Upper Extremity Prosthetic Devices (for Indiana Only)

Policy Number: CS360IN.02
Effective Date: June 1, 2024

Ü Instructions for Use

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Related Policies
None

Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

For coverage guidelines for prosthetic devices and medical necessity clinical coverage criteria for myoelectric upper extremity prosthetics, refer to the Indiana Health Coverage Programs Provider Reference Module: Durable and Home Medical Equipment and Supplies.

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;
- 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]

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: "Medically necessary service" means a covered service that is required for the care or well-being of the patient and is provided in accordance with generally accepted standards of medical or professional practice. For a service to be reimbursable by the office, it must:

1. Be medically necessary, as determined by the office, which shall, in making that determination, utilize generally accepted standards of medical or professional practice; **and**
2. Not be listed in this title as a noncovered service, or otherwise excluded from coverage (405 IAC 5-2-17)

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 guideline 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 Codes	Description
Upper Limb Prosthetics	
*L6026	Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes and cables, two batteries, charger, myoelectric control of terminal device, excludes terminal device(s)
*L6611	Addition to upper extremity prosthesis, external powered, additional switch, any type
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)

HCPCS Codes	Description
Upper Limb Prosthetics	
*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
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

HCPCS Codes	Description
Upper Limb Prosthetics	
*L8465	Prosthetic shrinker, upper limb, each

Note: Codes labeled with an asterisk (*) are not managed for medical necessity review for the state of Indiana at the time this policy became effective. Refer to the most up to date prior authorization list for Indiana at Prior Authorization and Notification: UnitedHealthcare Community Plan of Indiana.

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.

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

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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 Indiana Only)* **Coverage Rationale** • Revised language to indicate: o Refer to the *Indiana Health Coverage Programs Provider Reference Module: Durable and Home Medical Equipment and Supplies* for coverage guidelines for prosthetic devices and medical necessity clinical coverage criteria for myoelectric upper extremity prosthetics o 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

Date	Summary of Changes
	§ 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 § 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 **Definitions** • Added definition of: o Activities of Daily Living (ADLs) o Instrumental Activities of Daily Living (IADLs) o Medically Necessary o Myoelectric Prosthetic o Prosthesis o Prosthetist **Supporting Information** • Added *Description of Services*, *Clinical Evidence*, and *FDA* sections • Updated *References* section to reflect the most current information • Archived previous policy version CS360IN.01

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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