Myoelectric Prosthetic Components for the Upper Limb

Policy #  00443  
Original Effective Date:  09/17/2014  
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Microprocessor Controlled Prostheses for the Lower Limb is addressed separately in medical policy 00426.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider myoelectric upper-limb prosthetic components to be eligible for coverage.

Patient Selection Criteria

Coverage eligibility for myoelectric upper-limb prosthetic components will be considered when ALL of the following criteria are met:

- 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 arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device; AND
- The patient has demonstrated sufficient neurologic 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 (eg, 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.

When Services Are Considered Not Medically Necessary

The use of myoelectric upper-limb prosthetic components when patient selection criteria are not met is considered to be not medically necessary.**
When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers a prosthesis with individually powered digits, including but not limited to a partial hand prosthesis, to be investigational.*

Note: Amputees should be evaluated by an independent qualified professional to determine the most appropriate prosthetic components and control mechanism (eg, body-powered, myoelectric, or combination of body-powered and myoelectric). A trial period may be indicated to evaluate the tolerability and efficacy of the prosthesis in a real-life setting.

Background/Overview

Upper-limb prostheses are used for amputations at any level, from the hand to the shoulder. The need for a prosthesis can occur for a number of reasons, including trauma, surgery, or congenital anomalies. 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.

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. 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 use muscle activity from the remaining limb for 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 1 joint at a time, myoelectric control of movement may be considered the most physiologically natural.
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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 FDA or Other Governmental Regulatory Approval 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 control of 2 joints at once (i.e., 1 body-powered, 1 myoelectric) and are generally lighter and less expensive than a prosthesis composed entirely of myoelectric components.

Technology in this area is rapidly changing, driven by advances in biomedical engineering and by the U.S. Department of Defense Advanced Research Projects Agency (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 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 DEKA Arm System, developed in a joint effort with DARPA and approved by the Food and Drug Administration (FDA) in May 2014, 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.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration
Manufacturers must register prostheses with the restorative devices branch of the U.S. 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, now called the LUKE™‡ arm (DEKA Integrated Solutions, now DEKA Research & Development) was cleared for marketing by FDA through the de novo 513(f)(2) classification process for some novel low- to moderate-risk medical devices that are first-of-a-kind. FDA product codes: GXY, IQZ.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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Rationale/Source

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 myoelectric prostheses improve function and health-related quality of life. Most studies identified describe the development of interfaces and signal processing algorithms for myoelectric prosthetic control.

The available indirect evidence is based on 2 assumptions: (1) use of any prosthesis confers clinical benefit and (2) self-selected use is an acceptable measure of the perceived benefit (combination of utility, comfort, appearance) of a particular prosthesis for that person. Most 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

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. 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 are limited by sampling bias from isolated populations and the generally poor quality of studies selected.

One prospective controlled study compared preferences for body-powered and myoelectric hands in children. Juvenile amputees (toddlers to teenagers, n=120) were fitted in a randomized order with 1 of the 2 types of prostheses; after a 3-month period, the terminal devices were switched, and the children selected one of the prostheses to use. After 2 years, some (n=11) of the original study sites agreed to reevaluate the children, and 78 (74% follow-up from the 11 sites) appeared for interview and examination. At the time of follow-up, 34 (44%) were wearing the myoelectric prosthesis, 26 (34%) were wearing a body-powered prosthesis (13 used hands, 13 used hooks), and 18 (22%) were not using a prosthesis. There was no difference in the children’s ratings of the myoelectric and body-powered devices (3.8 on a 5-point scale). Of
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the 60 children who wore a prosthesis, 19 were considered to be “passive” users (i.e., they did not use the prosthesis to pick up or hold objects [prehensile function]). A multicenter within-subject randomized study, published in 1993, compared function with myoelectric and body-powered hands (identical size, shape, color) in 67 children with congenital limb deficiency and 9 children with traumatic amputation. Each type of hand was worn for 3 months before functional testing. Some specific tasks were performed slightly faster with the myoelectric hand; others were performed better with the body-powered hand. Overall, no clinically important differences were found in performance. Interpretation of these results is limited by changes in technology since this study was published.

Silcox et al 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 9 (20%) owned a passive prosthesis. Twenty-two (50%) patients had rejected the myoelectric prosthesis, 13 (32%) had rejected the body-powered prosthesis, and 5 (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%) than in those with heavy work demands (26%). There was also a trend toward higher use of the myoelectric prosthesis (n=16) in compared with a body-powered prosthesis (n=10) in social situations. Appearance was cited more frequently (19 patients) as a reason for using a myoelectric prosthesis than any other factor. Weight (16 patients) and speed (10 patients) were more frequently cited than any other factor as reasons for nonuse of the myoelectric prosthesis.

McFarland et al 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. In the first year of limb loss, the Vietnam group received a mean of 1.2 devices (usually body-powered), while the Iraq group received a mean of 3.0 devices (typically 1 myoelectric/hybrid, 1 body-powered, 1 cosmetic). At the time of the survey, upper-limb prosthetic devices were used by 70% of the Vietnam group and 76% of the Iraq group. Body-powered devices were favored by the Vietnam group (78%), while a combination of myoelectric/hybrid (46%) and body-powered (38%) devices were favored by the Iraq group. Replacement of myoelectric/hybrid devices was 3 years or longer in the Vietnam group while 89% of the Iraq group replaced myoelectric/hybrid devices in under 2 years. All types of upper-limb prostheses were abandoned in 30% of the Vietnam group and 22% of the Iraq group; the most common reasons for rejection included short residual limbs, pain, poor comfort (e.g., weight of the device), and lack of functionality.

Biddiss and Chau published results from an online or mailed survey of 242 upper-limb amputees from the United States, Canada, and Europe in 2007. Of the survey respondents, 14% had never worn a prosthesis and 28% had rejected regular prosthetic use; 64% were either full-time or consistent part-time wearers. Factors in device use and abandonment were the level of limb absence, sex, and perceived need (e.g., working vs unemployed). Prosthesis rejectors were found to discontinue use due to a lack of functional need, discomfort (excessive weight and heat), and impediment to sensory feedback. Dissatisfaction with available prosthesis technology was a major factor in abandoning prosthesis use. No differences between
users and nonusers were found for experience with a particular type of prosthesis (passive, body-powered, myoelectric) or terminal device (hand or hook).

In another online survey, most of the 43 responding adults used a myoelectric prosthetic arm and/or hand for 8 or more hours at work/school (≈86%) or for recreation (67%), while most of the 11 child respondents used their prosthesis for 4 hours or less at school (72%) or for recreation (88%). Satisfaction was greatest (≥50% of adults, 100% of children) for the appearance of the myoelectric prosthesis and least (>75% of adults, 50% of children) for the grasping speed, which was considered too slow. Of 33 respondents with a transradial amputation, 55% considered the weight “a little too heavy” and 24% considered the weight to be “much too high.” The types of activities that most adults (between 50% and 80%) desired to perform with the myoelectric prosthesis were handicrafts, operation of electronic and domestic devices, using cutlery, personal hygiene, dressing and undressing, and, to a lesser extent, writing. Most (80%) of the children indicated that they wanted to use their prosthesis for dressing and undressing, personal hygiene, using cutlery, and handicrafts.

A 2009 study evaluated the acceptance of a myoelectric prosthesis in 41 children between 2 and 5 years of age. 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 in-patient occupational training, and in those 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 discussed that a more important selection criteria than age was 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.

An evaluation of a rating scale called the Assessment of Capacity for Myoelectric Control (ACMC) was described by Lindner et al in 2009. For this evaluation, a rater identified 30 types of hand movements in 96 patients (age range, 2-57 years) who performed a self-chosen bimanual task, such as preparation of a meal, making the bed, doing crafts, or playing with different toys; each of the 30 types of movements was rated on a 4-point scale (not capable or not performed, sometimes capable, capable on request, spontaneously capable). The types of hand movements were variations of 4 main functional categories (gripping, releasing, holding, coordinating), and the evaluations took approximately 30 minutes. Statistical analysis indicated that the ACMC is a valid assessment for measuring differing ability among users of upper-limb prostheses, although the instrument was limited by having the task difficulty determined by the
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patients (e.g., a person with low ability might have chosen a very easy and familiar task). Lindner et al. recommended that further research with standard tasks is needed and that additional tests of reliability are required to examine the consistency of the ACMC over time.

**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.

**SUMMARY OF EVIDENCE**

For individuals who have a missing limb at the wrist or above who receive myoelectric upper limb prosthesis components at the wrist or proximal to the wrist, the evidence includes cohort studies and survey data. Relevant outcomes are functional outcomes and quality of life. The goals of upper-limb prostheses relate to restoration of both appearance and function while maintaining sufficient comfort for continued use. The identified literature focuses primarily on patient acceptance and reasons for disuse; detailed data on function and functional status, and direct comparisons between body-powered and newer model myoelectric prostheses are limited or lacking. The limited evidence suggests that, compared with body-powered prostheses, myoelectric components may improve range of motion to some extent, have similar capability for light work, but may have reduced performance under heavy working conditions. The literature also indicates that the percentage of amputees who accept use of a myoelectric prosthesis is approximately the same as those who prefer to use a body-powered prosthesis, and that self-selected use depends at least in part on the individual’s activities of daily living. Appearance is most frequently cited as an advantage of myoelectric prostheses, and for patients who desire a restorative appearance, the myoelectric prosthesis can provide greater function than a passive prosthesis, with equivalent function to a body-powered prosthesis for light work. Nonuse of any prosthesis is associated with lack of functional need, discomfort (excessive weight and heat), and impediment to sensory feedback. Because of the differing advantages and disadvantages of 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 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.

**References**

2. Biddiss EA, Chau TT. Upper limb prosthesis use and abandonment: a survey of the last 25 years. Prosthet Orthot Int. Sep 2007;31(3):236-257. PMID 17979010
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08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015 Medical Policy Committee review
09/08/2016 Medical Policy Committee review
09/21/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
09/07/2017 Medical Policy Committee review
09/20/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:
A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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