KAISER PERMANENTE® Mid-Atlantic States	**Prostheses, Lower Extremity** **Medical Coverage Policy**

UTILIZATION * ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit MUST be verified in the member's EOC or benefit document if it includes the optional rider.
- Please refer to CMS guidelines or National Coverage Determination (NCD) for Medicare members.
- If no NCD/LCD/LCA is found, then use the policy referenced above for coverage guidelines After searching the Medicare Coverage Database
- Please see section VI for specific expanded benefits and medical necessity requirements for Maryland Commercial and Medicaid members

I. Procedure: Prostheses, Lower Extremity (LE)

Related guideline: ***Orthosis, Lower Extremity Medical Coverage Policy***

II. Clinical Indications for Referral

A lower extremity prosthesis is considered medically necessary when **ALL** of the following criteria are met.

A. Medical History

1. Documentation of past clinical history including prior prosthetic use if applicable; **and**
2. Documentation of current medical condition and the nature of other medical problems; **and**

B. Cognitive and Behavioral Status

1. Motivation and desire to ambulate and participate in prosthetic rehabilitation; **and**
2. Cognitive or behavioral status does not prohibit learning or automation (repetitive learning) for function; **and**
3. The ability to understand and apply knowledge to fitting and use of prosthesis by patient and/or caregiver; **and**

C. Functional and Physical Status

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Documentation of current functional and physical capabilities and their expected functional potential or ability including an explanation for the difference. This documentation should provide the specific K level/functional level of the member.
Note: Bilateral amputees often cannot be strictly bound by functional level classifications

1. Potential or ability to ambulate or transfer safely with or without assistance; **and**
2. Physical condition is adequate to tolerate transferring, walking, or both, with prosthesis: **and**
3. Status of the residual limb that clearly indicates that the limb is ready to accept a test prosthesis; **and**
4. Adequacy of contralateral limb to tolerate weight bearing; **and**
5. The rehabilitation potential of the patient to reach the potential functional ability or maintain a defined functional state within a reasonable period of time; **and**
6. The patient has adequate projected functional level, as indicated by **1 or more** of the following:
   a. Adult and **1 or more** of the following:
      i. Active adult;
      ii. Community ambulator;
      iii. Limited community ambulator;
      iv. Household ambulator;
   b. Infant or child using prosthesis for development and mobility
7. The patient is enrolled in prosthetic training with rehab professionals in both physical and occupational therapy to maximize their functional outcome with a lower extremity prosthesis.

D. LE Prosthesis Prescription
Multi-specialty team of practitioners/specialist with appropriate expertise in patient's condition has evaluated the patient and recommended the prosthesis; **and**

E. The criteria and functional potential for a given type of lower extremity are met.
See section IV for details on specific requirements.

III. Functional Level Assessments[1]

The member's functional level assessment should only be confirmed by their qualified treating physiatrist.

The clinical assessment of patient's rehabilitation potential is based on the following classification levels[1]:

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Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.

Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence, typical of the limited and unlimited household ambulator.

Level 2: Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces, typical of the limited community ambulator.

Level 3: Has the ability or potential for ambulation with variable cadence, typical of the community ambulator who can traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete.

IV. Clinical Indications: Requirements and Functional Potential for LE Prosthesis

Amputation level specified is **1 or more** of the following:

A. **Hip disarticulation** with prescription specifying **ALL** of the following components:
   1. **Socket specified** as 1 or more of the following:
      a. Ischial containment for limited community ambulator, community ambulator, or active adult
      b. Modified quadrilateral for any anticipated functional level

   2. **Socket interface** specified as 1 or more of the following:
      a. Gel liner for any anticipated functional level
      b. Hard socket (no liner) for any anticipated functional level
      c. Soft socket for household ambulator

   3. **Suspension specified** as 1 or more of the following:
      a. Hip joint/pelvic band for active adult
      b. Lanyard for household ambulator or limited community ambulator

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c. Pin for any anticipated functional level
d. Shuttle for any anticipated functional level
e. Silesian for any anticipated functional level
f. Suction for limited community ambulator, community ambulator, or active adult
g. Total-elastic support for household ambulator

4. **Knee system specified** as 1 or more of the following:
   a. Electronic or microprocessor for limited community ambulator, community ambulator, or active adult
   b. Fluid-controlled for community ambulator or active adult
   c. Manual-locking for household ambulator or limited community ambulator
   d. Polycentric for community ambulator or active adult
   e. Single-axis friction for household ambulator or limited community ambulator
   f. Weight-controlled for household ambulator or limited community ambulator

5. Endoskeletal pylon

6. **Foot/ankle system specified** as 1 or more of the following:
   a. Dynamic-response for community ambulator or active adult
   b. Energy-storing for community ambulator or active adult
   c. Flexible-keel for community ambulator or active adult
   d. Multiaxial for community ambulator or active adult
   e. SACH (solid ankle cushion heel) for household ambulator or limited community ambulator
   f. Single-axis for household ambulator or limited community ambulator

B. **Knee disarticulation**, with prescription specifying **ALL** of the following components:
   1. **Socket specified** as 1 or more of the following:
      a. Modified quadrilateral socket
      b. Subischial containment for community ambulator or active adult

   2. **Socket interface** specified as 1 or more of the following:
      a. Gel liner for any anticipated functional level
      b. Hard socket (no liner) for any anticipated functional level
      c. Soft liner for household ambulator, limited community ambulator, community ambulator, or active adult

   3. **Suspension specified** as 1 or more of the following:

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a. Shuttle/pin for any anticipated functional level
b. Sleeve for any anticipated functional level
c. Suction for any anticipated functional level of active adult
d. Supracondylar cuff for any anticipated functional level

4. **Knee system specified** as 1 or more of the following:
   a. Electronic or microprocessor for limited community ambulator, community ambulator, or active adult
   b. Fluid-controlled for community ambulator or active adult
   c. Outside hinges for limited community ambulator
   d. Polycentric for household ambulator, limited community ambulator, or community ambulator
   e. Weight-activated for household ambulator or limited community ambulator

5. **Pylon specified** as 1 or more of the following:
   a. **Endoskeletal** and 1 or more of the following:
      i. Rigid for any anticipated functional level
      ii. Torsion for limited community ambulator, community ambulator, or active adultVertical shock for limited community ambulator, community ambulator, or active adult

   b. **Exoskeletal** and 1 or more of the following:
      i. Rigid for any anticipated functional level
      ii. Torsion for limited community ambulator, community ambulator, or active adult
      iii. Vertical shock for limited community ambulator, community ambulator, or active adult

6. **Foot/ankle system specified** as 1 or more of the following:
   a. Dynamic-response for active adult
   b. Energy-storing for active adult
   c. Flexible-keel for household ambulator, limited community ambulator, community ambulator, or active adult
   d. Multiaxial for community ambulator or active adult
   e. SACH (solid ankle cushion heel) for household ambulator or limited community ambulator
   f. Single-axis for limited community ambulator
   g. Specialty for active adult

c. **Partial foot amputation** (e.g., Chopart, Lisfranc, trans metatarsal), and **forefoot specified** as 1 or

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more of the following:
1. Silicone
2. Other filler

D. **Syme amputation** with prescription specifying ALL of the following components:
   1. **Suspension system specified** as 1 or more of the following:
      a. Canadian Syme socket for any anticipated functional level
      b. Expandable-air for any anticipated functional level
      c. Removable-liner for any anticipated functional level

   2. **Foot system specified** as 1 or more of the following:
      a. SACH (solid ankle cushion heel) for household ambulator or limited community ambulator
      b. Seattle Syme for community ambulator or active adult
      c. Single-axis for household ambulator or limited community ambulator
      d. Syme flex foot for community ambulator or active adult

E. **Transfemoral amputation**, with prescription specifying **ALL** of the following components:
   1. **Socket specified** as 1 or more of the following:
      a. Ischial containment for limited community ambulator, community ambulator, or active adult
      b. Modified quadrilateral for household ambulator, limited community ambulator, or community ambulator
      c. Quadrilateral for limited community ambulator or community ambulator
      d. Subischial containment for community ambulator or active adult

   2. **Socket interface specified** as 1 or more of the following:
      a. Gel liner for any anticipated functional level
      b. Hard socket (no liner) for any anticipated functional level
      c. Soft liner for household ambulator

   3. **Suspension specified** as 1 or more of the following:
      a. Combination for active adult
      b. Lanyard for household ambulator or limited community ambulator
      c. Pin/shuttle for any anticipated functional level
      d. Silesian for any anticipated functional level
      e. Suction for limited community ambulator, community ambulator, or active adult
      f. Total-elastic support for household ambulator, limited community ambulator, or community ambulator

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4. **Knee system specified** as 1 or more of the following:
   a. Electronic or microprocessor for limited community ambulator, community ambulator, or active adult
   b. Fluid-controlled for community ambulator or active adult
   c. Manual-locking for household ambulator or limited community ambulator
   d. Polycentric for community ambulator or active adult
   e. Single-axis friction for household ambulator or limited community ambulator
   f. Transverse rotator for community ambulator or active adult
   g. Weight-activated for household ambulator or limited community ambulator

5. **Rigid endoskeletal pylon**

6. **Foot/ankle system specified** as 1 or more of the following:
   a. Dynamic-response for active adult
   b. Energy-storing for community ambulator or active adult
   c. Flexible-keel for limited community ambulator or community ambulator
   d. Multiaxial for limited community ambulator or community ambulator
   e. SACH (solid ankle cushion heel) for household ambulator or limited community ambulator
   f. Single-axis for household ambulator or limited community ambulator
   g. Specialty for active adult

F. **Trans-tibial amputation**, with prescription specifying **ALL** of the following components:
   1. **Socket specified** as 1 or more of the following:
      a. Bypass prosthesis for delayed healing
      b. Combination patella tendon-bearing/total-contact for any anticipated functional level
      c. Patella tendon-bearing for any anticipated functional level
      d. Total-contact for any anticipated functional level

   2. **Socket interface specified** as 1 or more of the following:
      a. Gel liner for any anticipated functional level
      b. Hard socket (no liner) for household ambulator, limited community ambulator, or community ambulator
      c. Soft liner for any anticipated functional level

   3. **Suspension specified** as 1 or more of the following:
      a. Shuttle/pin for any anticipated functional level

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b. Sleeve for any anticipated functional level
c. Suction for community ambulator or active adult
d. Supracondylar cuff for any anticipated functional level
e. Vacuum for community ambulator or active adult

4. **Pylon specified** as 1 or more of the following:
   a. **Endoskeletal** and 1 or more of the following:
      i. Rigid for any anticipated functional level
      ii. Torsion for community ambulator or active adult
      iii. Vertical shock for community ambulator or active adult

   b. **Exoskeletal** and 1 or more of the following:
      i. Rigid for any anticipated functional level
      ii. Torsion for community ambulator or active adult
      iii. Vertical shock for community ambulator or active adult

5. **Foot/ankle system specified** as 1 or more of the following:
   a. Dynamic-response for active adult
   b. Energy-storing for limited community ambulator, community ambulator, or active adult
   c. Flexible-keel for any anticipated functional level
   d. Multiaxial for limited community ambulator or community ambulator
   e. SACH (solid ankle cushion heel) for household ambulator or limited community ambulator
   f. Single-axis for household ambulator or limited community ambulator
   g. Specialty for active adult

V. Replacement, Exclusions and Limitations

A. Replacement

The replacement of a lower extremity prosthesis is not covered except for the following:

1. The prosthesis is broken and unrepairable; and
2. The cost of prosthesis repair will exceed the cost of replacement; or
3. The patient's functional need is not being met by the current prosthesis such as anatomical change (e.g., growth adjustments) or a change in the patient's physical condition;
4. When the prosthesis is at the end of its reasonable useful lifetime expectancy as established by the manufacturer (e.g., reasonable wear and tear render the item non-functional and unrepairable);
   Note: Kaiser Permanente does not cover repair or replacement of prosthesis if it becomes

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unusable or non-functioning because of member misuse, abuse, or neglect.

B. Exclusions

A lower extremity prosthesis and/or component(s)/accessories are considered not medically necessary and not covered for **any** of the following:

1. When the criteria cited in section II: Clinical indications are not met.
2. The prothesis is not prescribed by a qualified practitioner or prosthetist; or
3. The technology and/or components of a given type of LE prosthesis does not meet the patient's functional and/or physiological need; or
4. LE Prosthesis with upgraded functionality or feature(s) beyond what is clinically required for the management of the patient's current medical condition or duplication of a functional prosthesis device; or
5. When the prosthesis design features, components and/or accessories are primarily intended for the following:
   a. With luxury features when there is an existing appropriate standard alternative that will meet the patient's functional need; or
   b. Convenience or comfort; or
   c. Leisure, recreation, or sporting activities other than normal daily living including employment, except for Maryland Commercial and Medicaid members (see section VI); or
   d. 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. Passive/restorative devices (such as silicone devices to make the limb more life-like); or
6. Prosthesis is broken, unusable or non-functioning because of misuse, abuse, or neglect; or
7. Duplication or upgrade of a functional prosthesis; or
8. Water prosthesis designed to be used for showering or swimming.

C. **Experimental and Investigational**

The following LE prosthesis and/or components/accessories are considered experimental, investigational, or unproven as there is insufficient evidence to establish its' safety and/or effectiveness:

1. Knee

a. Power knee™
b. DAW Sure Stance™ Knee

2. Feet

a. Microprocessor foot or ankle system addition with power assist including any type of motor unless there is sufficient clinical documentation of functional need for the

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technologic or design feature of a given type of foot.
b. A user-adjustable heel height feature on the prosthesis
c. Ossur Pro-Flex® Pivot Foot

3. Other LE Prosthesis
a. LE Prosthesis for patient who do not meet the required functional level; *or*
b. Adjustable click prostheses (such as Revo, RevoFit®, and Boa® click systems) C-leg Protector
c. Osseo integrated with or without microprocessor-control lower extremity prosthetic devices
d. Microprocessor-controlled leg prostheses (such as Intelligent Prosthesis, Ossur Rheo® Knee, Otto Bock C-Leg, and Otto-Bock Genium Bionic Prosthetic System, Ossur Symbionic® Leg)
e. Otto Bock Kenevo microprocessor-controlled knee for members with functional level 2 or below
f. Powered ankle (addition to lower limb prosthesis): a multiaxial ankle with swing phase active dorsiflexion feature
g. Robotic lower body exoskeleton suits such as ReWalk™ by Argo Medical Technologies Ltd.

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 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

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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)

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KAISER PERMANENTE® Mid-Atlantic States	**Prostheses, Lower Extremity** **Medical Coverage Policy**

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
12/23/2024	12/23/2024
01/22/2025	01/22/2025

*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. 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.

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