

## Medical Policy



### Title: Myoelectric Prosthetic Components for the Upper Limb

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*Related Policies:*   ▪   *Microprocessor-Controlled Prostheses for the Lower Limb medical policy*

#### **Professional**

Original Effective Date: January 1, 2021

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Populations	Interventions	Comparators	Outcomes
Individuals: • With a missing limb at the wrist or higher	Interventions of interest are: • Myoelectric upper-limb prosthesis components at or proximal to the wrist	Comparators of interest are: • Body-powered prosthesis	Relevant outcomes include: • Functional outcomes • Quality of life
Individuals: • With a missing limb at the wrist or higher	Interventions of interest are: • Sensor and myoelectric controlled upper-limb prosthetic components	Comparators of interest are: • Conventional prosthesis	Relevant outcomes include: • Functional outcomes • Quality of life
Individuals: • With a missing hand distal to the wrist	Interventions of interest are: • Myoelectric hand prosthesis with individually powered digits	Comparators of interest are: • Body-powered prosthesis	Relevant outcomes include: • Functional outcomes • Quality of life

## **DESCRIPTION**

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

### **Objective**

The objective of this evidence review is to determine whether myoelectric upper-limb prostheses improve the net health outcome in individuals with upper-limb amputations, weakness, or paresis.

### **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 (ie, 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.

### **REGULATORY STATUS**

Manufacturers must register prostheses with the Restorative and Repair Devices Branch of the U.S. Food and Drug Administration (FDA) and keep a record of any complaints, but do not have to undergo a full FDA review.

Available myoelectric devices include ProDigits™ and i-limb™ (Touch Bionics), the SensorHand™ Speed and Michelangelo® Hand (Otto Bock), the LTI Boston Digital Arm™ System (Liberating Technologies), the Utah Arm Systems (Motion Control), and bebionic (steeper).

In 2014, the DEKA Arm System (DEKA Integrated Solutions, now DEKA Research & Development), now called the LUKE™ Arm (Mobius Bionics), was cleared for marketing by FDA through the de novo 513(f)(2) classification process for novel low- to moderate-risk medical devices that are first-of-a-kind. FDA product codes: GXY, IQZ.

**Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

## **POLICY**

I. Electronic prosthetics meeting criteria below may be allowed when provided by a certified Orthopedic / Prosthetic Device Supplier.

## II. **Upper-Limb**

- A. Myoelectric upper-limb prosthetic components with or without a sensor may be considered **medically necessary** when **all** of the following conditions are met:
1. The patient has an amputation or missing limb at the wrist or above (e.g., forearm, elbow)  
**AND**
  2. 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**
  3. The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device  
**AND**
  4. The patient has demonstrated sufficient neurologic and cognitive function to operate the prosthesis effectively  
**AND**
  5. The patient is free of comorbidities that could interfere with function of the prosthesis (e.g., neuromuscular disease)  
**AND**
  6. Functional evaluation indicates that with training, use of a myoelectric prosthesis is likely to meet the functional needs of the individual (e.g., gripping, releasing, holding, coordinating movement of the prosthesis) when performing activities of daily living. This evaluation should consider the patient's needs for control, durability (maintenance), function (speed, work capability), and usability.
- B. Myoelectric upper-limb prosthetic components with or without a sensor are **not covered** in individuals who do not meet the criteria in II A.

### III. **Powered digits / Partial hand prosthesis**

- A. A prosthesis with individually powered digits, including but not limited to a partial hand prosthesis, is considered **medically necessary** when **all** of the following conditions are met:
1. The patient has an amputation or missing hand or digits  
**AND**
  2. 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**
  3. The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device  
**AND**
  4. The patient has demonstrated sufficient neurologic and cognitive function to operate the prosthesis effectively  
**AND**
  5. The patient is free of comorbidities that could interfere with function of the prosthesis (e.g., neuromuscular disease)  
**AND**
  6. Functional evaluation indicates that with training, use of a myoelectric prosthesis is likely to meet the functional needs of the individual (e.g., gripping, releasing, holding, coordinating movement of the prosthesis) when performing activities of daily living. This evaluation should consider the patient's needs for control, durability (maintenance), function (speed, work capability), and usability.
- B. A prosthesis with individually powered digits, including but not limited to a partial hand prosthesis is **not covered** in individuals who do not meet the criteria in III A.

**Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

#### **Policy Guidelines**

1. Amputees are evaluated by an independent, qualified professional to determine the most appropriate prosthetic components and control mechanism. A trial period may be indicated to evaluate the tolerability and efficacy of the prosthesis in a real-life setting.
2. Benefits are not provided for repair or replacement of prosthetic devices due to misuse, malicious damage or gross neglect, or to replace lost or stolen items.
3. Benefits are not provided for implantable prosthetic components and limbs, exoskeleton prosthetic devices or cosmetic components and coverings for prosthetic devices

#### **RATIONALE**

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through December 13, 2020.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific

outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

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

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

## **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 question addressed in this evidence review is: Does the use of myoelectric upper-limb prosthesis components at or proximal to the wrist improve the net health outcome in 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 (see Table 1).<sup>1</sup> For pediatric patients, the mean rejection rate was 38% for passive prostheses (1 study), 45% for body-powered prostheses (3 studies), and 32% for myoelectric prostheses (12 studies) (see Table 2). For adults, there was considerable variation between studies, with mean rejection rates of 39% for passive (6 studies), 26% for body-powered (8 studies), and 23% for myoelectric (10 studies) prostheses. Reviewers found no evidence that the acceptability of passive prostheses had declined over the period from 1983 to 2004, "despite the advent of myoelectric devices with functional as well as cosmetic appeal." Body-powered prostheses were also found to have remained a popular choice, with the type of hand attachment being the major factor in acceptance. Body-powered hooks were considered acceptable by many users, but body-powered hands were frequently rejected (80%-87% rejection rates) due to slowness in movement, awkward use, maintenance issues, excessive weight, insufficient grip strength, and the energy needed to operate. Rejection rates of myoelectric prostheses tended to increase with longer follow-up. There was no evidence of a change in rejection rates over the 25 years of study, but the results were limited by sampling bias from isolated populations and the generally poor quality of studies selected.

#### **Within-Subject Comparisons**

One prospective controlled study (1993) compared preferences for body-powered with myoelectric hands in children.<sup>2</sup> 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.<sup>3</sup> Of 44 patients fitted with a myoelectric prosthesis, 91% also owned a body-powered prosthesis, and 20% owned a passive prosthesis. Rejection rates of these prostheses are shown in Table 2. Use of a body-powered prosthesis was unaffected by the type of work; good-to-excellent use was reported in 35% of patients with heavy work demands and 39% of patients with light work demands. In contrast, the proportion of patients using a myoelectric prosthesis was higher in the group with light work demands (44%) than in those with heavy work demands (26%). There was also a trend toward the higher use of the myoelectric prosthesis compared with a body-powered prosthesis in social situations. Appearance was cited more frequently as a reason for using a myoelectric prosthesis than any other factor. Weight and speed were more frequently cited than any other factors as reasons for nonuse of the myoelectric prosthesis.

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

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

Author	Study Type	N	Dates	Participants	Intervention	FU
<i>Rejection rates</i>						
Biddiss et al (2007) <sup>1</sup> ,	Systematic review	40 articles	1983-2004	Pediatric and adult		25 y
Silcox et al (1993) <sup>3</sup> ,	Within-subject comparison	44		Adult	All fitted with a myoelectric prosthesis	
Sjoberg et al (2017) <sup>5</sup> ,	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
<i>Acceptance rates</i>						
Kruger and Fishman (1993) <sup>2</sup> ,	Randomized within-subject comparison	78		Pediatric	Trial period for both myoelectric and body-powered	2 y
McFarland et al (2010) <sup>4</sup> ,	Cross-sectional survey	50		Veterans and service members	Provided with all 3 device types	
Egermann et al (2009) <sup>6</sup> ,	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
<i>Rejection rates</i>						
Biddiss et al (2007) <sup>1</sup> ,	Mean rejection rates	Pediatric	32%	45%	38%	
		Adult	23%	26%	39%	
Silcox et al (1993) <sup>3</sup> ,	Rejection of own prosthesis	Adult	22 (50%)	13 (32%)	5 (55%)	
Sjoberg et al (2017) <sup>5</sup> ,	Rejection of a myoelectric prosthesis	<2.5 y	3 (33%)			
		2.5 to 4 y	4 (15%)			
<i>Acceptance and preference rates</i>						
Kruger and Fishman (1993) <sup>2</sup> ,	Preference rates		34 (44%)	26 (34%)		18 (22%)
McFarland et al (2010) <sup>4</sup> ,	Preference rates	Iraq veterans	18 (36%)	15 (30%)		11 (22%)
Egermann et al (2009) <sup>6</sup> ,	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.<sup>5</sup> 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.<sup>6</sup> 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**

### **Clinical Context and Therapy Purpose**

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

The question addressed in this evidence review is: Does the use of implantation of sensor and myoelectric controlled upper-limb prosthetic components improve the net health outcome in 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 who receive sensor and myoelectric controlled upper-limb prosthetic components.

### ***Intervention***

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

### ***Comparator(s)***

Use of a conventional prosthesis.

### **Outcomes**

Relevant outcomes include: Functional outcomes in the use of the Myoelectric upper limb prosthesis and impact on quality of life. Outcomes were both performance-based and self-reported measures.

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

### **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

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

### **Review of Evidence**

Investigators from 3 Veterans Administration medical centers and the Center for the Intrepid at Brooke Army Medical Center published a series of reports on home use of the LUKE prototype (DEKA Gen 2 and DEKA Gen 3) in 2017 and 2018.<sup>7,8,9,10,11,12</sup> Participants were included in the in-laboratory training if they met criteria and had sufficient control options (e.g., myoelectric and/or active control over one or both feet) to operate the device. In-lab training included a virtual reality training component. At the completion of the in-lab training, the investigators determined, using a priori criteria, which participants were eligible to continue to the 12-week home trial. The criteria included the independent use of the prosthesis in the laboratory and community setting, fair, functional performance, and sound judgment when operating or troubleshooting minor technical issues. On ClinicalTrials.gov, the total enrollment target is listed as 100 patients with study completion by February 2018 (NCT01551420).

Resnick et al (2017)] reported on the acceptance of the LUKE prototype before and after a 12-week trial of home use.<sup>7</sup> 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 ( $p=0.047$ ).<sup>8</sup> Reasons for attrition during the in-laboratory training were reported in a separate publication by Resnik and Klinger (2017).<sup>9</sup> 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).<sup>10</sup> 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.<sup>11</sup> This conclusion is similar to those from earlier prosthesis surveys, which found that the selection of a specific prosthesis type (myoelectric, powered, or passive) could differ depending on the specific activity during the day. In the DEKA Gen 2 and Gen 3 study reported here, 29% of participants had a body-powered device, and 71% had a conventional myoelectric prosthesis.

### **Section Summary: Sensor and Myoelectric Upper-Limb Components**

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

## **MYOELECTRIC HAND WITH INDIVIDUAL DIGIT CONTROL**

### **Clinical Context and Therapy Purpose**

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

The question addressed in this evidence review is: Does the use of a myoelectric upper-limb prosthesis with individually powered digits improve the net health outcome in patients with a missing hand distal to the wrist?

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

***Population***

Individuals with a missing hand distal to the wrist.

***Intervention***

A myoelectric upper-limb prosthesis with individually powered digits.

***Comparator***

Body-powered prosthesis.

***Outcome(s)***

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

**Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

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

**Review of Evidence**

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

**MYOELECTRIC ORTHOTIC**

**Clinical Context and Therapy Purpose**

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

The question addressed in this evidence review is: Does the use of a myoelectric powered upper-limb orthotic device improve the net health outcome in patients who are stable post-stroke, who have upper-limb weakness or paresis?

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

***Population***

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

***Intervention***

A myoelectric powered upper-limb orthotic device.

***Comparator***

Usual care post-stroke.

### **Outcomes**

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

### **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

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

### **Review of Evidence**

Peters et al (2017) evaluated the immediate effect (no training) of a myoelectric elbow-wrist-hand orthosis on paretic upper-extremity impairment.<sup>13</sup> 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. 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 limb at the wrist or higher who receive myoelectric upper-limb prosthesis components at or proximal to the wrist, the evidence includes a systematic review and comparative studies. Relevant outcomes are functional outcomes and quality of life. The goals of upper-limb prostheses relate to restoration of both appearance and function while maintaining sufficient comfort for continued use. The identified literature focuses primarily on patient acceptance and rejection; data are limited or lacking in the areas of function and functional

status. The limited evidence suggests that, when compared with body-powered prostheses, myoelectric components possess the similar capability to perform light work; however, myoelectric components could also suffer a reduction in performance when operating under heavy working conditions. The literature has also indicated that the percentage of amputees who accept the use of a myoelectric prosthesis is approximately the same as those who prefer to use a body-powered prosthesis, and that self-selected use depends partly on the individual's activities of daily living. Appearance is most frequently cited as an advantage of myoelectric prostheses, and for patients who desire a restorative appearance, the myoelectric prosthesis can provide greater function than a passive prosthesis with equivalent function to a body-powered prosthesis for light work. Because of the different advantages and disadvantages of currently available prostheses, myoelectric components for persons with an amputation at the wrist or above may be considered when passive, or body-powered prostheses cannot be used or are insufficient to meet the functional needs of the patient in activities of daily living. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a missing limb at the wrist or higher who receive sensor and myoelectric controlled upper-limb prosthetic components, the evidence includes a series of publications from a 12-week home study. Relevant outcomes are functional outcomes and quality of life. The prototypes for the advanced prosthesis were evaluated by the U.S. military and Veterans Administration. Demonstration of improvement in function has been mixed. After several months of home use, activity speed was shown to be similar to the conventional prosthesis, and there were improvements in the performance of some activities, but not all. There were no differences between the prototype and the participants' prostheses for outcomes of dexterity, prosthetic skill, spontaneity, pain, community integration, or quality of life. Study of the current generation of the sensor and myoelectric controlled prosthesis is needed to determine whether newer models of this advanced prosthesis lead to consistent improvements in function and quality of life. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a missing limb distal to the wrist who receive a myoelectric prosthesis with individually powered digits, no peer-reviewed publications evaluating functional outcomes in amputees were identified. Relevant outcomes are functional outcomes and quality of life. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with upper-extremity weakness or paresis who receive a myoelectric powered upper-limb orthosis, the evidence includes a small within-subject study. Relevant outcomes are functional outcomes and quality of life. The largest study (N=18) identified tested participants with and without the orthosis but did not provide any training with the device. Performance on the tests was inconsistent. Studies are needed that show consistent improvements in relevant outcome measures. Results should also be replicated in a larger number of patients. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## **SUPPLEMENTAL INFORMATION**

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

### **Clinical Input From Physician Specialty Societies and Academic Medical Centers**

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

#### **2012 Input**

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

#### **2008 Input**

In response to requests, input was received from 1 physician specialty society and 4 academic medical centers while this policy was under review in 2008. The American Academy of Physical Medicine & Rehabilitation and all 4 reviewers from academic medical centers supported the use of electrically powered upper-extremity prosthetic components. Reviewers also supported evaluation of the efficacy and tolerability of the prosthesis in a real-life setting, commenting that outcomes are dependent on the personality and functional demands of the individual patient.

### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

### **Ongoing and Unpublished Clinical Trials**

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

**Table 3. Summary of Key Trials**

<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date (Status)</b>
<i>Ongoing</i>			
NCT03178890 <sup>a</sup>	The Osseointegrated Human-machine Gateway	18	Feb 2020 (recruiting)
NCT02349035	Application of Targeted Reinnervation for People With Transradial Amputation	10	Jan 2021 (active, not recruiting)



NCT No.	Trial Name	Planned Enrollment	Completion Date (Status)
NCT03401762	Wearable MCI [myoelectric computer interface] to Reduce Muscle Co-activation in Acute and Chronic Stroke	96	Aug 2023
<i>Unpublished</i>			
NCT02274532	Myoelectric SoftHand Pro to Improve Prosthetic Function for People With Below-elbow Amputations: A Feasibility Study	18	May 2016 (completed)
NCT03215771 <sup>a</sup>	Longitudinal Observation of Myoelectric Upper Limb Orthosis Use Among Veterans With Upper Limb Impairment	15	Jan 2020 (completed)

NCT: national clinical trial.

<sup>a</sup>Denotes industry-sponsored or cosponsored trial.

## **CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

### CPT/HCPCS

- L6026 Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes and cables, two batteries, charger, myoelectric control of terminal device, excludes terminal device(s)
- L6611 Addition to upper extremity prosthesis, external powered, additional switch, any type
- L6638 Upper extremity addition to prosthesis, electric locking feature, only for use with manually powered elbow
- L6646 Upper extremity addition, shoulder joint, multipositional locking, flexion, adjustable abduction friction control, for use with body powered or external powered system
- L6648 Upper extremity addition, shoulder lock mechanism, external powered actuator
- 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)
- L6881 Automatic grasp feature, addition to upper limb electric prosthetic terminal device
- L6882 Microprocessor control feature, addition to upper limb prosthetic terminal device
- L6920 Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal switch, cables, two batteries and one charger, switch control of terminal device
- L6925 Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device

- L6930 Below elbow, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal switch, cables, two batteries and one charger, switch 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
- L6940 Elbow disarticulation, external power, molded inner socket, removable humeral shell, outside locking hinges, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch 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
- L6960 Shoulder disarticulation, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch 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
- L6970 Interscapular-thoracic, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch 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
- L7040 Prehensile actuator, switch controlled
- L7045 Electric hook, switch or myoelectric controlled, pediatric
- L7170 Electronic elbow, Hosmer or equal, switch controlled
- L7180 Electronic elbow, microprocessor sequential control of elbow and terminal device
- L7181 Electronic elbow, microprocessor simultaneous control of elbow and terminal device
- L7185 Electronic elbow, adolescent, Variety Village or equal, switch controlled
- L7186 Electronic elbow, child, Variety Village or equal, switch 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
- L7360 Six volt battery, each

L7362	Battery charger, six volt, each
L7364	Twelve volt battery, each
L7366	Battery charger, 12 volt, each
L7367	Lithium ion battery, rechargeable, replacement
L7368	Lithium ion battery charger, replacement only
L8701	Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated
L8702	Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated
L9900	Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS L code

### ICD-10 Diagnoses

S48.011A	Complete traumatic amputation at right shoulder joint, initial encounter
S48.011D	Complete traumatic amputation at right shoulder joint, subsequent encounter
S48.011S	Complete traumatic amputation at right shoulder joint, sequela
S48.012A	Complete traumatic amputation at left shoulder joint, initial encounter
S48.012D	Complete traumatic amputation at left shoulder joint, subsequent encounter
S48.012S	Complete traumatic amputation at left shoulder joint, sequela
S48.111A	Complete traumatic amputation at level between right shoulder and elbow, initial encounter
S48.111D	Complete traumatic amputation at level between right shoulder and elbow, subsequent encounter
S48.111S	Complete traumatic amputation at level between right shoulder and elbow, sequela
S48.112A	Complete traumatic amputation at level between left shoulder and elbow, initial encounter
S48.112D	Complete traumatic amputation at level between left shoulder and elbow, subsequent encounter
S48.112S	Complete traumatic amputation at level between left shoulder and elbow, sequela
S58.011A	Complete traumatic amputation at elbow level, right arm, initial encounter
S58.011D	Complete traumatic amputation at elbow level, right arm, subsequent encounter
S58.011S	Complete traumatic amputation at elbow level, right arm, sequela
S58.012A	Complete traumatic amputation at elbow level, left arm, initial encounter
S58.012D	Complete traumatic amputation at elbow level, left arm, subsequent encounter
S58.012S	Complete traumatic amputation at elbow level, left arm, sequela
S58.111A	Complete traumatic amputation at level between elbow and wrist, right arm, initial encounter
S58.111D	Complete traumatic amputation at level between elbow and wrist, right arm, subsequent encounter
S58.111S	Complete traumatic amputation at level between elbow and wrist, right arm, sequela
S58.112A	Complete traumatic amputation at level between elbow and wrist, left arm, initial encounter
S58.112D	Complete traumatic amputation at level between elbow and wrist, left arm, subsequent encounter
S58.112S	Complete traumatic amputation at level between elbow and wrist, left arm, sequela

- S68.411A Complete traumatic amputation of right hand at wrist level, initial encounter
- S68.411D Complete traumatic amputation of right hand at wrist level, subsequent encounter
- S68.411S Complete traumatic amputation of right hand at wrist level, sequela
- S68.412A Complete traumatic amputation of left hand at wrist level, initial encounter
- S68.412D Complete traumatic amputation of left hand at wrist level, subsequent encounter
- S68.412S Complete traumatic amputation of left hand at wrist level, sequela

## REVISIONS

01-01-2021	Policy published 11-03-2020. Policy effective 01-01-2021.
05-05-2021	Rationale section updated

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