaining
- L6010 Partial hand, little and/or ring finger remaining
- L6020 Partial hand, no finger remaining

The use of L6715 on initial issue will be denied as unbundling. *(L6715 has a fee assigned)*

HCPCS code L6880 describes a complete hand prosthesis, which consists of the terminal device, all articulating digits and motors. This base procedure code does not include a custom fabricated socket. This base procedure code includes all necessary components. The use of L6715 on initial issue will be denied as unbundling. *(L6880 has a fee assigned)*

HCPCS code L7499 (Upper extremity prosthesis, not otherwise specified) must not be used for the billing of any additional features or components, programming, adjustment, etc. with L6880, as these codes are considered all-inclusive. The use of L7499 on initial issue will be denied as unbundling.

Medicare does not specifically address upper limb prosthetic devices. According to the Medicare coverage manual, section 120 – Prosthetic Devices:

Prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ are covered when furnished on a physician's order. This does not require a determination that there is no possibility that the patient's condition may improve sometime in the future. If the medical record, including the judgment of the attending

physician, indicates the condition is of long and indefinite duration, the test of permanence is considered met. (Such a device may also be covered under §60.l as a supply when furnished incident to a physician's service.)

Examples of prosthetic devices include artificial limbs, parenteral and enteral (PEN) nutrition, cardiac pacemakers, prosthetic lenses (see subsection B), breast prostheses (including a surgical brassiere) for postmastectomy patients, maxillofacial devices, and devices which replace all or part of the ear or nose.

Medicare covers myoelectronic upper limb prostheses based on individual consideration review. Medicare has no written policy on the specific subject of myoelectric upper limb prostheses.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Prosthetic Devices
- Orthotic Devices
- Myoelectronic Upper Limb Prostheses (BCN), retired
- Microprocessor Lower Limb Prostheses

References

1. Biddiss EA, Chau TT. Upper limb prosthesis use and abandonment: a survey of the last 25 years. *Prosthet Orthot Int.* Sep 2007;31(3):236-257. PMID 17979010
2. Kruger LM, Fishman S. Myoelectric and body-powered prostheses. *J Pediatr Orthop.* Jan-Feb 1993;13(1):68-75. PMID 8416358
3. Silcox DH, 3rd, Rooks MD, Vogel RR, et al. Myoelectric prostheses. A long-term follow-up and a study of the use of alternate prostheses. *J Bone Joint Surg Am.* Dec 1993;75(12):1781-1789. PMID 8258548
4. McFarland LV, Hubbard Winkler SL, Heinemann AW, et al. Unilateral upper-limb loss: satisfaction and prosthetic-device use in veterans and service members from Vietnam and OIF/OEF conflicts. *J Rehabil Res Dev.* Aug 2010;47(4):299-316. PMID 20803400
5. Sjoberg L, Lindner H, Hermansson L. Long-term results of early myoelectric prosthesis fittings: A prospective case-control study. *Prosthet Orthot Int.* Sep 1 2017:309364617729922. PMID 28905686
6. Egermann M, Kasten P, Thomsen M. Myoelectric hand prostheses in very young children. *Int Orthop.* Aug 2009;33(4):1101-1105. PMID 18636257
7. Resnik LJ, Borgia ML, Acluche F. Perceptions of satisfaction, usability and desirability of the DEKA Arm before and after a trial of home use. *PloS One.* Jun 2017;12(6):e0178640. PMID 28575025

8. Resnik L, Cancio J, Klinger S, et al. Predictors of retention and attrition in a study of an advanced upper limb prosthesis: implications for adoption of the DEKA Arm. *Disabil Rehabil Assist Technol.* Feb 2018;13(2):206-210. PMID 28375687
9. Resnik L, Klinger S. Attrition and retention in upper limb prosthetics research: experience of the VA home study of the DEKA arm. *Disabil Rehabil Assist Technol.* Nov 2017;12(8):816-821. PMID 28098513
10. Resnik LJ, Borgia ML, Acluche F, et al. How do the outcomes of the DEKA Arm compare to conventional prostheses? *PloS One.* Jan 2018;13(1):e0191326. PMID 29342217
11. Resnik L, Acluche F, Lieberman Klinger S, et al. Does the DEKA Arm substitute for or supplement conventional prostheses. *Prosthet Orthot Int.* Sep 1 2017:309364617729924. PMID 28905665
12. Resnik L, Acluche F, Borgia M. The DEKA hand: A multifunction prosthetic terminal device-patterns of grip usage at home. *Prosthet Orthot Int.* Sep 1 2017:309364617728117. PMID 28914583
13. Peters HT, Page SJ, Persch A. Giving them a hand: wearing a myoelectric elbow-wrist-hand orthosis reduces upper extremity impairment in chronic stroke. *Ann Rehabil Med.* Sep 2017;98(9):1821-1827. PMID 28130084
11. Blue Cross Blue Shield Association. Myoelectric Prosthetic Components for the Upper Limb. Medical Policy Reference Manual. Policy #1.04.04. Issue: 6:2015. Last review date April 2024.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/16	8/16/16	8/16/16	Joint policy established
11/1/17	8/15/17	8/15/17	Routine policy maintenance. No change in policy status.
11/1/18	8/21/18	8/21/18	Added and exclusion to MPS regarding orthosis in upper limb weakness/paresis. Updated rationale, added reference # 5, 7-13.
11/1/19	8/20/19		Added codes L8701 and L8702. Added "Myoelectric controlled upper-limb orthoses (e.g., MyoPro) are considered E/I." No change in policy status.
11/1/20	8/18/20		Routine policy maintenance, no changes in policy status.
11/1/21	8/17/21		Routine policy maintenance, no change in policy status.
11/1/22	8/16/22		Routine policy maintenance, no change in policy status.
11/1/23	8/15/23		Routine policy maintenance, no change in policy status. Vendor managed: Northwood. (ds)
11/1/24	8/20/24		Routine policy maintenance, no change in status. Vendor managed: Northwood (ds)

Next Review Date: 3rd Qtr. 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: MYOELECTRIC PROSTHETIC AND ORTHOTIC COMPONENTS FOR THE UPPER LIMB

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered per medical policy criteria
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- *Duplicate (back-up) equipment is not a covered benefit.*