KAISER PERMANENTE® Mid-Atlantic States	**Upper Limb Prostheses** **Medical Coverage Policy**

UTILIZATION * ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document. Please review and verify the availability of member's benefits before applying the terms of this medical policy as benefits may vary according to benefit plan.
- For Medicare members, there is no national coverage determination. This policy serves as guidance for the medical necessity of upper limb prosthesis for Medicare members
- Note: After searching the Medicare Coverage Database, if no NCD/LCD/LCA is found, then use the policy referenced above for coverage guidelines

I. **Procedure: Upper Limb Prosthesis**

II. **Specialties: Orthopedic, DME, Rehabilitation**

III. **Clinical Indication for Referral**

A. **Passive and Body-Powered Upper Limb Prosthetics** are manually operated prostheses for replacement of a partial or total, permanently malfunctioning, or inoperable upper limb extremity.

The initial upper limb prosthesis is considered medically necessary when the member meets **ALL** the following criteria:

1. Partial or total amputation or missing anatomical part of the upper limb, (digits, wrist, forearm, elbow, shoulder); and
2. The prosthesis is reasonable and necessary for the diagnosis or treatment of illness or injury or for improvement of the functioning of a malformed or missing anatomical part; and
3. Absence of comorbidities or other clinical condition that may interfere with the function and safe/ effective operation of the prosthesis; and
4. A comprehensive evaluation has been performed by a prosthetic clinician or a qualified licensed professional including residual limb and contralateral limb evaluation and pain assessment to determine the most appropriate prosthesis, prosthetic components, and control mechanism (such as body-powered, myoelectric, or a combination of body-powered and myoelectric). To evaluate the fit of the prosthesis, patient's tolerability & compatibility with the use of the device, a trial period may be indicated in a real-life setting; and

5. The patient has sufficient neurological and adequate cognitive function to complete the prosthetic training to successfully use the prosthesis for activities of daily living (ADLs); and
6. Functional level and functional ability evaluation indicate that the prosthesis is the most appropriate model and type to adequately meet the functional needs of the patient; and
7. The requested prosthesis or component(s) does not exceed what is reasonable and medically necessary to adequately meet the member's medical and functional needs.

B. Myoelectric Upper Limb Prostheses

A Myoelectric prosthesis for the upper limb is an electrically powered device that uses power to facilitate limb movement. It is medically necessary when the individual meets **ALL** the following criteria:

1. The patient has met the requirements set forth in section III, A
2. The patient has a minimum of the wrist or above the wrist partial limb amputation (forearm, elbow, shoulder); and
3. The patient meets the anatomy specific criteria below:
   a. Partial-Hand:
      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. Trans-radial 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. Trans-humeral and Elbow:
      i. Amputation or absence of the limb below at or above the elbow
      ii. Individual's functional goals require functional analogue of elbow flexion and extension

4. A standard body-powered prosthetic device is insufficient or cannot be used to meet the functional needs of the individual to perform ADL and
5. The musculature of the remaining arm(s) has sufficient microvolt threshold to allow proper operation of the myoelectric prosthetic device; and
6. Adequate cognitive, neurological, musculoskeletal, and sufficient myo-cutaneous ability to operate the prosthesis effectively; and
7. Free of comorbidities or condition that may interfere with the function and safe or effective operation of the prosthesis (such as neuromuscular disease, etc.); and
8. A patient's current level of function considers the need for control, durability (maintenance), function (speed, work capability), and usability.
9. With proper training, the functional needs of the patient when performing ADLs (such as gripping,

releasing, holding, and coordinating movement of the prosthesis) is more likely to be met with the use of a myoelectric prosthetic device; and

10. The member is in an environment or condition that will not inhibit the function of the prosthesis such as situations or conditions involving electrical discharges or wet environment.

IV. Replacement, Repair or Adjustment

A. The **repair or adjustment** of an approved upper limb prosthesis or prosthetic components are covered based on their medical necessity (such as age, activity level, and growth) and their reasonable lifetime expectancy as established by the manufacturer of the device.

B. The **replacement** of an upper limb prosthetic device or prosthetic components is considered medically necessary if the individual meets the following criteria:
   1. Provider documentation that demonstrates patients continued prosthetic use; ***and***
   2. Documentation by the ordering physician of the change in patients physical or physiological condition or functional level and/or the ordering physician's rationale for the replacement such as but not limited to the following:
      a. Bone growth or
      b. Reasonable weight loss; or
      c. Significant weight gain; or
   3. Normal wear and tear with normal usage of the prosthesis and repairs or adjustments to the device have failed and/or not possible; or
   4. The cost to repair the device or part of the device that requires repair will exceed 70 percent of the cost of the prosthesis, or part of the device if replaced; or
   5. Loss of prosthesis is covered with supporting documentation in the following situation and at the discretion of the plan:
      a. Theft – a copy of the police report and a letter from the appropriate individual who has the knowledge of the situation such as the security office, school principal, social worker etc.; or
      b. Destruction by fire – a copy of the fire report; or
      c. Specific accident or natural disaster causing severe damage beyond repair or irreparable change in the condition of the prosthesis or prosthetic component - a copy of the police report and a letter from the appropriate individual who has the knowledge of specific circumstances such as the security office, school principal, social worker, etc.

V. Limitations and Exclusions

A. A request for a **new prosthesis,** an **upgrade, enhancement, repair or replacement** of the current prosthesis or prosthetic component(s) is not considered to be medically necessary and not covered when:

1. The patient does not meet the criteria in section III and IV; **and**
2. The current prosthesis or prosthetic component(s) is within the average life of the device as defined by the manufacturer, in good functional order and meets the medical needs of the patient to perform activities of daily living; **or**
3. Prosthetics or prosthetic components primarily to be used for the following:
   a. The upgrade of a functional prosthesis or prosthetic component(s) is for convenience or
   b. Activities other than normal daily living such as devices intended for leisure, recreation, sport interests or work-related purposes; **or**
   c. Designed to be used for showering or swimming such as water prosthesis; **or**
   d. Artificial limb or parts thereof for cosmetic purpose or appearance (such as nonfunctional prostheses, non-functional finger prostheses, nonfunctional prosthetic covers etc.); or
4. Additional or duplication of prosthesis or prosthetic parts; **or**
5. The request for repair or replacement of a damaged prosthesis or its parts was due to patient's improper use, misuse, abuse, or neglect of prosthesis.

B. **Exclusions and Limitation**s

The following upper limb prostheses, prosthetic component(s), or related procedures are considered experimental and investigational as their effectiveness and/or safety have not been established. The list is not exhaustive.

1. Myoelectric upper limb and hand prostheses for other indications other than those stated in section III and IV.
2. Bilateral myoelectric prostheses.
3. Transcranial direct current stimulation for enhancing performance of myoelectric prostheses.
4. Targeted muscle re-innervation for improved control of myoelectric upper limb prostheses and treatment of painful post-amputation neuromas.
5. Partial-hand myoelectric prostheses (e.g., ProDigits).
6. Implantable myoelectric sensors for upper limb prostheses and hand prostheses.
7. Adjustable click systems (e.g. Revo and Boa click systems).
8. Prosthesis with experimental and investigational components including the following:

a. Trans-carpal/metacarpal or partial hand disarticulation prosthesis.
b. Terminal device, multiple articulating digit; or
c. Electric hand, switch or myoelectric controlled, independently articulating digits, any grasp pattern or combination of grasp patterns

VI. Description

Upper limb prosthesis is artificially made external device that is used as a substitute for a partial or total amputation or missing anatomical part at any level of the upper extremity from the hand to the shoulder due to trauma or injury, accident, surgery, illness, or congenital defect. It typically comprises a shaft, sockets, and components to imitate the limb's attachment to a joint or ball and socket and is attached to the body with cable system.

Passive prostheses are cosmetic upper limb prostheses, designed to resemble a natural arm, hand and fingers. They are lightweight and most comfortable. While they cannot restore function and do not have active movement, these prostheses may improve a person's function by providing a surface for stabilizing or carrying objects. These prostheses rely on manual repositioning by moving it with the opposite arm.

Body-powered prostheses are functional upper limb prostheses, operated typically by a body harness and cable system to provide functional manipulation of the elbow and hand. Voluntary movements of the upper arm, shoulder and/or limb stump and chest are captured by the harness and transferred to the cable system, transmitting the force to the terminal device to open and close the hook or hand which is like how a bicycle handbrake system works. Prosthetic hand attachments, for example, claw-like devices, allow good grip strength and visual control of objects. Latex-gloved devices, on the other hand, provide a more natural appearance at the expense of control and can be opened and closed by the cable system. Harness discomfort, particularly the wear temperature, the unattractive appearance and wire failure are typical complaints from users of this device.

Myoelectric Prostheses are upper limb prostheses or orthoses. They are powered by myoelectric components that use muscle activity detected by surface electrodes from the remaining limb. The Electromyographic (EMG) signals generated through microchip-processed electrical activity from the muscles of the remaining limb or limb stump are amplified and processed by a controller (battery-powered or electric motor connected to an external power source) to trigger joint movement(s) of the prosthesis. (e.g., digits, hand, wrist, elbow and/or shoulder).

Example of myoelectric devices include:
- MyoPro® (Myomo)
- ProDigits™ and i-LIMB™ (Touch Bionics),
- SensorHand™
- Speed and the Michaelangelo® Hand (Otto Bock),
- LTI Boston Digital Arm™ System (Liberating Technologies Inc.)

- Utah Arm Systems (Motion Control), and bebioinic (steeper).

Myoelectric Orthoses
The MyoPro (Myomo) is a class I upper-extremity orthotic device that detects weak muscle activity from the affected muscle groups. The myoelectric powered device has manual wrist articulation and myoelectric initiated bi-directional elbow movement.

Hybrid systems use a combination of body-powered and myoelectric components, allowing control of two joints at once (one body-powered and one myoelectric). They are intended for high-level amputations such as above the elbow prosthetics. They are lighter and less expensive than myoelectric orthoses.

References

1. Cordella, F. et al. Literature Review on Needs of Upper Limb Prosthesis Users. *Front. Neurosci*., 12 May 2016 | https://doi.org/10.3389/fnins.2016.00209
2. Vujaklija I, Farina D, Aszmann O. New developments in prosthetic arm systems. *Orthop Res Rev*. 2016; 8:31-39. https://doi.org/10.2147/ORR.S71468
3. Stevens, Phillip M. MEd, CPO, FAAOP; DePalma, Russell R. CP; Wurdeman, Shane R. PhD, MSPO, CP Transtibial Socket Design, Interface, and Suspension: A Clinical Practice Guideline, Journal of Prosthetics and Orthotics: July 2019 - Volume 31 - Issue 3 - p 172-178. doi: 10.1097/JPO.0000000000000219 https://journals.lww.com/jpojournal/Fulltext/2019/07000/Transtibial_Socket_Design,_Interface,_and.5.aspx?WT.mc_id=HPxADx20100319xMP
4. Uellendahl, Jack CPO Myoelectric versus Body-Powered Upper-Limb Prostheses: A Clinical Perspective, Journal of Prosthetics and Orthotics: October 2017 - Volume 29 - Issue 4S - p P25-P29. doi: 10.1097/JPO.0000000000000151 https://journals.lww.com/jpojournal/Fulltext/2017/10001/Myoelectric_versus_Body_Powered_Upper_Limb.5.aspx?WT.mc_id=HPxADx20100319xMP
5. Denham, Susan P. EdD, OTR/L, CHT; Hawkins, Taylor OTR/L; Johnson, Kelsey OTR/L; Rhoads, Jenna OTR/L; Sims, Sara OTR/L The Functionality of the Bio-Mechanical Prosthetic Finger When Compared With Results on Standardized and Functional Assessments: A Single-Case Study, Journal of Prosthetics and Orthotics: April 2019 - Volume 31 - Issue 2 - p 140-144 doi: 10.1097/JPO.0000000000000242 https://journals.lww.com/jpojournal/Fulltext/2019/04000/The_Functionality_of_the_Bio_Mechanical_Prosthetic.10.aspx
6. Murali, B, Huddle, S, Weir, R. Design and evaluation of a distally actuated powered finger prosthesis with self-contained transmission for individuals with partial hand loss. *Sage Journals*. April 15, 2019, Research Article. https://doi.org/10.1177/1687814019834114
7. Difonso, E, Zappatore, G. Mantriota, G. Reina, G. Advances in Finger and Partial Hand Prosthetic Mechanisms. *Robotics 2020*, October 2020 9(4), 80; https://doi.org/10.3390/robotics9040080 https://www.mdpi.com/2218-6581/9/4/80/htm

8. Atzori, M., & Müller, H. (2015). Control Capabilities of Myoelectric Robotic Prostheses by Hand Amputees: A Scientific Research and Market Overview. *Frontiers in systems neuroscience*, *9*, 162. https://doi.org/10.3389/fnsys.2015.00162
9. Department of Veterans Affairs and the Department of Defense. VA/DoD clinical practice guideline for the management of upper extremity amputation rehabilitation. 2014. Available at: https://www.healthquality.va.gov/guidelines/Rehab/UEAR/VADoDCPGManagementOfUEAR090214FINAL2508.pdf. Accessed on 02/16/2022.
10. WorkSafeBC Evidence-Based Practice Group, Edeer D., Martin CW. Upper limb prosthesis: a review of the literature with a focus on myoelectric hands. Richmond, BC: WorkSafe BC Evidence-Based Practice Group. 2011. Available at: https://www.worksafebc.com/en/resources/health-care-providers/guides/upper-limb-prostheses-a-review-of-the-literature-with-a-focus-on-myoelectric-hands. Accessed on 02/16/2022.
11. Elaine L Bukowski, PT, Atlas of Amputations and Limb Deficiencies: Surgical, Prosthetic, and Rehabilitation Principles, ed 3, *Physical Therapy*, Volume 86, Issue 4, 1 April 2006, Pages 595–596, https://doi.org/10.1093/ptj/86.4.595. Accessed on 02/16/2022.
12. CMS Medicare Coverage Database Local Coverage Determination (LCD): Lower Limb Prostheses (L33787) https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52496&ver=24&
13. CMS Medicare Coverage Database Local Coverage Determination (LCD):0155-Upper Limb Orthotics within the Reasonable UsefulLifetime: Excessive Units. https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Approved-RAC-Topics-Items/0155-Upper-Limb-Orthoses-within-the-Reasonable-Useful-Lifetime
14. Centers for Medicare and & Medicaid Services. CMS Manual System Department of Health &Human Services, Pub 100-04 Medicare Claims, Processing Transmittal 656. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r656cp.pdf
15. Kuiken, T. A., Barlow, A. K., Hargrove, L., & Dumanian, G. A. (2017). Targeted Muscle Reinnervation for the Upper and Lower Extremity. *Techniques in orthopaedics (Rockville, Md.)*, *32*(2), 109–116. https://doi.org/10.1097/BTO.0000000000000194
16. Jan, S., Arsh, A., Darain, H., & Gul, S. (2019). A randomized control trial comparing the effects of motor relearning programme and mirror therapy for improving upper limb motor functions in stroke patients. *JPMA. The Journal of the Pakistan Medical Association*, *69*(9), 1242–1245.
17. Mioton, L. M., Dumanian, G. A., Shah, N., Qiu, C. S., Ertl, W. J., Potter, B. K., Souza, J. M., Valerio, I. L., Ko, J. H., & Jordan, S. W. (2020). Targeted Muscle Reinnervation Improves Residual Limb Pain, Phantom Limb Pain, and Limb Function: A Prospective Study of 33 Major Limb Amputees. *Clinical orthopaedics and related research*, *478*(9), 2161–2167. https://doi.org/10.1097/CORR.0000000000001323
18. Dhawan, A. S., Mukherjee, B., Patwardhan, S., Akhlaghi, N., Diao, G., Levay, G., Holley, R., Joiner, W. M., Harris-Love, M., & Sikdar, S. (2019). Proprioceptive Sonomyographic Control: A novel method for intuitive and proportional control of multiple degrees-of-freedom for individuals with upper extremity limb loss. *Scientific reports*, *9*(1), 9499. https://doi.org/10.1038/s41598-019-45459-7
19. MCG 28th edition Copyright 2024 MCG Health, LLC. Myoelectric Prosthesis ACG: A-0701 (AC) Accessed: 12/18/2023

20. Bates, T. J., Fergason, J. R., & Pierrie, S. N. (2020). Technological Advances in Prosthesis Design and Rehabilitation Following Upper Extremity Limb Loss. *Current reviews in musculoskeletal medicine*, *13*(4), 485–493. https://doi.org/10.1007/s12178-020-09656-6
21. Kerver, N., Karssies, E., Krabbe, P. F. M., van der Sluis, C. K., & Groen, H. (2023). Economic evaluation of upper limb prostheses in the Netherlands including the cost-effectiveness of multi-grip versus standard myoelectric hand prostheses. *Disability and rehabilitation*, *45*(25), 4311–4321. https://doi.org/10.1080/09638288.2022.2151653
22. Kulkarni, P. G., Paudel, N., Magar, S., Santilli, M. F., Kashyap, S., Baranwal, A. K., Zamboni, P., Vasavada, P., Katiyar, A., & Singh, A. V. (2023). Overcoming Challenges and Innovations in Orthopedic Prosthesis Design: An Interdisciplinary Perspective. *Biomedical materials & devices (New York, N.Y.)*, 1–12. Advance online publication. https://doi.org/10.1007/s44174-023-00087-8

Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
04/25/2022	04/25/2022
03/22/2023	03/22/2023
03/19/2024	03/19/2024

*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Whenever possible, Medical Coverage Policies are evidence-based and may also include expert opinion. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.