Name of Policy:

Myoelectric Prosthetic and Orthotic Components for the Upper Limb

Policy #: 124
Category: DME

Latest Review Date: April 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *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 that patient's illness, injury or disease.*

Description of Procedure or Service:

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

Upper-Limb Amputation

The need for a prosthesis can occur for a number of reasons, including trauma, surgery, or congenital anomalies.

Treatment

The primary goals of the upper limb prosthesis are to restore natural appearance and function. Achieving these goals also requires sufficient comfort and ease of use for continued acceptance by the wearer. The difficulty of achieving these diverse goals with an upper limb prosthesis increases as the level of amputation (digits, hand, wrist, elbow, and shoulder), and thus the complexity of joint movement, increases.

Upper limb prostheses are classified 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 prosthesis relies on manual repositioning, typically by moving with the opposite arm and cannot restore function. It is the lightest of the 3 prosthetic types and is thus generally the most comfortable.

Body-Powered Prostheses

The body-powered prosthesis uses a body harness and cable system to provide functional manipulation of the elbow and hand. Voluntary movement of the shoulder and/or limb stump extends the cable and transmits the force to the terminal device. Prosthetic hand attachments, which may be claw-like devices that allow good grip strength and visual control of objects or latex-gloved devices that provide a more natural appearance at the expense of control, can be opened and closed by the cable system. Patient complaints with body-powered prostheses include harness discomfort, particularly the wear temperature, wire failure, and the unattractive appearance.

Myoelectric Prostheses

Myoelectric prostheses use muscle activity from the remaining limb for the control of joint movement. Electromyographic (EMG) signals from the limb stump are detected by surface electrodes, amplified, and then processed by a controller to drive battery-powered motors that move the hand, wrist, or elbow. Although upper arm movement may be slow and limited to one joint at a time, myoelectric control of movement may be considered the most physiologically natural.

Myoelectric hand attachments are similar in form to those offered with the body-powered prosthesis, but are battery-powered. Commercially available examples include:

- The Michelangelo Hand (Advanced Arm Dynamics)
- i-limb (Touch Bionics)
- benionic (steeper)

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 control of 2 joints at once (i.e., 1 body-powered and 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 (DARPA), which is funding a public and private collaborative effort on prosthetic research and development. Areas of development include the use of skin-like silicone elastomer gloves, "artificial muscles," and sensory feedback. Smaller motors, microcontrollers, implantable myoelectric sensors, and re-innervation of remaining muscle fibers are being developed to allow fine movement control. Lighter batteries and newer materials are being incorporated into myoelectric prostheses to improve comfort.

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 EMG electrodes, the DEKA Arm System 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.

Policy:

Effective for dates of service on or after March 12, 2018:

Myoelectric prostheses meet Blue Cross and Blue Shield of Alabama's **medical criteria for coverage** for patients with upper limb amputations:

- The patient 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 arms(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device; **AND**
- The patient has demonstrated sufficient neurological and cognitive function to operate the prosthesis effectively; **AND**
- The patient 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, and coordination 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.
- 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.

Blue Cross and Blue Shield of Alabama will cover **one** myoelectric prosthesis per limb **per five years when medically indicated.** Coverage will not be provided if the prosthesis is functioning properly and in good general condition.

A prosthesis with individually powered digits, including but not limited to a partial hand prosthesis, does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

High-definition silicone used to make a prosthesis **resemble a patient's skin does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **cosmetic**.

Myoelectric prostheses are **contraindicated,** and therefore **do not meet** Blue Cross and Blue Shield of Alabama's **medical criteria for coverage** for patients with upper limb amputations:

- Whose ADLs require frequent lifting of heavy objects (16lbs or greater);
- Whose environments involve frequent contact with dirt, dust, grease, water, and solvent;
- Whose neuromas and/or phantom limb pain are exacerbated with the use of the prosthesis.

Myoelectric orthoses for upper extremities do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational.**

Upper-limb prosthetic components with both sensor and myoelectric controls (LUKE/DEKA), does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

Effective for dates of service June 25, 2012 through March 12, 2018:

Myoelectric prostheses meet Blue Cross and Blue Shield of Alabama's **medical criteria for coverage** for patients with upper limb amputations:

- The patient 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 arms(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device; **AND**
- The patient has demonstrated sufficient neurological and cognitive function to operate the prosthesis effectively; **AND**
- The patient 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, and coordination 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.
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Myoelectric prostheses are **contraindicated,** and therefore **do not meet** Blue Cross and Blue Shield of Alabama's **medical criteria for coverage** for patients with upper limb amputations:

- Whose ADLs require frequent lifting of heavy objects (16lbs or greater);
- Whose environments involve frequent contact with dirt, dust, grease, water, and solvent;
- Whose neuromas and/or phantom limb pain are exacerbated with the use of the prosthesis.

Myoelectric orthoses for upper extremities do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational.**

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature update was performed through January 25, 2018. Most studies identified describe the development of interfaces and signal processing algorithms for myoelectric prosthetic control.

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, and appearance) of a particular prosthesis for that individual. 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. Upper limb amputee's needs may 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.

Myoelectric Upper Limb Prosthesis

Systematic Reviews

A 2007 systematic review of 40 articles published over the previous 25 years assessed upper-limb prosthesis acceptance and abandonment. 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 with myoelectric hands in children. 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. Of 44 patients who had been fitted with a myoelectric prosthesis, 40 (91%) also owned a body-powered prosthesis and nine (20%) owned a passive prosthesis. Twenty-two (50%) patients had rejected the myoelectric prosthesis, 13 (32%) had rejected the body-powered prosthesis, and five (55%) had rejected the 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 (ten patients) were more frequently cited than any other factor as reasons for non-use 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. 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 one myoelectric/hybrid, one body-powered, and one 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 three years or longer in the Vietnam group while 89% of the Iraq group replaced myoelectric/hybrid devices in under two 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)	Systematic review	40 articles	1983-2004	Pediatric and adult		25 y
Silcox et al (1993)	Within-subject comparison	44		Adult	All fitted with a myoelectric prosthesis	
Sjoberg et al (2017)	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)	Randomized within-subject comparison	78		Pediatric	Trial period for both myoelectric and body-powered	2 y
McFarland et al (2010)	Cross-sectional survey	50		Veterans and service members	Provided with all 3 device types	
Egermann et al (2009)	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)	Mean rejection rates	Pediatric	32%	45%	38%	
		Adult	23%	26%	39%	

Silcox et al (1993)	Rejection of own prosthesis	Adult	22 (50%)	13 (32%)	5 (55%)	
Sjoberg et al (2017)	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)	Preference rates		34 (44%)	26 (34%)		18 (22%)
McFarland et al (2010)	Preference rates	Iraq veterans	18 (36%)	15 (30%)		11 (22%)
Egermann et al (2009)	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. 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

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. 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.

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. 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). Reasons for attrition during the in-laboratory training were reported in a separate publication by Resnik and Klinger (2017). 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). 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. 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. 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 poststroke participants who had no prior experience with the device. Outcomes were inconsistent. Studies are needed that show consistent improvements in relevant outcome measures. Results should also be replicated in a larger number of patients.

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 a systematic review and comparative studies. Relevant outcomes are functional outcomes and quality of life. The goals of upper-limb prostheses relate to restoration of both appearance and function while maintaining sufficient comfort for continued use. The identified literature focuses primarily on patient acceptance and rejection; data are limited or lacking in the areas of function and functional status. The limited evidence suggests that, when compared with body-powered prostheses, myoelectric components possess the similar capability to perform light work; however, myoelectric components could also suffer a reduction in performance when operating under heavy working conditions. The literature has also indicated that the percentage of amputees who accept the use of a myoelectric prosthesis is approximately the same as those who prefer to use a body-powered prosthesis, and that self-selected use depends partly on the individual's activities of daily living. Appearance is most frequently cited as an advantage of myoelectric prostheses, and for patients who desire a restorative appearance, the myoelectric prosthesis can provide greater function than a passive prosthesis-with equivalent function to a body-powered prosthesis for light work. Because of the different advantages and disadvantages of currently available prostheses, myoelectric components for persons with an amputation at the wrist or above may be considered when passive, or body-powered prostheses cannot be used or are insufficient to meet the functional needs of the patient in activities of daily living. The evidence is sufficient to determine that the technology results in 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 is needed to determine whether newer models of this advanced prosthesis lead to consistent improvements in function and quality of life. The evidence is insufficient to determine 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 insufficient 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.

Practice Guidelines and Position Statements
No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Key Words:

Myoelectric hand, myoelectric arm, myoelectric elbow, electric prosthesis, electronic prosthesis, Utah Arm and Hand System, Otto Bock myoelectric prosthesis, LTI Boston Digital arm System, SensorHand™, ProDigits™ and i-LIMB™, LIVINGSKIN™, MyoPro™, MyoMo, Inc., LUKE™ arm, The Michelangelo Hand (Advanced Arm Dynamics), DEKA Gen 2 and DEKA Gen 3

Approved by Governing Bodies:

Manufacturers must register prostheses with the restorative 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 the ProDigits™ and i-LIMB™ (touch Bionics), Otto Bock myoelectric prosthesis and the Michelangelo® Hand (Otto Bock), the LTI Boston Digital Arm™ System (Liberating Technologies Inc.), and the Utah Arm Systems (Motion Control).

In 2014, the Deka Arm System (Deka Integrated Solutions), now called the LUKE™ arm, was cleared 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 a first-of-a-kind.

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

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan.

Current Coding:

HCPC codes:

L3999	Upper limb orthosis, not otherwise specified
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)
L6629	Upper extremity addition, quick disconnect lamination collar with coupling piece, otto bock or equal
L6672	Upper extremity addition, harness, chest or shoulder, saddle type
L6680	Upper extremity addition, test socket, wrist disarticulation or below elbow
L6682	Upper extremity addition, test socket, elbow disarticulation or above elbow
L6684	Upper extremity addition, test socket, shoulder disarticulation or interscapular thoracic
L6686	Upper extremity addition, suction socket
L6687	Upper extremity addition, frame type socket, below elbow or wrist disarticulation
L6688	Upper extremity addition, frame type socket, above elbow or elbow disarticulation
L6689	Upper extremity addition, frame type socket, shoulder disarticulation
L6690	Upper extremity addition, frame type socket, interscapular-thoracic
L6715	Terminal device, multiple articulating digit, includes motor(s), initial issue or replacement.
L6880	Electric hand, switch or myoelectric controlled, independently articulating digits, any grasp pattern or combination of grasp patterns, includes motor(s).
L6890	Terminal device, glove for above hands, production glove
L6895	Terminal device, glove for above hands, custom glove
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
L6950	Above elbow, external power, molded inner socket, removable humeral shell, internal locking elbow, forearm, otto bock or equal switch, cables, two batteries and one charger, switch 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
L7180	Electronic elbow, Boston, Utah or equal, myoelectronically controlled
L7190	Electronic elbow, adolescent, Variety Village or equal, myoelectronically controlled
L7191	Electronic elbow, child, Variety Village or equal, myoelectronically controlled
L7259	Electronic wrist rotator, any type
L7261	Electronic wrist rotator, for Utah arm
L7360	Six volt battery, otto bock or equal, each
L7362	Battery charger, six volt, otto bock or equal
L7364	Twelve volt battery, Utah or equal, each
L7366	Battery charger, twelve volt, Utah or equal
L7499	Upper extremity prosthesis, not otherwise specified
L8465	Prosthetic shrinker, upper limb, each

References:

1. Atkins DJ, Heard DCY and Donovan WH. Epidemiologic overview of individuals with upper-limb loss and their reported research priorities. J Pros and Orth, 1996: 8(1).
2. Berke GM and Nielsen CC. Establishing parameters affecting the use of myoelectric prostheses in children: A preliminary investigation. J Pros and Orth, 1991: 3(4).

3. Biddiss EA and Chau TT. Upper limb prosthesis use and abandonment: A survey of the last 25 years. Prosthet Orthot Int, September 2007; 31(3): 236-257.
4. Biddiss E and Chau T. Upper-limb prosthetics: Critical factors in device abandonment. Am J Phys Med Rehabilitation, December 2007; 86(12): 977-987.
5. Blue Cross Blue Shield Association. Myoelectric prosthesis for the upper limb. Medical Policy Reference Manual, December 2008.
6. Bonivento C, Davalli A, Fantuzzi C, Sacchetti R and Terenzi S. Automatic tuning of myoelectric prostheses. J Rehab Research and Develop, 1998: 35(3); 294-304.
7. Edelstein JE and Berger N. Performance comparison among children fitted with myoelectric and body-powered hands. Arch Phys Med Rehabil, April 1993; 74(4): 376-380.
8. Egermann M, Kasten P, Thomsen M. Myoelectric hand prostheses in very young children. Int Orthop 2009; 33(4):1101-5.
9. Greatting, MD, Creek B, Hill JJ and Supan TJ. Myoelectric prostheses in upper extremity amputees: Cost, mechanical reliability and long-term wear rate. American Academy of Orthopaedic Surgeons 1991 Annual Meeting-Scientific Program; Paper No. 314.
10. James MA, Bagley AM, Brasington K, et al. Impact of prostheses on function and quality of life for children with unilateral congenital below-the-elbow deficiency. J Bone Joint Surg Am, November 2006; 88(11): 2356-2365.
11. Kampas P. The optimal use of myoelectrodes, Translation of: Med Orth Tec 2001; 121: 21-27.
12. Kruger LM and Fishman S. Myoelectric and body-powered prostheses. J Pediatr Orthop, Jan-Feb 1993; 13(1): 68-75.
13. Lindner HY, Linacre JM, Norling Hermansson LM. Assessment of capacity for myoelectric control: evaluation of construct and rating scale. J Rehabil Med 2009;41(6):467-74.
14. McFarland LV, Hybbard 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 conflict. J Rehabil Res Dev 2010;47(4):299-316.
15. Moseley Chris. A study of upper-extremity myoelectric prosthetics and their external power sources. The Official Journal of ISPE, March/April 2002, Vol. 22, No. 2.
16. 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.
17. Pylatiuk C, Schulz S and Doderlein L. Results of an Internet survey of myoelectric prosthetic hand users. Prosthet Orthot Int, December 2007; 31(4): 362-370.
18. 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.
19. 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.
20. 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.
21. 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.
22. 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.

23. 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.
24. Silcox III DH, Rooks MD et al. Myoelectric prostheses. A long-term follow-up and a study of the use of alternate prostheses. J Bone Joint Surg Am, December 1993; 75(12): 1781-1789.
25. 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.
26. Skewes E, Haas J and Kruger AM. Surlyn sockets for below-elbow myoelectric prostheses, Journal of Association of Children's Pros-Ortho Clin, 1988; 23(1): 19-20.

Policy History:

Medical Policy Group, June 2003 **(2)**
Medical Policy Administration Committee, June 2003
Available for comment July 1-August 14, 2003
Medical Policy Group, December 2004 **(1)**
Medical Policy Group, April 2005 (2)
Medical Policy Administration Committee, April 2005
Available for comment April 27-June 10, 2005
Medical Policy Group, April 2006 **(1)**
Medical Policy Group, April 2007 **(1)**
Medical Policy Group, May 2009 **(1)**
Medical Policy Panel, February 2010
Medical Policy Group, March 2010 **(2)**
Medical Policy Administration Committee, April 2010
Available for comment April 7-May 21, 2010
Medical Policy Panel, March 2011
Medical Policy Group, June 2011 **(2):** Key Points, Key Words, Regulatory Status updated
Medical Policy Group, December 2011 **(1)**: 2012 Code Updates; Delete code L7274 effective January 1, 2012
Medical Policy Panel, June 2012
Medical Policy Group, June 2012 **(2):** Updated policy to indicate a prosthesis with individually powered digits as investigational. Description, Key Words, Approved by Governing Bodies, Coding, References updated. Key Points rewritten.
Medical Policy Administration Committee, June 2012
Available for comment June 29, 2012 through August 12, 2012
Medical Policy Panel, June 2013
Medical Policy Group, September 2013 **(2):** title changed to Myoelectric Prosthetic Components for the Upper Limb, Policy statements unchanged, Codes added for partial hand myoelectric prosthesis, child and adolescent myoelectric arm prosthesis.
Medical Policy Panel, June 2014
Medical Policy Group, June 2014 **(5):** Policy updated with literature review through May 23, 2014; Updated Approved by Governing Bodies; no references added; policy statement unchanged.

Medical Policy Group, November 2014: 2015 Annual Coding update. Added HCPCS L6026 and L7259 and moved deleted HCPCS code L6025 to previous coding.
Medical Policy Group, December 2014 (**5**) Added statement of coverage of one computerized prostheses per limb per five years when medically indicated. Coverage will not be provided if the prosthesis is functioning properly and in good general condition. This language of limits has always been applied to prosthesis.
Medical Policy Panel, June 2015
Medical Policy Group, June 2015 **(6):** Updates to Key Points and Approved by Governing Bodies; no change to policy statement.
Medical Policy Group, August 2015 **(6):** Updates to Title, Description, Key Points, Approved by Governing Bodies, Key Words and Coding sections to include myoelectric orthotic upper extremity devices. Policy statement updated to include myoelectric orthotic devices for the upper extremity as investigational. No changes in coverage as these devices have been considered investigational.
Medical Policy Panel, December 2016
Medical Policy Group, December 2016 **(6)**: Updates to Description, Key Points, Key Words, Governing Bodies and Summary. No change in policy statement.
Medical Policy Panel, September 2017
Medical Policy Group, September 2017 **(6)**: Updates to Description and Key Points.
Medical Policy Panel, March 2018
Medical Policy Group, April 2018 **(6)**: Updates to Policy statement to include investigational status of LUKE/DEKA prosthetic, Key Points, Key Words and References.
