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| **Department of Origin:**<br>Integrated Healthcare Services | **Effective Date:**<br>12/06/22 |
| **Approved by:**<br>Medical Policy Quality Management Subcommittee | **Date Approved:**<br>12/06/22 |
| **Clinical Policy Document:**<br>DMEPOS, Lower Limb Prostheses | **Replaces Effective Clinical Policy Dated:**<br>12/07/21 |
| **Reference #:**<br>MC/D005 | **Page:**<br>1 of 6 |

**PURPOSE:**
The intent of this clinical policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

**POLICY:**
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

**GUIDELINES:**
Medical Necessity Criteria for a definitive prosthesis - Must satisfy the following: I, and any of II – VII

I. Clinical documentation by the ordering physician and/or prosthetist specifying medical necessity to perform *activities of daily living* (ADLs). Documentation should include the following: A – D

   A. Past medical history including prior prosthetic use.

   B. An explanation of the member's current medical condition, including the status of the residual limb and the nature of other medical problems.

   C. Confirmation of the member's motivation and desire to use the limb.

   D. Confirmation of the member's ability to obtain or maintain a defined functional state for *ADLs* within a reasonable period of time.

II. Lower limb prosthesis (see Table 1 for the components of a lower limb prosthesis) – must satisfy any of the following: A - D

   A. The member displays *functional ambulation level 1* – any of the following: 1 - 2
      1. External-keel SACH foot (L5970) or single axis ankle/foot (L5974)

      2. Knee systems (L5611, L5616, L5710-L5718, L5810-L5818)

   B. The member displays *functional ambulation level 2* – any of the following: 1 - 3
      1. Prosthetic options available for *functional ambulation level 1*

      2. Foot – any of the following: a - b
         a. Flexible keel foot (L5972)
         b. Multi-axial ankle/foot (L5978)

      3. Ankle axial rotation unit (L5982, L5984, L5985, L5986)

C. The member displays *functional ambulation level 3* – any of the following: 1 - 4
   1. Prosthetic options available for *functional ambulation levels 1 and 2*

   2. Foot – any of the following: a – f
      a. Energy storing foot (L5976)
      b. Dynamic response with multi-axial ankle (L5979)
      c. Flex-foot system (L5980)
      d. Flex-walk system or equal (L5981)
      e. Shank system with vertical loading pylon (L5987)
      f. Electronic (*microprocessor*-controlled ankle/foot (L5973) (fitted by a prosthetist experienced in fitting a *microprocessor*-controlled/computer-controlled prosthesis)

   3. Knee System – any of the following: a – b
      a. Fluid or pneumatic knee (L5610, L5613, L5614, L5722-L5780, L5822-L5840, L5848)
      b. Electronic (*microprocessor*-controlled knee) (L5856, L5857, L5858) (fitted by a prosthetist experienced in fitting a *microprocessor*-controlled/computer-controlled prosthesis)

   4. Hip – a pneumatic or hydraulic *polycentric hip joint* (L5961)

D. The member displays *functional ambulation level 4* – any of the following: 1 – 2
   1. Prosthetic options available for *functional ambulation levels 1, 2, and 3*

   2. Knee system – *High activity knee control frame* (L5930)

Table 1: Lower Limb Prosthesis Components

| Component | Description |
|---|---|
| Socket | Connection between the residual limb and prosthesis |
| Suspension system | Method of attachment of the socket to the prosthesis |
| Knee joint | • Provides support, leg control, and unrestricted motion for sitting and kneeling<br>• Include single axis, constant friction knee |
| Shank or pylon | Internal frame or skeleton that provides structural support |
| Terminal device | • Usually includes a foot and ankle<br>• Includes a solid ankle cushion heel (SACH) foot |

III. Prosthetic shoe (L3250) – The member has a partial foot amputation with all or most of the forefoot missing

IV. Socket/socket insert and sleeve - allow less than or equal to 2 test/diagnostic sockets (L5618, L5620, L5622, L5624, L5626, L5628) for each prosthesis at the same time

V. Lower limb prosthetic protective cover, custom-shaped (L5704, L5705, L5706, L5707) (offers shape, protection and waterproofing for normal daily usage of the prosthesis)

VI. Accessories, such as, but not limited to, prosthetic sheaths/socks or sleeves (including a gel cushion layer/gel stocking), a prosthetic donning sleeve (L7600), harnesses, and batteries – must be essential to the effective use of the prosthesis

VII. Addition to lower extremity prosthesis, endoskeletal, knee disarticulation, above knee, hip disarticulation, positional rotation unit, any type - Ottobock 4R57 Rotation Adapter (K1022) will be assessed on a case-by-case basis.

**NOT ROUTINELY COVERED:**

- Routine periodic servicing such as testing, cleaning, and checking of the prosthesis
- Replacement of non-functional components of a prosthesis or prosthetic covering is considered cosmetic
- Accessories or enhancements of the prosthesis for the purpose of recreation, comfort or convenience are not considered medically necessary and are not covered
- Duplicate or similar items are not routinely covered
- User adjustable heel height feature for a prosthetic foot (L5990) is not considered medically necessary
- A prosthesis is not considered medically necessary when the functional level is 0
- A prosthesis is considered cosmetic and is not covered when requested for appearance alone. Medical Necessity requires that the prosthesis enables the member to conduct *ADLs.*
- Repairs, components, or prosthesis replacement if the plan determines that malicious damage, culpable neglect or wrongful disposition of the prosthesis has occurred.

**EXCLUSIONS:**

Refer to member's Certificate of Coverage or Summary Plan Description

The following is considered investigative (see Investigative List)

- Powered microprocessor components (L5859 and L5969)

**DEFINITIONS:**

Activities of Daily Living (ADL):
Activities related to personal self-care and independent living, which include eating, bathing, dressing, transferring, walking/mobility, and toileting/continence

Adjustment:
Any modification to the prosthesis

Functional ambulation levels related to lower limb *prosthesis*:

- Level 0: Lacks ability or potential to ambulate or transfer safely, whether with or without assistance; *prosthesis* does not enhance quality of life or mobility
- Level 1: Presence of ability or potential to use *prosthesis* for transfers or ambulation on level surfaces at fixed cadence (typical of the limited/unlimited household ambulator)
- Level 2: Presence of ability or potential for ambulation; presence of ability to traverse low level environmental barriers such as, but not limited to, curbs, stairs, and uneven surfaces (typical of the limited community ambulator)
- Level 3: Presence of ability or potential for ambulation with variable cadence; presence of ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activities that demand prosthetic utilization beyond simple locomotion

- Level 4: Presence of ability or potential for prosthetic ambulation that exceeds basic ambulation skills; may exhibit high impact, stress, or energy levels (typical of children, active adults, or athletes)

Microprocessor:
A component of every myoelectric prosthesis and is used to interpret and analyze signals from the joint - angle sensors and moment sensors. The microprocessor receives signals from its sensors to determine the type of motion being employed by the amputee. Most microprocessor controlled joints are powered by a battery housed inside the prosthesis.

Polycentric hip joint:
Has many pivot points; mimics natural hip. Also referred to as “four-bar” joints. It provides a smooth walking pattern by closely mirroring the range of motion of a biological hip. It provides a smooth walking pattern by closely mirroring the range of motion of a biological hip.

Prosthesis:
An artificial substitute of a part of the body.

Repair:
Restoration of the prosthesis to correct problems

**BACKGROUND:**
GENERAL PROSTHETIC DESIGNS
There are two basic types of prosthetic designs, and, although they are made differently, they provide many of the same functions.

- Exoskeletal prostheses: This design is typically composed of wood or urethane foam interiors and an outer plastic-laminated skin or shell.
- Endoskeletal prostheses: This design utilizes aluminum, titanium, graphite, and other tubular material to form the supporting interior structure with a flexible foam cover that is cosmetically topped with a nylon hose.

COMPONENT PARTS OF A LOWER LIMB PROSTHESIS
All lower limb prostheses generally have the following components:

- Socket: The custom-made top portion that fits around the residual limb. Socket designs vary depending on the level of amputation, the needs of the individual, and the resulting materials selected for fabrication of the socket. Most sockets are custom fabricated directly from molds or based upon empirical data about an individual's residual limb. Some prefabricated and volume-adjustable sockets are available; these are most often used in the early fitting stages. The socket is secured to the individual's residual limb by a number of methods that can include a belt, a sleeve, or other techniques such as suction within the socket or a tight fit around the condyles of the residual limb.
- Foot: The bottom or terminal portion of the prosthesis that contacts the ground. There is an abundance of prosthetic foot designs available, with a range of functional characteristics to suit the functional level of the individual. Most feet attach solidly to the shank (shin) and do not require a moveable ankle unit; these feet simulate ankle motion in their function. Some feet require ankle units, whereas others are functionally enhanced by these units.

Additional lower limb components:

- Prostheses for transtibial (below the knee) and higher levels include:

    - Shank (shin) -- The portion connecting the foot and ankle (if used) to the upper prosthesis, usually to the socket of the knee unit. In exoskeletal prostheses, the shank is tubular, usually aluminum or graphite, with either stainless steel or titanium connectors at the foot and socket or knee. The connectors generally have alignment capability, even after the prosthesis is fabricated and finished.
- Prostheses for knee disarticulation (through the knee) and higher levels include:
    - Knee -- This component bends (flexes) and straightens (extends) to allow for standing, normal walking, sitting, and kneeling.
- Prostheses for transfemoral (above the knee) and higher levels include:
    - Thigh -- The component between the top of the knee and the bottom of the socket in transfemoral amputees, or to the hip joint in higher level amputees.
- Prostheses for hip disarticulation (at the hip) and higher levels include:
    - Hip joint -- This hinged component bends (flexes) and straightens (extends) to allow for standing, walking, and sitting.

TYPES OF PROSTHETIC DEVICES

- PREPARATORY/IMMEDIATE POSTOPERATIVE PROSTHESIS (IPOP)

Immediately following the amputation procedure, an IPOP is employed.
In the initial postoperative period, cast changes are necessary as the residual limb muscles atrophy, usually at seven- to ten-day intervals.
In the intermediate period between the amputation procedure and definitive prosthetic fitting, the following preparatory prostheses:
The type of preparatory prosthesis used is based on the provider/prosthetists' clinical judgment, considering the status of the residual limb and the individual's history, current condition, and desire to ambulate.
This period of prosthetic utilization is defined by continued rapid changes in limb volume due to the initiation of ambulation and consistent prosthetic use.
Transition from a preparatory prosthesis should only occur with relative stabilization of the residual limb size and consistency of prosthetic fit for several months.

- DEFINITIVE PROSTHESIS

A definitive prosthesis is fitted for an individual whose residual limb is no longer changing shape or volume. This period of prosthetic utilization is defined by relatively full residual limb maturation and stability (this occurs after an individual has utilized a preparatory prosthesis consistently for approximately six months and limb volume has stabilized, resulting in a relatively constant socket fit).
Component selection for the definitive prosthesis is based on the potential functional ability of the individual.

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| **Reference #:**<br>MC/D005 | **Page:**<br>6 of 6 |

Prior Authorization: Yes**,** per network provider agreement.

**CODING:**
CPT or HCPCS - See guidelines



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2. Clinical Policy: MP/C009 Coverage Determination Guidelines
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# Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. *We* do not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

*We* will:

- Provide free aids and services to people with disabilities to communicate effectively with us, such as:
    - Qualified sign language interpreters
    - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provide free language services to people whose primary language is not English, such as:
    - Qualified interpreters
    - Information written in other languages

If *you* need these services, contact *us* at the phone number shown on the inside cover of this *COC*, *your* id card, or aspirushealthplan.com.

If *you* believe that *we* have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1. 866.631.5404 (TTY: 1.866.631.8597)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

*You* can file a grievance in person or by mail, fax, or email. If *you* need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help *you*.

*You* can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

# Language Assistance Services

**Albanian**: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1.866.631.5404 (TTY: 1.866.631.8597).

تنبيه :إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية 1.866.631.5404(رقم هاتف الصم والبك : 1.866.631.8597) متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف **Arabic**

**French**: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.866.631.5404 (ATS : 1.866.631.8597).

**German**: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1.866.631.5404 (TTY: 1.866.631.8597).

**Hindi**: _यान द_: य_द आप ि◌हंदी बोलते ह_ तो आपके ि◌लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-650 (TTY: 1.866.631.8597) पर कॉल कर_।

**Hmong**: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 1.866.631.8597).

**Korean**: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1.866.631.5404 (TTY: 1.866.631.8597)번으로 전화해 주십시오.

**Polish**: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 1.866.631.8597).

**Russian**: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1.866.631.5404 (телетайп: 1.866.631.8597).

**Spanish**: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 1.866.631.8597).

**Tagalog**: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 1.866.631.8597).

**Traditional Chinese**: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1.866.631.5404 (TTY：1.866.631.8597)

**Vietnamese**: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 1.866.631.8597).

**Pennsylvania Dutch**: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 1.866.631.8597).

**Lao**: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.866.631.5404 (TTY: 1.866.631.8597).