MEDICAL POLICY	Myoelectric Upper Limb Prosthesis
Effective Date: 2/1/2022  2/1/2022 Medical Officer Date	Medical Policy Number: 26 Technology Assessment Committee Approved Date: 1/11; 1/12; 10/13; 10/14; 10/15 Medical Policy Committee Approved Date: 11/16; 1/18; 1/19; 10/19; 6/2020; 1/2021; 1/2022

See Policy HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Note: Equipment must be used primarily and customarily to serve a medical purpose. Additional features whose main function is for convenience or improvement of quality of life are not considered medical indications and are therefore not covered.

Upper Limb Myoelectric Prosthetic Device

I. Myoelectric upper limb prosthetic components may be considered **medically necessary and covered** when **all** of the following criteria are met (A.-F.):

   A. The patient has an amputation or missing limb at the wrist or above (forearm, elbow, etc.); **and**
   B. 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 (e.g. self-feeding, bathing, dressing, grooming, work, toileting, hygiene); **and**

C. The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device, as demonstrated by functional testing using a physical or computer model prosthesis; **and**
D. The patient has demonstrated sufficient neurological and cognitive function to operate the prosthesis effectively; **and**
E. The patient is free of comorbidities that could interfere with function of the prosthesis (e.g. neuromuscular disease, etc.); **and**
F. The patient does not function in an environment that would inhibit function of the prosthesis (i.e. a wet environment or an environment involving electrical discharges that would affect the prosthesis)
G. Functional evaluation by a qualified professional (e.g., prosthetist) indicates that with training, use of a myoelectric prosthesis is likely to meet the functional needs of the individual (e.g. gripping, releasing, holding, and 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.

Note: Medical necessity may be established for **either** upper limb prosthesis with myoelectric components if criterion I. above are met or for a mechanical prosthesis without myoelectric function, but not for both.

II. Myoelectric upper limb prosthetic components are considered **not medically necessary and are not covered** when the above criterion I is not met, including but not limited to replacement of an existing, functioning prostheses (e.g. as an "upgrade" for a prosthesis that still works and fits).

III. Upper-limb prosthetic components that use both sensor and myoelectric control are considered **investigational and not covered**.

IV. Gloves for an upper extremity prosthesis are **considered not medically necessary and not covered**.

Partial-hand Myoelectric Prosthetic Device

V. Partial-hand myoelectric prostheses (L6026) (e.g. i-digit quantum (formerly, ProDigits)) is considered **investigational and not covered** for the treatment of any indication.

BILLING GUIDELINES

Computerized or microprocessor limbs are based on a patient's current functional capabilities and his/her expected functional rehabilitation potential. If more than one prosthetic limb meets a patient's prosthetic rehabilitation needs, the least costly prosthetic will be approved.

The following codes may be used, depending on what prosthesis was ordered. There may also be supplies/components that could be used in conjunction with of these devices.

HCPCS CODES

All Lines of Business	
Prior Authorization Required	
L6628	Upper extremity addition, quick disconnect hook adapter, otto bock or equal
L6629	Upper extremity addition, quick disconnect lamination collar with coupling piece, otto bock or equal
L6632	Upper extremity addition, latex suspension sleeve, each
L6680	Upper extremity addition, test socket, wrist disarticulation or below elbow
L6687	Upper extremity addition, frame type socket, below elbow or wrist disarticulation
L6715	Terminal device, multiple articulating digit, includes motor(s), initial issue or replacement
L6810	Addition to terminal device, precision pinch device
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
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
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 electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
L7400	Addition to upper extremity prosthesis, below elbow/wrist disarticulation, ultralight material (titanium, carbon fiber or equal)

L7403	Addition to upper extremity prosthesis, below elbow/wrist disarticulation, acrylic material
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
L8465	Prosthetic shrinker, upper limb, each
No Prior Authorization Required	
L7368	Lithium ion battery charger, replacement only
Not Covered	
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)

DESCRIPTION

Myoelectric Prosthesis

Myoelectric prostheses are powered by electric motors with an external power source, utilizing muscle activity from the residual limb for control of joint movement. Surface electrodes placed on the limb stump detect electromyographic signals. A controller then amplifies and processes these signals to drive battery-powered motors that move the hand, wrist and elbow.

LUKE Arm

The LUKE/DEKA prosthetic arm, developed by DEKA Integrations Corp, is a prosthetic arm developed for individuals who have lost all or part of their upper limb. The prosthesis is primarily controlled by a micro-electromechanical system operated through an inertial measurement unit located in a sensor device attached to the top of the shoe. The prosthesis also utilizes signals from myoelectric technology, using EMG electrodes from muscles in the shoulder/upper arm to control movement.[1]

Partial-Hand Myoelectric Prostheses (e.g. i-digit quantum (formerly, ProDigits)

Partial-hand myoelectric prostheses are designed to replace the function of digits in individuals missing 1 or more fingers. This type of prosthetic device requires the level of loss or deficiency be distal to the wrist and proximal to the metacarpophalangeal joint.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of myoelectric upper extremity prosthesis as a treatment for an amputation or congenitally missing upper limb. Below is a summary of the available evidence identified through November 2021.

Systematic Reviews

- In 2021, Hayes conducted an evidence review evaluating the safety and efficacy of the LUKE Arm (DEKA Arm; Mobius Bionics) for upper extremity amputation.[1] Searching the literature through September 2021, 2 pretest/posttest studies were internal controls were identified: a study conducted by the Department of Veterans Affairs to optimize the DEKA arm system and a home study of an advanced upper limb prosthesis. In total, 81 patients were addressed across the two studies. Outcomes of interest to the report included function and performance of activities of daily living, quality of life (QOL), community integration and patient satisfaction with device. Results from the VA's optimization study suggested that scores of dexterity and speed were superior than after 20 to 30 hours of training with the DEKA arm. Nonetheless, patient satisfaction was significantly higher with the DEKA arm compared with their existing prosthesis. At 12-week follow-up, there was little difference in scores on observer-administered measures of dexterity and speed between the DEKA arm and patients' current prostheses. Overall results suggested no significant difference in patients' quality of life or community integration between the DEKA arm and existing prostheses. Hayes ultimately assigned a "D2" rating (insufficient evidence) for the use of the DEKA arm in adults with upper extremity amputation, citing a "very-low-quality body of evidence" in which results did not suggest consistent improvement in patients' function or performance relative to existing prostheses. Other limitations included the studies' small sample sizes and lack of adequate follow-up to compensate for the potential learning curve associated with the new prosthesis.

- In 2015, Carey and colleagues conducted a systematic review evaluating outcomes in patients with either myoelectric (MYO) or body-powered (BP) upper-limb prosthesis.[2] Investigators systematically searched the literature through July 2013, identified eligible studies, assessed study quality and extracted data. In total, 31 publications were included for review (1 systematic review, 5 clinical trials, 11 cross-sectional studies, 1 qualitative study, 3 case series, 4 case study, and 6 expert opinions), from which 11 empirical evidence statements were developed. Sample sizes ranged from 1 to 1,216 adults, with a median sample size of 12. Outcomes measures included motion analysis, including range of motion; joint angles during ADLs; kinematics and compensatory motion; reaching/pointing velocity and accuracy; and surveys assessing quality of life. Of the 31 publications included for qualitative review, evidence for ranged between "low" (n=18), "moderate" (n=11), and "high" (n=2). The majority of the empirical evidence statements were issued with "low" levels of confidence, and none with "high" confidence.

  Overall results were mixed. Body-powered prostheses have been shown to have advantages in durability, training time, frequency of adjustment, maintenance, and feedback. Myoelectric prostheses were shown to improve cosmesis and phantom-limb pain and are more accepted for light-intensity work. Collectively, studies disagreed as to the relative functional superiority between BP or MYO prostheses. The following evidence statements were drafted:

- Depending on functional needs, control scheme familiarity and user preference, either BP prostheses with conventional hook or MYO are advantages compared with each other or other alterative. (moderate level of confidence)
- Cosmesis is improved with MYO prosthesis over BP prostheses (low level of confidence)
- Prosthetic rehabilitation plan addressing critical factors such as EMG site selection, controls and task training, and comfort by cohesive team will improve function and long-term success of electrically powered prosthesis user. (low level of confidence)
- Roll-on sleeve improves suspension and increases range of motion compared with self-suspending sockets. (insufficient level of confidence)
- Regular MYO prosthetic use supports reduced cortical reorganization and phantom-limb pain intensity (low level of confidence)
- Proportion of rejections are not different between BP or MYO prostheses (insufficient level of confidence)

Limitations included the small sample size and low study quality of the majority of studies included for review (e.g. lack of controlled studies). Investigators concluded that while MYO prostheses can be improved with more advanced control methods, evidence was insufficient to suggest that these methods might apply in larger controlled studies and. significant general advantage. Investigators concluded that evidence is insufficient to determine functional differences between upper-limb prostheses.

Nonrandomized Studies

- In 2019, Ku and colleagues published results of a prospective observational study of 3D-printed myoelectric interface prostheses in patients with upper-am transradial amputation. The primary outcome was change in Orthotics Prosthetics User Survey-Upper Extremity Functional Status (OPUS-UEFS) scores at 3 months follow up. 10 patients were included in the study. At 3 months, the mean OPUS-UEFS score significantly increased from 45.50 to 60.10 (p= 0.0014). VAS scores insignificantly decreased at 3 months, implying long term use without discomfort. Limitations of the study include small sample size, short follow up, and lack of randomization or a comparator group. The authors conclude that 3D-printed myoelectric arm prostheses may offer a lower-cost option for patients with amputations, but more research is needed into the longevity of the device.[3]
- In 2018, Salminger and colleagues reported functional outcome scores in below-elbow amputees using four objective measurements related to activities of daily living.[4] In total, 17 patients who underwent prosthetic fitting after unilateral below-elbow amputation were enrolled. Global upper extremity function was evaluated using the Action Research Arm Test, Southampton Hand Assessment Procedure, the Clothespin-Relocation Test, and the Box and Block Test, which monitor hand and extremity function. Scores for these tests were, respectively: 35.06 ±4.42 of 57; 65.12 ± 13.95 points, 22.57 ± 7.50 secs; 22.57 ± 7.50 secs; and 20.90 ± 5.74. No significant correlation was detected between prosthetic wearing time and functional outcome scores. Study limitations include small sample size, lack of long-term follow-up, and the potentially unrepresentative patient cohort (e.g. 1 female, 16 males). Moreover, high device functionality and consequently high scores in functional evaluation do not predict actual is in daily life.

Partial-Hand Myoelectric Prosthesis (e.g. i-digit quantum (formerly ProDigits)

No evidence was identified addressing the use of partial-hand myoelectric prostheses (e.g. i-digit quantum (formerly ProDigits)).

CLINICAL PRACTICE GUIDELINES

Department of Veteran Affairs and Department of Defense

In 2014, the Department of Veteran Affairs and Department of Defense issued a clinical practice guideline for the management of upper extremity amputation rehabilitation.[5] No specific recommendations addressing myoelectric prostheses were issued, however, the guideline stated that:

> "when considering a myoelectric prosthesis, the [patient's] therapist and prosthetist should work to identify the best possible electrode placement and the most effective control scheme for each patient's particular abilities and needs. The care team should also implement a program to test and train the patient's muscles for use of a myoelectric prosthetic device through single and dual channel activation as well as muscle pattern training (e.g. co-contraction, pattern recognition programming)."[5]

Investigators called for additional research to determine which pre-prosthetic exercise protocols are most effective to prepare patients with upper limb loss to use prosthetic devices; and which myoelectric and body-powered prosthesis components and terminal devices are associated with the best functional outcomes with patients with upper limb loss.

CENTERS FOR MEDICARE & MEDICAID

As of 12/28/2021, no Centers for Medicare & Medicaid (CMS) coverage criteria were identified specifically for myoelectric upper limb prosthetic components. However, CMS does address coverage requirements for prosthetics in general.[6] According to the Social Security Act §1861(s)(9), prostheses are covered under the Medicare Artificial Legs, Arms and Eyes benefit.[7] While prosthetics are eligible for coverage, Medicare requires that all durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) are both medically reasonable and necessary to meet the functional needs of the individual patient.[8] This includes determining if there is a "less costly alternative" which can provide the needed and appropriate therapeutic benefit for the individual.[9] For myoelectric prosthetic coverage, documentation must include, but is not limited to, rationale for why a body powered device is not sufficient to meet the functional medical needs of the member to complete their activities of daily living (ADLs). Items which provide features beyond what is medically reasonable and necessary to support the body member would fall under the category of an "upgrade." Upgraded items include "excess components" to a prosthetic device (e.g., a feature, an accessory, or a service) that are in addition to, or more extensive than, the item that is reasonable and necessary under Medicare's coverage requirements.[10] For individuals for whom myoelectric prosthetics are being considered, the health plan's policy criteria will apply.

In addition, while not related to medical necessity, CMS also provides billing and coding guidance for the reporting of powered L-coded items. Specifically, Medicare doesn't allow additional coding for extra

components for use with prostheses reported with HCPCS code L6880 because this code is considered "all-inclusive."[11-13] Finally, effective January 1, 2022, only products which have received code verification review by the PDAC Contractor are eligible to be reported or billed using HCPCS codes L6715 or L6880.[14] The PDAC Product Classification List search tool can be used to determine which products have received this review.

POLICY SUMMARY

Despite the lack of evidence regarding the clinical utility of myoelectric upper limb prostheses, these devices have become a standard of care when the criteria listed above are met. Limited evidence suggests myoelectric devices may improve patients' range of motion and capacity for light work. No published evidence was identified evaluating partial-hand myoelectric prostheses with individually powered digits, therefore partial-hand myoelectric prostheses are considered investigational.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and PHP and PHA Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Food and Drug Administration

Prosthetic	*Device Name, Product Code*	*Indication*
Myoelectric Upper Limb Prosthetic* **Manufacturers must register prostheses with the FDA, but prostheses not have to undergo full FDA review*	Coapt Complete Control System (K123795)[15], IQZ	To be used exclusively for external prosthetic fittings of the upper limbs.
	DEKA Arm System (DEN120016)[16], PAE	Indicated for individuals, age 18 years and older, who have partial or full upper limb amputations or congenital defects
Partial-Hand Myoelectric Prosthesis	n/a	No FDA approval documents located.

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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