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<b>Subject:</b>	Myoelectric Upper Extremity Prosthetic Devices	<b>Publish Date:</b>	11/18/2021
<b>Guideline #:</b>	CG-OR-PR-05	<b>Last Review Date:</b>	11/11/2021
<b>Status:</b>	Revised		

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## Description

This document addresses the use of myoelectric prosthetic devices for individuals with an amputation or absence of a portion of an upper extremity at any level from the hand, including partial-hand, to the shoulder. A myoelectric prosthetic is controlled by electromyographic (EMG) signals generated naturally by an individual's own muscles. When an individual engages residual muscles, EMG signals from those muscles relay information to electrodes that are built into the prosthesis. The information is then sent to a controller, which translates the information and sends it to electric motors that move the prosthetic. The electric motors are powered by a rechargeable battery pack.

**Note:** For information on related devices, please refer to the following documents:

- CG-DME-13 Lower Limb Prosthesis
- OR-PR.00005 Upper Extremity Myoelectric Orthoses

## Clinical Indications

### Medically Necessary:

The use of myoelectric upper extremity prosthetic devices is considered **medically necessary** when ALL of the criteria set forth in (A) and (B) below have been met:

#### A. Selection criteria

1. The individual has an amputation or absence of a portion of an arm; **and**
2. The individual has sufficient ability to operate the higher level technology effectively; **and**
3. A standard body-powered prosthetic device cannot be used or is insufficient to meet the functional goals and needs of the individual; **and**
4. A myoelectric device is likely to help the individual regain or maintain function better than a standard body-powered prosthetic device; **and**
5. The remaining musculature of the affected arm contains the minimum microvolt threshold to allow operation of a myoelectric device; **and**
6. The following anatomy specific criteria apply:
  - a. Transhumeral and Elbow:
    - i. Amputation or absence of the limb at or above the elbow.
    - ii. Individual's functional goals require functional analogue of elbow flexion and extension.
  - b. Transradial and Wrist:
    - i. Amputation or absence of the limb below the elbow or wrist disarticulation
    - ii. Individual's functional goals require functional analogue of forearm rotation
  - c. Partial-Hand:

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- i. Amputation or absence of 1 to 5 digits, where the level of loss or deficiency is distal to the wrist and proximal to the metacarpophalangeal joint.
- ii. Individual’s functional goals require prehension.

**B. Documentation and performance criteria:**

- 1. Complete multidisciplinary assessment of individual including an evaluation by a trained prosthetic clinician. The assessment must objectively document that all of the above selection criteria have been evaluated and met.

**Not Medically Necessary:**

The use of myoelectric upper extremity prosthetic devices is considered **not medically necessary** when any of the criteria above are not met.

**Coding**

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

**When services may be Medically Necessary when criteria are met:**

**HCPCS**

*Prostheses*

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)
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
L6965	Shoulder disarticulation, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
L6975	Interscapular-thoracic, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal

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electrodes, cables, two batteries and one charger, myoelectronic control of terminal device

*Additions*

- L6611 Addition to upper extremity prosthesis, external powered, additional switch, any type
- L6677 Upper extremity addition, harness, triple control, simultaneous operation of terminal device and elbow
- 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
- L7007 Electric hand, switch or myoelectric controlled, adult [when specified as myoelectric]
- L7008 Electric hand, switch or myoelectric controlled, pediatric [when specified as myoelectric]
- L7009 Electric hook, switch or myoelectric controlled, adult [when specified as myoelectric]
- L7045 Electric hook, switch or myoelectric controlled, pediatric [when specified as myoelectric]
- 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

**ICD-10 Diagnosis**

- Q71.00-Q71.93 Reduction deformities of upper limb
- S48.011A-S48.929S Traumatic amputation of shoulder and upper arm
- S58.011A-S58.929S Traumatic amputation of elbow and forearm
- S68.011A-S68.729S Traumatic amputation of wrist, hand and fingers
- Z89.121-Z89.239 Acquired absence of limb

**When services are Not Medically Necessary:**

For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed.

**Discussion/General Information**

Myoelectric prostheses of the upper extremity are sophisticated alternatives to standard body-powered devices used for the replacement of upper extremities due to trauma, disease or congenital causes. A myoelectric prosthetic is controlled by EMG signals generated naturally by an individual’s own muscles. This type of prosthesis uses an external battery pack to supply power to electric motors and microprocessors that enable movement of the prosthetic elbow, wrist, and/or fingers in several planes. Several benefits of myoelectric upper extremity prostheses have been proposed, including greater pinch and grip force over standard prosthetic devices and a more realistic appearance. A myoelectric device may be recommended if an individual is unable to use a body-powered device or requires improved grip function or motion for the performance of daily activities.

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Myoelectric prosthetic devices operate through the use of surface electrodes embedded in the socket of the prosthesis. When these electrodes come into contact with the skin, they are able to detect and amplify the electrical activity of muscle groups in the residual limb. These potentials are translated through the microprocessor units into limb movement via the electric motors in the limb function (for instance, terminal device operation, wrist rotation, elbow flexion). The newest electronic control systems perform multiple functions and allow for sequential operation of elbow motion, wrist rotation and hand motion. Sensation cannot be attained by a myoelectric prosthesis.

Partial-hand myoelectric prostheses, for example, i-Digits™ Quantum (Össur, Reykjavik, Iceland), are designed to replace the function of digits in individuals missing one or more of their fingers as a result of a partial-hand amputation. This type of prosthetic device requires a very specific range of amputation such as amputation level through, or just proximal to, the metacarpal phalangeal level of one or more digits.

*Upper Extremity Myoelectric Prosthetic Devices*

In 2020, Resnik and colleagues published the results of a comparative study of various prosthetic devices and evaluated the individual reported outcomes concerning disability, difficulty with activity, and health-related quality of life (HRQOL). A total of 755 veterans with unilateral upper limb amputation were included, of these, 306 had no prosthesis, 325 used body-powered devices, 62 used myoelectric or hybrid single degree of freedom (DOF) terminal device, 40 used a myoelectric multi-DOF terminal device, and 22 used cosmetic devices. Upper limb related disability was measured by the Disabilities of the Arm, Shoulder, and Hand score (QuickDASH) which measures perceived disability by evaluating the difficulty performing activities, amount of limitation, the extent of interference with activities, and extent of arm, shoulder, and hand pain or tingling. HRQOL was assessed by the Veterans RAND 12-item Health Survey (VR-12). The mean age was  $63.5 \pm 13.9$  and the average years since amputation was  $31.4 \pm 18.3$ . Difficulty of performing tasks that require 2 hands were rated as most difficult by the cosmetic device group, followed by myoelectric multi-DOF, then single-DOF users. Cosmetic device users reported greater difficulty in all 3 of the 2-handed tasks compared with the body powered group, and more difficulty than the myoelectric single-DOF group when lifting heavy objects and spreading peanut butter on bread. Challenges with 1-handed tasks varied amongst prosthesis type as well ( $p < 0.005$ ) with the cosmetic group reporting more difficulty ( $\alpha = 0.05$ ). Single-DOF and body powered devices were rated better than multi-DOF on the QuickDASH as the users of the multi-DOF reported greater disability, but no differences were noted in tasks that require grasp of small and round objects. Early prosthetic training and active prosthetic use resulted in higher HRQOL. The authors noted that further study is needed to compare the fine motor performance of single versus multi-DOF devices. Limitations of this study include the cross-sectional, observational design and self-reported data, as well as generalizability to non-veteran individuals.

Resnik and colleagues (2018) compared the Generation 3 DEKA Arm (marketed as the Luke™ Arm, Mobius Bionics, Manchester, NH) to conventional prostheses. Participants were evaluated after in-laboratory training ( $n = 23$ ), and some of those participants were also evaluated after 12 weeks of home use ( $n = 15/23$ ). Inclusion criteria included regular personal prosthetic use and an upper limb amputation at the transradial, transhumeral, shoulder disarticulation, or scapulothoracic level. Performance measures and self-reported outcomes were collected at baseline, after in-laboratory training, and after home use. The researchers found that the DEKA arm was equivalent to conventional prostheses for measurements of dexterity, prosthetic skill, spontaneity, community integration, and

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quality of life. After home use experience, the DEKA participants had lower perceived disability and higher prosthetic engagement in everyday tasks.

Several smaller studies evaluating the clinical outcomes associated with the use of myoelectric prosthetic devices for the upper extremity have provided mixed results (Salminger, 2018; Luchetti, 2015; Ostlie, 2012; Kyberd, 2011; McFarland, 2010; Otr, 2010). Generally, these are small case studies that used various objective and subjective factors, such as adherence, comfort, and functional performance, as indicators that the device contributed to a successful improvement of quality of life. A few of the assessment tools included were the Southampton Hand Assessment Procedure (SHAP), the Box and Blocks Test (BBT), and the Orthotics and Prosthetics Users' Survey (OPUS) which is a self-report questionnaire measuring functional status, quality of life, and satisfaction with the device. One study used the Actual Use Index (AUI) to measure actual daily use of the device (Ostlie, 2012) and many of the studies reported on device adherence and abandonment to some degree. In a single case study, van der Niet and colleagues (2013) investigated functional outcomes of the i-LIMB hand and i-LIMB pulse, the latter a newer iteration of the device. They found improvements in functionality over time and noted the participant's high degree of motivation and training may have impacted results. Although these studies tend to support the use of myoelectric prostheses, methodological and population sample differences inhibit confirmation of results between studies.

Biddiss and colleagues (2007) provided a critical review of evidence on prosthesis use and abandonment found in 200 articles published from 1980 through 2006. Mean rejection rates in pediatric populations were 45% for body-powered and 35% for electric devices. Lower rejection rates were noted in adult populations with a mean of 26% for body-powered and 23% for electric devices. The authors found no statistically significant differences in the proportion of rejections between passive and myoelectric ( $p=0.2$ ) nor body-powered ( $p=0.1$ ) devices. The investigators noted a large variance in rejection rates between studies and also noted that the diverse study methods and heterogeneous population samples restrict comparison between studies.

In 2011, Ritchie and colleagues published the results of a systematic review of literature evaluating user perception of upper limb prosthetic devices cosmesis and function. Literature from 1990 through 2010 was researched and a total of 15 articles were included. Three major themes were identified, user satisfaction with current prosthesis, priorities for future development of prostheses, and social implications of wearing a prosthesis. The results showed that functional ability was considered more important than cosmesis and that future design requires improvement in function and movement.

Salminger and colleagues (2018) studied functional outcome scores in below-elbow amputees who were fitted with a myoelectric prosthetic. A total of 17 subjects were evaluated using the following function tests: Action Research Arm Test (ARAT), SHAP, the Clothespin-Relocation Test (CPRT) and the BBT. The tests were chosen to evaluate gross and fine manual dexterity, activities of daily living, repeatability, and full arm motion. Tests were observed by the same physical therapist for all subjects. The mean results were the following: ARAT  $35.06 \pm 4.42$  of 57, SHAP  $65.12 \pm 13.95$  points, CPRT  $22.57 \pm 7.50$  seconds, and BBT  $20.90 \pm 5.74$ . The authors stated:

Overall success of prosthetic rehabilitation should be based on a combination of objective function, rated performance in daily-life activities, wearing time, patient satisfaction and participation. As concluded by different working groups, this will not be possible with one single

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standard measure, but with a combination of assessment tools evaluating function and activities as well as questionnaires for reporting participation and quality of life.

Burger and colleagues (2016) conducted a survey aimed at estimating the frequency of overuse problems in persons with acquired or congenital upper limb absence and identifying the factors relevant for the development of those problems. The survey included 65 participants with unilateral upper limb absence and excluded those with other possible medical causes of overuse-type problems. They found the most frequent problems were carpal tunnel syndrome (43%) and shoulder pain (40%). There were no statistically significant associations between deficiency level, cause of deficiency, time since deficiency, extent of daily prosthesis use or type of prosthesis with the frequency or severity of pain or number of problems, with the exception of carpal tunnel syndrome. The presence of carpal tunnel syndrome decreased from wearing no prosthesis (100%) through aesthetic (46%) and body-powered (33%) to myoelectric prosthesis (0%;  $p=0.014$ ). Though the findings support the use of myoelectric devices, they are limited. Only 4 of the 65 participants reported using a myoelectric device. Additional studies are needed to identify factors associated with overuse injuries to support appropriate selection in prosthesis management.

In 2011, the WorkSafeBC Evidence-Based Practice Group conducted a review of available evidence on the usage of myoelectric prostheses in acquired, below-elbow, upper limb deficiencies excluding partial-hand. Their recommendations are predominantly based on Level of Evidence: 4, their second weakest level, defined as “evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included here.” They acknowledged the limited clinical evidence and scarce number of studies on myoelectric prostheses. They concluded:

The overall conclusion from this review is that prosthetic choice should be decided on an individual basis and needs a thorough evaluation and follow up of the amputee by a multidisciplinary team. Research to date supports that the myoelectric prosthesis has become one of the standard prosthetic options... Prosthetic use may increase the functional capacity of a person with a missing hand and could shorten the return-to-work process.

### *Partial-Hand Myoelectric Prosthesis*

In an instructional narrative review, Geary and colleagues (2021) provided a summary of advances in prosthetics for upper limb amputees including partial-hand myoelectric prostheses. In their review, they briefly discuss some of the advantages and disadvantages of three different available types of prostheses: cosmetic, body-powered, and myoelectric. While myoelectric options can provide improved grip strength and decreased energy demands, their disadvantages include the weight of the prosthetic, battery life, and decreased durability.

Wanamaker and colleagues (2019) reported the results of an observational study evaluating upper limb function and kinematics of 10 individuals with partial-hand amputations fitted with a partial-hand prosthesis. Three-dimensional kinematics were collected as the participants performed a functional assessment using the SHAP with and without their prosthesis. Larger joint motions were observed without prosthesis use in all participants. There was a significant improvement of function for participants with five-digit limb loss between conditions ( $p<0.05$  for 6 of 7 SHAP score categories) though there were no statistical differences in SHAP scores for those with four-digit limb

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loss. All participants exhibited a reduction in overall joint compensation while wearing a prosthesis compared to their non-prosthesis results.

In 2018, Whelan and colleagues reported the results of a case series evaluating functional outcomes in individuals using the externally powered i-Digits partial-hand prosthesis. The participants (n=15) included individuals with four- (with thumb remaining) or five-digit partial hand limb loss or absence. Outcomes were assessed using the SHAP and Patient-Specific Functional Scale (PSFS). The PSFS was used to identify individualized priority functional goals and have the participant rank their current level of performance both before and after the prosthetic intervention. All participants demonstrated a clinically significant change in scores on both the PSFS and the SHAP. There was a significant improvement in the ability to complete priority functional tasks in both the four- and five-digit groups. There was also a significant improvement in SHAP scores for all users. However, a larger change was seen for those fit with a five-digit system compared to the four-digit system. The results indicate that use of the partial hand prosthesis demonstrated functional improvements in objective hand function and individualized goals. However, factors that may potentially influence results such as a participant's remaining range of motion, strength, and function in the thumb and wrist were not fully accounted for in the sample selection. Future studies may help refine the assessment and selection of individuals that would benefit from the use of these devices.

The Veterans Affairs/Department of Defense (VA/DOD) Clinical Practice Guideline for the Management of Upper Extremity Amputation Rehabilitation (2014) included the following statements:

Though it is currently impossible to replace all of the lost functions of any part of the upper limb that has been amputated, it is possible for a patient to potentially restore a significant amount of function when prescribed an appropriate prosthesis.

...

A comprehensive assessment should be conducted by the care team to determine the most appropriate type of prostheses to prescribe. Education on the various types of available prostheses should be provided to the patient and his or her family and/or caregiver(s) by the care team prior to the initiation of a prosthetic prescription.

...

Prescriptions for upper extremity prostheses should be based on a collaborative decision between the patient and the care team.

Although the partial-hand myoelectric prosthesis has been widely reported in the lay press since its market entry in 2009, there continues to be a scarcity of peer-reviewed publications evaluating the utility (improved function and health-related quality of life) of individual digit control using this device in randomized trials. In the absence of standardized tools and guidelines to assist with prosthesis selection, the choice of device remains individualized based on a comprehensive assessment of functional needs in order to maximize an individual's restoration of function. While the evidence is limited, it tends to support that prosthesis selection is a highly individualized process and myoelectric devices, including partial-hands, can provide benefits for a prudently selected population of individuals with complex functional needs met by these devices and help reduce the risk of overuse injuries.

Prostheses are class I devices exempt from U.S. Food and Drug Administration (FDA) review. Upon market entry, the manufacturer is required to register the device with the Restorative Devices Branch of the FDA and maintain a record of complaints.

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**Government Agency, Medical Society, and Other Authoritative Publications:**

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**Index**

- Arm
- Bebionic™
- DEKA Arm System
- DynamicArm®
- Elbow
- Electrohand 2000™
- Finger
- i-Digits Quantum
- i-Digits Access
- i-LIMB™
- LTI Boston Digital™ Arm System
- LUKE Arm
- Michelangelo®

Federal and State law, as well as contract language including definitions and specific coverage provisions/exclusions, and Medical Policy take precedence over Clinical UM Guidelines and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Clinical UM Guidelines, which address medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Clinical UM Guidelines periodically. Clinical UM guidelines are used when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether or not to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the back of the member's card.

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**Myoelectric Upper Extremity Prosthetic Devices**

Myoelectric Prosthesis  
 Partial hand amputation  
 Partial hand loss  
 SensorHand™  
 Utah Arm

**The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.**

**History**

Status	Date	Action
Revised	11/11/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Moved content regarding partial-hand prosthesis from OR-PR.00004 Partial-Hand Myoelectric Prosthesis to this clinical utilization management guideline document. Added new MN criteria for partial-hand myoelectric prosthesis. Updated Description, Discussion/General Information, References and Index sections. Updated Coding section; added L6026, L6715 previously addressed in OR-PR.00004.
Reviewed	11/05/2020	MPTAC review. References were updated. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review. Discussion/General Information and References sections updated.
Reviewed	01/24/2019	MPTAC review. Description, Discussion/General Information, and References sections updated.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Description, Discussion/General Information, and Index sections updated.
Reviewed	02/02/2017	MPTAC review.
Reviewed	02/04/2016	MPTAC review. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review.
Revised	02/13/2014	MPTAC review. Changed document number from CG-DME-28 to CG-OR-PR-05. Clarified medically necessary criteria #5. Clarified the not medically necessary statement.
Reviewed	02/14/2013	MPTAC review. Updated Discussion and References sections.
	07/10/2012	Updated Coding section to remove codes L6025, L6715 now addressed in a separate document.
Reviewed	02/16/2012	MPTAC review. Updated Index section.
	01/01/2012	Updated Coding section with 01/01/2012 HCPCS changes.
Reviewed	02/17/2011	MPTAC review.
Reviewed	02/25/2010	MPTAC review.
Reviewed	02/26/2009	MPTAC review.
Reviewed	02/21/2008	MPTAC review.
Reviewed	03/08/2007	MPTAC review.

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	01/01/2007	Updated coding section with 01/01/2007 CPT/HCPCS changes; removed HCPCS L7025, L7030, L7035 deleted 12/31/2006.
New	03/23/2006	MPTAC initial document development.

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Document Number</b>	<b>Title</b>
Anthem Connecticut	09/01/2004		CT DME Coverage Guidelines, Section G: Prostheses: Upper and Lower Limb

Historical

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Federal and State law, as well as contract language including definitions and specific coverage provisions/exclusions, and Medical Policy take precedence over Clinical UM Guidelines and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Clinical UM Guidelines, which address medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Clinical UM Guidelines periodically. Clinical UM guidelines are used when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether or not to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the back of the member's card.

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