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
- Please see section VI for specific expanded benefits and medical necessity requirements for Maryland Commercial and Medicaid members

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. **Maryland Commercial and Maryland Medicaid members**

As of 1/1/2025, Maryland commercial and Medicaid members have a benefit for prostheses for use both in their home, school or place of employment and also for the purpose of participating in certain physical activities to maximize their whole-body health and lower or upper limb function.

A. Medical Necessity Criteria

1. Those members requesting a prosthesis for use in their home, school, place of employment or specifically for physical or leisure activities will need to meet the medical necessity criteria established in Sections II, III and IV of this policy; and

2. Any request for a prosthesis specifically for the purpose of physical or leisure activities requires documentation by the ordering provider of the patient's past medical history and intention to utilize the additional prosthesis for the purpose of participating in physical or leisure activities.

B. Repairs and Replacement: All medically necessary prosthetic devices less than 3 years old are covered for replacement once annually only for the following reasons:

1. Due to a change in the physiological condition of the patient; or

2. Due to an irreparable change in the condition of the prosthesis or the component of the prosthetic device unless necessitated by misuse; or

3. Because the condition of the prosthetic device or the component of the prosthetic device requires repairs, and the cost of the repairs would be more than 60 percent of the cost of replacing the prosthetic device or the component of the prosthetic device unless necessitated by misuse.

C. Exclusions

1. Duplication or upgrade of a functional prosthesis; or

2. When the prosthesis design features, components and/or accessories are primarily intended for the following:

   a. Luxury features when there is an existing appropriate standard alternative that will meet the patient's functional needs; or

   b. Convenience or comfort; or

c. Decorative, aesthetic, or cosmetic purpose (e.g., custom-shaped prosthetic covers cosmetically shaped to the person's limb) unless there is a medical function and documentation of medical need; or
d. Passive/restorative devices (such as silicone devices to make the limb more life-like)

VII. Descriptions

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.

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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
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*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.