Upper Extremity Prosthetic Devices (for Kentucky Only)

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Instructions for Use

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Related Policy

- Lower Extremity Prosthetics (for Kentucky Only)

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

An upper extremity prosthetic for amputations is proven and Medically Necessary when all of the following criteria are met:

- Member has a traumatic or surgical amputation of upper extremity or a congenital absence or defect; and
- Prosthetic replaces all or part of a missing limb; and
- Prosthetic will help the member regain or maintain function; and
- Prosthetic device is ordered by or under the direction of a physician; and
- Prosthetic needs evaluated for member by a healthcare professional with appropriate prosthetic qualifications and training under the supervision of the ordering physician; and
- Member is willing and able to participate in the training for the use of the prosthetic; and
- Member with expected rehabilitation potential undergoes functional assessment [including Activities of Daily Living (ADLs) and Instrumental ADLs (IADLs)] evaluation

An upper extremity Myoelectric Prosthetic for amputations above the wrist is proven and Medically Necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Prosthetics, Myoelectric, Upper Extremity.

Click here to view the InterQual® criteria.

An upper extremity Myoelectric Prosthetic hand, partial-hand, or artificial digit(s) for amputations below the wrist is Medically Necessary when all of the following criteria are met:

- Member has a traumatic or surgical amputation below the wrist or a congenital missing or dysfunctional hand or finger; and
- Prosthetic replaces all or part of a missing limb; and
- Prosthetic will help the member regain or maintain function; and
- Prosthetic needs evaluated for member by a healthcare professional with appropriate prosthetic qualifications and training under the supervision of the ordering physician; and

- Member is willing and able to participate in the training for the use of the prosthetic; and
- Member is able to operate the stimulator of the computerized prosthetic or microprocessor; and
- Member with expected rehabilitation potential undergoes functional assessment [including activities of daily living (ADLs) and Instrumental ADLs (IADLs)] evaluation; and
- Remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a Myoelectric Prosthetic device (usually 3-5 muscle groups must be activated to use a computerized hand), no external switch; and
- Ordering physician authorizes the final prosthetic proposal

Myoelectric Prosthetic components for hand, partial-hand, and artificial digit(s) below the wrist are considered not Medically Necessary in members who do not meet the criteria above.

Definitions

Activities of Daily Living (ADLs): Basic tasks people need to do to function and interact such as bathing, grooming, dressing, toilet use, eating, and physical ambulation (Mlinac and Feng, 2016, Edemekong et al., 2022).

Instrumental Activities of Daily Living (IADLs): A higher cognitive and complex activity related to independent living such as shopping, transportation, meal preparation, housecleaning, managing finances and managing medications (Mlinac and Feng, 2016, Edemekong et al., 2022).

Medically Necessary: The determination of whether a covered benefit or service is medically necessary shall:
- Be based on an individualized assessment of the recipient's medical needs; and
- Comply with the requirements established in this paragraph. To be medically necessary or a medical necessity, a covered benefit shall be:
  - Reasonable and required to identify, diagnose, treat, correct, cure, palliate, or prevent a disease, illness, injury, disability, or other medical condition, including pregnancy;
  - Appropriate in terms of the service, amount, scope, and duration based on generally-accepted standards of good medical practice;
  - Provided for medical reasons rather than primarily for the convenience of the individual, the individual's caregiver, or the health care provider, or for cosmetic reasons;
  - Provided in the most appropriate location, with regard to generally-accepted standards of good medical practice, where the service may, for practical purposes, be safely and effectively provided;
  - Needed, if used in reference to an emergency medical service, to exist using the prudent layperson standard.
  - Provided in accordance with early and periodic screening, diagnosis, and treatment (EPSDT) requirements established in 42 U.S.C. 1396d(r) and 42 C.F.R. Part 441 Subpart B for individuals under twenty-one (21) years of age; and
  - Provided in accordance with 42 C.F.R. 440.230. (907 KAR 3:130)

Myoelectric Prosthetic: A prosthetic device operated by battery-powered electric motors that are activated through electrodes by the myoelectric potentials provided by muscles (Medical Dictionary).

Prosthesis: A man-made substitute for a missing body part (American Cancer Society®).

Prosthetist: A healthcare professional who makes and fits artificial limbs (prostheses) for people with disabilities. This includes artificial legs and arms for people who have had amputations due to conditions such as cancer, diabetes, or injury (John Hopkins Medicine).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
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)

HCPCS Code	Description
L6611	Addition to upper extremity prosthesis, external powered, additional switch, any type
L6621	Upper extremity prosthesis addition, flexion/extension wrist with or without friction, for use with external powered terminal device
L6629	Upper extremity addition, quick disconnect lamination collar with coupling piece, Otto Bock or equal
L6632	Upper extremity addition, latex suspension sleeve, each
L6677	Upper extremity addition, harness, triple control, simultaneous operation of terminal device and elbow
L6680	Upper extremity addition, test socket, wrist disarticulation or below elbow
L6682	Upper extremity addition, test socket, elbow disarticulation or above elbow
L6686	Upper extremity addition, suction socket
L6687	Upper extremity addition, frame type socket, below elbow or wrist disarticulation
L6688	Upper extremity addition, frame type socket, above elbow or elbow disarticulation
L6694	Addition to upper extremity prosthesis, below elbow/above elbow, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism
L6695	Addition to upper extremity prosthesis, below elbow/above elbow, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism
L6696	Addition to upper extremity prosthesis, below elbow/above elbow, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L6694 or L6695)
L6697	Addition to upper extremity prosthesis, below elbow/above elbow, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L6694 or L6695)
L6698	Addition to upper extremity prosthesis, below elbow/above elbow, lock mechanism, excludes socket insert
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
L6883	Replacement socket, below elbow/wrist disarticulation, molded to patient model, for use with or without external power
L6884	Replacement socket, above elbow/elbow disarticulation, molded to patient model, for use with or without external power
L6890	Addition to upper extremity prosthesis, glove for terminal device, any material, prefabricated, includes fitting and adjustment
L6925	Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, otto bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
L6935	Below elbow, external power, self-suspended inner socket, removable forearm shell, otto bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
L6945	Elbow disarticulation, external power, molded inner socket, removable humeral shell, outside locking hinges, forearm, otto bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
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
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

HCPCS Code	Description
L7007	Electric hand, switch or myoelectric controlled, adult
L7008	Electric hand, switch or myoelectric, controlled, pediatric
L7009	Electric hook, switch or myoelectric controlled, adult
L7045	Electric hook, switch or myoelectric controlled, pediatric
L7180	Electronic elbow, microprocessor sequential control of elbow and terminal device
L7181	Electronic elbow, microprocessor simultaneous control of elbow and terminal device
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
L7364	Twelve volt battery, each
L7366	Battery charger, twelve volt, each
L7367	Lithium ion battery, rechargeable, replacement
L7368	Lithium ion battery charger, replacement only
L7400	Addition to upper extremity prosthesis, below elbow/wrist disarticulation, ultralight material (titanium, carbon fiber or equal)
L7401	Addition to upper extremity prosthesis, above elbow disarticulation, ultralight material (titanium, carbon fiber or equal)
L7403	Addition to upper extremity prosthesis, below elbow/wrist disarticulation, acrylic material
L7404	Addition to upper extremity prosthesis, above elbow disarticulation, acrylic material
L8465	Prosthetic shrinker, upper limb, each

Description of Services

A prosthesis is an artificial device used to replace all or part a missing body part and is intended to restore normal function. Meier and Melton (2014) identify the most common levels of amputations for the upper limb are the transradial (TR) (below elbow, BE) and the transhumeral (TH) (above elbow, AE). The prosthesis is a tool that helps the single-limb amputee gain functional independence. Ideally, upper limb unilateral amputees should be able to accomplish things such as wearing the prosthetic during waking hours, perform basic ADLs, and return to work whenever possible.

Upper limb prosthesis can be classified into four categories of prosthesis:

- Passive prosthesis is the lightest of all the prosthesis and often termed as cosmetic. It has no motors and contains limited mechanical features
- Body-powered prosthesis comes from the patient's movements and utilizes a body harness and strap which connects to a cable system that operates the device. Advantages include lightweight, durable and may be waterproof; disadvantages include a required harness, strength and range of motion capability from user
- Externally powered prosthesis is powered by batteries contained within the system and controlled by EMG signals, force-sensing resistors, and pull/push switches and most often reserved for high-level amputees. Advantages include little or no harnessing of the device, generate more force and appear more cosmetic; disadvantages include battery life and daily charging, not waterproof, more complex and therefore prone to breakage and repair
- Hybrid prosthesis combines body-powered components and myoelectric/externally powered components in one device. This type of prosthesis is most commonly used by transhumeral and shoulder disarticulation amputees and reserved for high-level amputees

(National Academies of Sciences, Engineering, and Medicine; 2017)

Clinical Evidence

Carey et al. (2015) conducted a systematic review to identify evidence statements regarding the differences between myoelectric (MYO) and body-powered (BP) prosthesis in persons with upper limb amputations. A search was conducted using PubMed, CINAHL, RECAL Legacy, Cochrane Database of Systematic Reviews, Cochrane Clinical Trials Registry, EMBASE, PMC-NIH Research Publication Database, Web of Science, and Google Scholar. A total of 31 articles were

found which spanned from 1993 to 2013, with most of the publications occurring in 2012. The median subject size was 12 and average age of participants was 43.3 years. Twenty-four articles were experimental or observational along with expert opinions in six publications which were therefore given a low quality of evidence. Device assessments fell into three categories with surveys being the most common in 12 of the 24 relevant articles; other assessments included laboratory and clinical functional assessments and ability to use ADLs. Eleven empirical evidence statements (EES) were created based on the following areas of interest: functionality, control, and feedback, cosmesis and psychosocial issues, and rejection. The EES were then divided into the following five categories: activity/sport specific, body-powered, control, myoelectric, and rejection rates. The authors found conflicting information in terms of the relative functional performance of BP and MYO prostheses. BP prostheses have advantages in training time, durability, and frequency in adjustments, measurements, and feedback. MYO prostheses have been shown to provide a cosmetic advantage, are more accepted for light-intensity work, and may have a positive effect on the patient's phantom limb pain. Study limitations included low number of controlled experiments and high number of observational studies.

Myoelectric Hand, Partial-Hand, or Artificial Digits

Kerver et al. (2023) compared the multi-grip myoelectric hand prosthesis (MHP) to that of a standard myoelectric hand prostheses (SHP) in all categories of the International Classification of Functioning, Disability, and Health-model (ICF-model). Thirty-three participants met the inclusion criteria. The nineteen members of the SHP group utilized a Myohand Variplus Speed (Ottobock; Duderstadt, Germany) or Motion Control Hand (Fillauer, USA), which has a movable thumb, index finger, and middle finger that can open and close in only one grip. The fourteen participants in the MHP group were in possession of a myoelectric prosthesis and consisted of one of the following: i-Limb Quantum/Ultra (Touch Bionics; Livingston, United Kingdom), BeBionic (Ottobock; Duderstadt, Germany) or VINCENT (Vincent Systems, Karlsruhe, Germany). Comparisons in joint coordination, dexterity, and prosthetic hand function were analyzed; in addition comparisons on user experience, satisfaction and quality of life were performed. This study had a cross-over design which consisted of two parts: between-group comparison using questionnaires and/or scales and within group comparison based on physical measurements. The authors found no clear benefit for MHP devices when compared to SHP; the SHP outperformed the MHP in several outcome measures. The authors concluded with the expenses and cost of repairs, a prescription for MHP should be carefully assessed. Limitations included small sample sizes, lack of randomization, and assumptions with users and their experience for device controls.

Widehammar et al. (2022) published the results of a single case study evaluating the effect of multi-grip myoelectric prosthetic hands-on performance of daily activities, pain-related disability and prosthesis use, in comparison with single-grip myoelectric prosthetic hands. Nine adults with upper-limb loss participated in the study and all had previous experience of single-grip myoelectric prostheses and were prescribed a prosthesis with multi-grip functions. Both a single-baseline (for ACMC and SHAP data) and a multiple baseline single-case AB design was used. At 6 months' follow-up self-perceived performance and satisfaction scores had increased, prosthesis wearing time had increased, and pain-related disability had reduced in participants with musculoskeletal pain at baseline. The authors concluded that the multi-grip myoelectric prosthetic hand has favorable effects on performance of, and satisfaction with, individually chosen activities, prostheses use and pain-related disability. A durable single-grip myoelectric prosthetic hand may still be needed for heavier physical activities. With structured training, a standard 2-site electrode control system can be used to operate a multi-grip myoelectric prosthetic hand. However, the authors summarized that there may be a mismatch between the patients' wish for better prosthetic devices and their actual use of the new devices. Current knowledge is inconclusive and further studies are needed to support rehabilitation clinicians in their prescription decisions.

A health technology assessment by Hayes (2021) found a very low-quality body of evidence that suggests the LUKE arm (referred to as the DEKA arm in many studies) appears to be safe and may allow some patients to perform certain ADLs, but not all. Some ADLs were more manageable with the patient's existing prosthesis; however, the limited evidence suggests inconsistent improvement on functional measures when compared to their existing prosthesis. Future studies which include larger sample sizes and long-term follow-up are needed to further compare the safety and efficacy of this device.

Resnik et al (2020) conducted a telephonic survey for 755 veterans with a prosthetic for upper limb amputation; 306 patients had no prosthesis, 325 had a body-powered device, 62 had a myoelectric or hybrid single-DOF terminal device and 22 utilized cosmetic devices. Overall, 35.8% had below elbow amputation, 30.9% above elbow, 16.4% wrist disarticulation, 9.1% shoulder disarticulation, 4.9% elbow disarticulation, and 2.9% forequarter amputation. The survey included scores from the Disabilities of the Arm, Shoulder, and Hand (QuickDASH), the Physical Component Summary (PCS) and the Mental Component Summary (MCS) score of the Veterans RAND 12-item Health Survey (VR-12) measured HRQOL. The authors found those veterans without a prosthesis reported more difficulty in activities, greater disability and more likely to need help with ADLs than those with any type of prothesis. However, the author did not find any differences observed between body-powered and myoelectric devices when it came to needing assistance with ADLs,

self-reported disability, or quality of life. Limitations included study design, lack of randomization, disproportionate groups, varying amount of training and experience with prosthetic use, and self-reported data.

Wanamaker et al. (2019) reported the results of a cross-sectional study evaluating upper limb function and kinematics in 10 males with partial-hand amputations fitted with a partial-hand prosthesis. Three-dimensional kinematics were compiled as they performed the Southampton Hand Assessment Procedure (SHAP) with and without a prosthesis. Without a prosthesis, larger joint movements were noted. There was significant improvement for the individuals with a five-digit limb loss using a prosthesis seen in the SHAP scores in comparison with those not using a prosthesis ($p < 0.05$ for 6 of 7 SHAP score categories). The authors concluded the prosthesis reduced functional deficits and decreased joint range of motion in individuals with partial hand loss which may reduce the overuse injury risk.

Validated performance-based outcome measures for upper limb (UL) prosthesis users are sparse and may not adequately address all necessary aspects of functional restoration. Wang et al. (2018) evaluated and compared the following characteristics of performance-based outcome measures for UL function: (1) location of task performance around the body, (2) possible grips employed, (3) bilateral versus unilateral task participation, and (4) details of the scoring mechanisms, including subjectivity, assessment of sensation, and assessment of quality of motion (QoM). A literature search was conducted using the EMBASE, Medline, and Cumulative Index to Nursing and Allied Health electronic databases from 1970 to June 2015 to identify relevant clinical studies that used UL performance-based outcome measures as functional endpoints; a final list of 7 articles was found. Inclusion criteria included one or more outcome measures that were developed for amputees or individuals with neurologic/musculoskeletal impairments or disabilities of the UL, were intended to measure the functional restoration/improvements through a series of activities or tasks and were intended for use in the adult population. For each identified outcome measured, specific characteristics were obtained: areas around the body in which tasks are performed; the types of grips that a user could possibly employ; bilateral versus unilateral task participation; and the subjectivity and details of the scoring mechanisms, with a particular focus on the assessment of sensation and quality of motion (QoM) (QoM was defined as any consideration of how a movement was performed). The authors suggested utilization or modification of existing measures designed for other clinical populations as first steps to more aptly measure prosthesis use while more complete assessments for UL prosthesis users are developed.

Resnik et al. (2018) conducted a two-part study on the Gen 3 DEKA arm when compared to conventional prosthesis. Part A consisted of laboratory training and part B addressed home training; 23 participants completed part A and then a subset (15) went on to complete part B. Participants in part A were at least 18 years old and had an upper limb amputation at the transradial, transhumeral, shoulder disarticulation or scapulothoracic level; participants were eligible for part B of the study if they had at least fair functional use of the DEKA Arm. The device includes 3 available configurations: radial configuration (RC) for persons with radial amputation; humeral configuration (HC) for persons with humeral amputation; and shoulder configuration (SC) for persons with shoulder disarticulation, forequarter amputation or very short transhumeral amputation. Unique features of all configuration levels are the powered wrist which allows flexion and extension and six programmable hand grip patterns. Performance based measures included a dexterity measure, the Jebsen-Taylor Hand Function Test (JTHFT), and measures of activity performance [Activities Measure for Upper Limb Amputees (AM-ULA); University of New Brunswick Test of Prosthetic Function for Unilateral Amputees (UNB); Timed Measure of Activity Performance (T-MAP), and Brief Activity Measure for Upper Limb Amputees (BAM-ULA)]. Each of the performance measures assess performance of daily activities but differ significantly in the scoring criteria and item content. For example, the T-MAP assesses the time it takes to perform an activity, while the AM-ULA assesses body compensation during activity performance. A variety of self-reported measures were completed as well. Upon completion of the data analysis for both performance and self-reported measures, the authors found at the end of part A participants using the DEKA arm had less perceived disability and more engagement in everyday tasks, but their activity performance was slower. However following completion of part B, participants perceived disability was lower, prosthesis engagement higher, activity performance was improved, and activity speed was equivalent to using a conventional prosthesis. It was also noted that the authors found no differences between the DEKA Arm and conventional prostheses in evaluation of dexterity, prosthetic skill, spontaneity, community integration or quality of life. Limitations included small sample size and participant experience with previous generations of DEKA.

Earley et al. (2016) developed a training protocol and a classifier that switches between long and short EMG analysis window lengths. A study involving 17 non-amputee and 2 partial-hand amputee subjects participated to determine the effects of including electromyogram (EMG) from different arm and hand locations during static and/or dynamic wrist motion. Several real-time classification techniques were evaluated to determine which control scheme yielded the highest performance in virtual real-time tasks using a three-way analysis of variance (ANOVA). The outcome identified significant interaction between analysis window length and the number of grasps available. Including static and dynamic wrist motion and intrinsic hand muscle EMG with extrinsic muscle EMG significantly reduced pattern recognition classification error by 35%. Classification delay or majority voting techniques significantly improved real-time task completion rates (17%),

selection (23%), and completion (11%) times, and selection attempts (15%) for non-amputee subjects, and the dual window classifier significantly reduced the time (8%) and average number of attempts required to complete grasp selections (14%) made in various wrist positions. Amputee subjects demonstrated improved task timeout rates, and made fewer grasp selection attempts, with classification delay or majority voting techniques. The authors concluded that the proposed techniques show promise for improving control of partial-hand prostheses and more effectively restoring function to individuals using these devices.

Due to few measures developed for or validated with adults, and limited research to guide, Resnik et al. (2013) found it is a challenge to collect or analyze data outcomes for persons with upper limb amputation. The authors identify a need for new function tests for adult amputees, as well as new measures for use with higher-level amputees, bilateral amputees, and body-powered users. 52 patients with upper limb amputation were evaluated. A set of activities from the Atkins activities of daily living checklist were identified and a simple grading scale was used. Therapists were oriented to the measures and asked each patient some basic instructions with their prosthetic limb and then their sound limb. Videotaping of sessions occurred and then adjustments for scoring were made. Final scoring criteria was comprised of the following: “(1) extent of completion of all activity subtasks; (2) speed of completion; (3) movement quality; (4) skillfulness of prosthetic use and control over voluntary grip functions; and (5) independence.” The authors developed and refined a new performance-based activity identified as Activities Measure for Upper Limb Amputees (AM-ULA) and demonstrated that the measure has acceptable reliability, consistency and known group validity.

Egermann et al. (2009) conducted a retrospective study on forty-one children (< six years of age) to evaluate the acceptance of myoelectric prostheses in preschool children. All patients suffered from a unilateral congenital upper limb deficiency or traumatic upper limb amputation; patients with bilateral amputations were excluded. Most of the children in the study received a passive device at the age of approximately one year. For the patient to be fitted with a myoelectric prosthesis, the following inclusion criteria needed to be met: 1) communicates well and follows instructions from strangers, 2) bi-manual handling and proactive interest in an artificial limb, and 3) family support for the child in using the myoelectric device. The myoelectric prosthesis was identical for all patients. A socket was manufactured using the “Muenster” technique and a single electrode which controlled the opening of the hand while closing automatically was placed. The “Elektrohand 2000” from Germany was used and powered by a six-volt rechargeable battery. Specialized occupational therapists made the initial introduction of the device to the children; structured training at the hospital occurred over one to two weeks by an interdisciplinary team. Families were asked to complete a specific questionnaire which included items such as information about internal/external occupational training, skin irritations at the stump, and activities of daily life. Successful use of the device was defined by daily wearing it for more than two hours per day. Over an observation period of two years, 76% of the study group was successful with the device. The actual mean time of daily use was 5.8 ±4.1 hours/day. The authors found children between two and four years of age (n = 23) showed a higher average time of daily use when compared to the older subgroup of patients in the four to six years of age (n = 18); in addition, they also found above elbow amputees wore the device more often than children with below elbow amputations. It was concluded under the right conditions the application of a myoelectric hand prosthesis in a young child can be very successful; family involvement was a major key factor in the child’s success. Limitations of the study included the small number of participants, weight of the prosthesis and low battery life span.

Crandall and Tomhave (2002) retrospectively evaluated 34 pediatric patients for long-term follow-up on a variety of prosthetic options given for below-elbow amputees. The patients were provided with a variety of prosthetic options, including a “passive” cosmetic upper extremity device. Most of the patients were fitted with conventional prostheses using a body-powered voluntary closing terminal device (97%) as well as myoelectric prostheses (82%). The average follow-up was 14 years, with many of the patients being followed up throughout their entire childhood. All patients were sent questionnaires, and patient interviews and chart review were completed. Final analysis indicated that 15 patients (44%) selected a simple cosmetic “passive hand” as their prosthesis of choice. In long-term follow-up 14 patients (41%) continued as multiple prosthetic users. Fourteen patients (41%) selected the conventional prosthesis using a voluntary closing terminal device as the prosthesis of choice. Only five patients (15%) selected the myoelectric device as their primary prosthesis. The authors concluded that successful unilateral pediatric amputees choose multiple prostheses based on function and that often the most functional prosthesis selected in the long-term was the simplest one in design. The authors felt strongly that unilateral pediatric amputees be offered a variety of prosthetic options to help with normal ADLs. Limitations included small sample size and focus on pediatric population.

Clinical Practice Guidelines

Department of Veterans Affairs(VA)/Department of Defense (DoD)

In a VA/DoD 2022 Clinical Practice Guideline for rehabilitation of individuals with lower limb amputation, the following is recommended:
Pre-Prosthetic Training Recommendation

- The care team should ensure that patients undergo pre-prosthetic training to help determine the most appropriate type of device to achieve functional goals (Expert Opinion)
- A comprehensive assessment should be conducted by the care team to determine the most appropriate types of prostheses to prescribe along with educating the patient and/or caregiver(s) on the various types of available prostheses
- Components of a comprehensive assessment include:
  - Present health status
  - Level of function
  - Modifiable/controllable health risk factors
  - Pain assessment
  - Cognition and behavioral health
  - Personal, family, social, and cultural context
  - Learning assessment
  - Residual limb assessment
  - Non-amputated limb and trunk assessment
  - Prosthetic assessment (if applicable)
  - Vocational assessment

Prosthesis Prescription:

- Once the appropriate type of prosthesis is identified, the care team should write a prescription for the device, including all necessary components (Expert Opinion)
  - Prescriptions for upper extremity prostheses should be based on a collaborative decision between the patient and the care team. Input should be received from all members of the care team and individualized for the patient based on the patient's specific needs and goals related to prosthesis use. Components for an upper extremity prosthesis should include:
    - Design (e.g., preparatory vs. definitive)
    - Control strategy (e.g., passive, externally powered, body powered, task specific)
    - The anatomical side and amputation level of the prosthesis
    - Type of socket interface (e.g., soft insert, elastomer liner, flexible thermoplastic)
    - Type of socket frame (e.g., thermoplastic or laminated)
    - Suspension mechanism (e.g., harness, suction, anatomical)
    - Terminal device
    - Wrist unit (if applicable)
    - Elbow unit (if applicable)
    - Shoulder unit (if applicable)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Prostheses are class I devices exempt from U.S. Food and Drug Administration (FDA) review. For additional information, use product codes: GXY, IQZ.

In 2014, the DEKA Arm System was cleared for marketing by FDA through the de novo 513(f)(2) classification process which is a low- to moderate-risk medical device. Refer to the following website for additional information:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN120016
https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN120016.pdf
(Accessed November 15, 2023)

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Policy History/Revision Information

Date	Summary of Changes

06/01/2024	**Title Change**
	• Previously titled *Upper Extremity Myoelectric Prosthetic Devices (for Kentucky Only)*
	Coverage Rationale
	• Added language to indicate:
	  ○ An upper extremity prosthetic for amputations is proven and Medically Necessary when **all** of the following criteria are met:
	  ▪ Member has a traumatic or surgical amputation of upper extremity or a congenital absence or defect
	  ▪ Prosthetic replaces all or part of a missing limb
	  ▪ Prosthetic will help the member regain or maintain function
	  ▪ Prosthetic device is ordered by or under the direction of a physician
	  ▪ Prosthetic needs evaluated for member by a healthcare professional with appropriate prosthetic qualifications and training under the supervision of the ordering physician

Date	Summary of Changes
	▪ Member is willing and able to participate in the training for the use of the prosthetic ▪ Member with expected rehabilitation potential undergoes functional assessment [including Activities of Daily Living (ADLs) and Instrumental ADLs (IADLs)] evaluation ○ An upper extremity Myoelectric Prosthetic for amputations above the wrist is proven and Medically Necessary in certain circumstances • Replaced language indicating "an upper extremity Myoelectric Prosthetic hand, partial-hand, or artificial digit(s) for amputations below the wrist is Medically Necessary when the [listed] criteria are met" with "an upper extremity Myoelectric Prosthetic hand, partial-hand, or artificial digit(s) for amputations below the wrist is Medically Necessary when *all of* [listed] criteria are met" • Revised coverage criteria for an upper extremity Myoelectric Prosthetic hand, partial-hand, or artificial digit(s) for amputations below the wrist; replaced criterion requiring: ○ "Member is evaluated *for his/her individual needs* by a healthcare professional with the qualifications and training *to make an evaluation* under the supervision of the ordering physician" with "*prosthetic needs* evaluated for member by a healthcare professional with *appropriate prosthetic* qualifications and training under the supervision of the ordering physician" ○ "Functional assessment [including Activities of Daily Living (ADLs) and Instrumental ADLs (IADLs)] evaluation and expected rehabilitation potential" with "*member with* expected rehabilitation potential *undergoes* functional assessment [including Activities of Daily Living (ADLs) and Instrumental ADLs (IADLs)] evaluation" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS360KY.01

Instructions for Use

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