BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Myoelectric Prosthetic Components for the Upper Limb

Policy # 00443
Original Effective Date: 09/17/2014
Current Effective Date: 09/17/2014

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.***

Myoelectric Prosthetic Components for the Upper Limb

Policy # 00443
Original Effective Date: 09/17/2014
Current Effective Date: 09/17/2014

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

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

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 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 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 is the lightest of the 3 types and is described as the most comfortable. Because the passive prosthesis must be repositioned manually, typically by moving it with the opposite arm, it cannot restore function.
- 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 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 1 joint at a time, myoelectric control of movement may be considered the most physiologically natural. Patient dissatisfaction with myoelectric prostheses includes the increased cost, maintenance (particularly for the glove), and weight.
- Myoelectric hand attachments are similar in form to those offered with the body-powered prosthesis but are battery-powered. An example of recently available technology is the SensorHand™‡ by Advanced Arm Dynamics, which is described as having an AutoGrasp feature, an opening/closing speed of up to 300 mm/s, and advanced EMG signal processing. The i-LIMB™‡ hand (Touch Bionics), sometimes referred to as the bionic hand, is the first commercially available myoelectric hand prosthesis with individually powered digits. ProDigits™‡, also from Touch Bionics, are

Myoelectric Prosthetic Components for the Upper Limb

Policy # 00443
Original Effective Date: 09/17/2014
Current Effective Date: 09/17/2014

prosthetic digits for 1 or more fingers in patients with amputation at a trans metacarpal level or higher. These may be covered by LIVINGSKIN™‡, a high-definition silicone prosthesis created to resemble a patient's natural skin.

- 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 (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 (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, is the first commercially available myoelectric upper limb that can perform complex tasks with multiple simultaneous powered movements (eg, 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 DEKA Arm System is the same shape and weight as an adult arm.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
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 Otto Bock myoelectric prosthesis (Otto Bock), the LTI Boston Digital Arm™‡ System (Liberating Technologies Inc.), and the Utah Arm Systems (Motion Control).

In 2014, FDA cleared the Deka Arm System (DEKA Integrated Solutions) for marketing. The FDA reviewed the DEKA Arm System through its de novo classification process, a regulatory pathway for some novel low- to moderate-risk medical devices that are first-of-a-kind.

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.

Rationale/Source

Most studies identified in the literature review describe the development of interfaces and signal processing algorithms for myoelectric prosthetic control.

Myoelectric Prosthetic Components for the Upper Limb

Policy # 00443
Original Effective Date: 09/17/2014
Current Effective Date: 09/17/2014

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

The available indirect evidence is based on 2 assumptions: (1) use of any prosthesis confers clinical benefit and (2) self-selected use is an acceptable measure of the perceived benefit (combination of utility, comfort, appearance) of a particular prosthesis for that person. Most of the studies identified describe amputees' self-selected use or rejection rates. The results are usually presented as hours worn at work, hours worn at home, and hours worn in social situations. Amputees' self-reported reasons for use and abandonment are also frequently reported. It should be considered that upper-limb amputee's needs 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.

Comparative Studies
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 the 60 children who wore a prosthesis, 19 were considered to be "passive" users, ie, 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%) in comparison with those with heavy work demands (26%). There was also a trend toward higher use of the myoelectric prosthesis (n=16) in comparison with a body-powered prosthesis (n=10) in social situations. Appearance was cited more frequently (19 patients) as a reason for

using a myoelectric prosthesis than any other factor. Weight (16 patients) and speed (10 patients) were more frequently cited than any other factor as reasons for nonuse of the myoelectric prosthesis.

McFarland et al 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 1 myoelectric/hybrid, 1 body-powered, and 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 (eg, weight of the device), and lack of functionality.

A cross-sectional study from 10 Shriners Hospitals assessed the benefit of a prosthesis (type not described) on function and health-related quality of life in 489 children between 2 and 20 years of age with a congenital below-the-elbow deficiency (specific type of hand malformation). Outcomes consisted of parent- and child-reported quality of life and musculoskeletal health questionnaires and subjective and objective functional testing of children with and without a prosthesis. Age-stratified results were compared for 321 children who wore a prosthesis and 168 who did not, along with normative values for each age group. The study found no clinically relevant benefit for prosthesis wearers compared with nonwearers, or for when the wearers were using their prosthesis. Nonwearers performed better than wearers on a number of tasks. For example, in the 13- to 20-year-old group, nonwearers scored higher than wearers for zipping a jacket, putting on gloves, peeling back the plastic cover of a snack pack, raking leaves, and throwing a basketball. Although prostheses have been assumed to improve function, no benefit was identified for young or adolescent children with this type of congenital hand malformation.

Noncomparative Studies

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.

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, gender, and perceived need (eg, 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 (approximately 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 (more than 50% of adults and 100% of children) for the appearance of the myoelectric prosthesis and least (>75% of adults and 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 (in-patient or out-patient) 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 hours). 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 of 5 children (60%) with amputations at or below the wrist refused use of any prosthetic device. There were trends (ie, did not achieve statistical significance in this sample) 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; for example, 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. Due to the poor durability of the myoelectric hand, this group provides a

variety of prosthetic options to use depending on the situation. The impact of multiple prostheses types (eg, providing both a myoelectric and body-powered prosthesis) on supply costs, including maintenance frequency, are unknown at this time.

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 of the ACMC, a rater identified 30 types of hand movements in a total of 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 assessment was limited by having the task difficulty determined by the patient (eg, 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.

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.

Clinical Input Received Through 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.

The American Academy of Physical Medicine and Rehabilitation and 4 reviewers from academic medical centers supported use of electrically powered upper extremity prosthetic components in 2008. 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.

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

Summary
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 of body-powered and newer model myoelectric prostheses are limited/lacking. The limited evidence available suggests that in comparison with body-powered prostheses, myoelectric components may improve range of motion to some

extent, have similar capability for light work but may have reduced performance under heavy working conditions. The literature also indicates that the percentage of amputees who accept use of a myoelectric prosthesis is approximately the same as those who prefer to use a body-powered prosthesis and that self-selected use depends at least in part on the individual's activities of daily living. Appearance is most frequently cited as an advantage of myoelectric prostheses, and for patients who desire a restorative appearance, the myoelectric prosthesis can provide greater function than a passive prosthesis, with equivalent function to a body-powered prosthesis for light work. Nonuse of any prosthesis is associated with lack of functional need, discomfort (excessive weight and heat), and impediment to sensory feedback. Because of the differing advantages and disadvantages of the currently available prostheses, myoelectric components for persons with an amputation at the wrist or above may be considered when passive or body-powered prostheses cannot be used or are insufficient to meet the functional needs of the patient in activities of daily living. Evidence is insufficient to evaluate full or partial hand prostheses with individually powered digits; these are considered investigational.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Myoelectric Prosthetic Components for the Upper Limb", 1.04.04, 6:2014.
2. Kruger LM, Fishman S. Myoelectric and body-powered prostheses. J Pediatr Orthop 1993; 13(1):68-75.
3. Edelstein JE, Berger N. Performance comparison among children fitted with myoelectric and body-powered hands. Arch Phys Med Rehabil 1993; 74(4):376-80.
4. Silcox DH, 3rd, Rooks MD, Vogel RR et al. Myoelectric prostheses. A long-term follow-up and a study of the use of alternate prostheses. J Bone Joint Surg Am 1993; 75(12):1781-9.
5. McFarland LV, Hubbard Winkler SL, Heinemann AW et al. Unilateral upper-limb loss: satisfaction and prosthetic-device use in veterans and servicemembers from Vietnam and OIF/OEF conflicts. J Rehabil Res Dev 2010; 47(4):299-316.
6. 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 2006; 88(11):2356-65.
7. Biddiss E, Chau T. Upper-limb prosthetics: critical factors in device abandonment. Am J Phys Med Rehabil 2007; 86(12):977-87.
8. Biddiss EA, Chau TT. Upper limb prosthesis use and abandonment: a survey of the last 25 years. Prosthet Orthot Int 2007; 31(3):236-57.
9. Pylatiuk C, Schulz S, Doderlein L. Results of an Internet survey of myoelectric prosthetic hand users. Prosthet Orthot Int 2007; 31(4):362-70.
10. Egermann M, Kasten P, Thomsen M. Myoelectric hand prostheses in very young children. Int Orthop 2009; 33(4):1101-5.
11. 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.

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of

Myoelectric Prosthetic Components for the Upper Limb

Policy # 00443
Original Effective Date: 09/17/2014
Current Effective Date: 09/17/2014

Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.
Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	L6025, L6880, L6925, L6935, L6945, L6955, L6965, L6975, L7007, L7008, L7009, L7045, L7190, L7191
ICD-9 Diagnosis	V49.64 thru V49.67, V52.0
ICD-9 Procedure	No codes

Policy History

Original Effective Date: 09/17/2014
Current Effective Date: 09/17/2014
09/04/2014 Medical Policy Committee review
09/17/2014 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 09/2015

*****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.

Myoelectric Prosthetic Components for the Upper Limb

Policy # 00443
Original Effective Date: 09/17/2014
Current Effective Date: 09/17/2014

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.