Elevance Health FINAL DRAFT – LOGO TO BE INSERTED UPON FINAL PRODUCTION DATE

Clinical UM Guideline

Subject:	Lower Limb Prosthesis		
Guideline #:	CG-DME-13	**Publish Date:**	10/05/2022~~12/29/2021~~
Status:	Revised	**Last Review Date:**	08/11/2022~~11/11/2021~~

Description

This document addresses the use of lower limb prostheses required to replace the function of a lower limb loss due to trauma, disease, or a congenital condition.

Note: For information addressing microprocessor-controlled leg or foot-ankle prosthesis please refer to:

- OR-PR.00003 Microprocessor Controlled Lower Limb Prosthesis

Clinical Indications

I. Lower Limb: Prosthesis Fitting and Selection

Medically Necessary:

A lower limb prosthesis is considered **medically necessary** when **all** the following are met and are documented in the medical record:

A. The prosthesis is prescribed by physician; **and**
B. The member will reach or maintain a defined functional state within a reasonable period of time; **and**
C. The member needs prosthesis for ambulation; **and**

D. The member's rehabilitation potential is based on Functional Levels (also known as 'K-Levels', see Discussion section below for more information); **and**
E. The following anatomy-specific criteria apply:
   1. **Ankles:**
      An axial rotation unit is considered **medically necessary** for individuals whose functional level is 2 or above.
   2. **Knees:**
      Basic lower extremity prostheses include a single axis, constant friction knee. Prosthetic knees are considered for medical necessity based upon functional classification:
      a. Fluid and pneumatic knees are considered **medically necessary** for members with a functional **Level 3** or above.
      b. Other knee systems are considered **medically necessary** for members with a functional **Level 1** or above.
   3. **Sockets:**
      a. Up to 2 test (diagnostic) sockets for an individual prosthesis are **medically necessary** without additional documentation.
      b. Socket replacements are considered **medically necessary** if there is adequate functional documentation of physiological need, including, but not limited to:
         i. Changes in the residual limb; **or**
         ii. Functional need changes; **or**
         iii. Irreparable damage; **or**
         iv. Wear/tear due to excessive member weight or prosthetic demands of very active amputees.
   4. **Feet:**
      The treating physician or the prosthetist will make the determination of the type of foot needed for the prosthesis based upon the functional needs of the individual. Basic lower extremity prostheses include a SACH foot. Other prosthetic feet are considered for medical necessity based upon functional classification.
      a. An external keel SACH foot or single axis ankle/foot is considered **medically necessary** for individuals whose functional level is 1 or above.
      b. A flexible-keel foot or multi-axial ankle/foot is considered **medically necessary** for individuals whose functional level is 2 or above.

c. A flex foot system, energy storing foot, multi-axial ankle/foot, dynamic response, or flex-walk system or equal, or shank foot system with vertical loading pylon is considered **medically necessary** for individuals whose functional level is 3 or above.

Not Medically Necessary:

A lower limb prosthesis is considered **not medically necessary** when the criteria above have not been met.

A lower limb prosthesis is considered **not medically necessary** for individuals with a functional level of 0.

Prosthetics utilized primarily for leisure or sporting activities are considered **not medically necessary**.

Test (diagnostic) sockets for immediate post-surgical or early fitting prostheses are considered **not medically necessary.**

More than two test (diagnostic) sockets for an individual prosthesis are considered **not medically necessary** without additional documentation of need.

More than two of the same socket inserts are considered **not medically necessary** per individual prosthesis at the same time.

II. Lower Limb: Accessories, Maintenance, Repairs and Replacement

Medically Necessary:

Accessories (for example, stump stocking for the residual limb, harness, etc.) are considered **medically necessary** when these appliances aid in, or are essential to, the effective use of the artificial limb.

Repairs to a prosthesis are considered **medically necessary** when necessary to make the prosthesis functional.

Maintenance that may be necessitated by manufacturer's recommendations or the construction of the prosthesis and must be performed by the prosthetist is considered **medically necessary** as a repair.

Adjustments to a prosthesis required by wear and tear or change in an individual's condition are considered **medically necessary.**

Replacement of a prosthesis or prosthetic component is considered **medically necessary** if the treating physician orders a replacement device or part because of either of the following:

A. A change in the physiological condition of the individual; **or**
B. Irreparable wear of the device or a part of the device.

Not Medically Necessary:

Prosthetic accessories, additions, or components used primarily for leisure or sporting activities are considered **not medically necessary** under all conditions.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Prostheses

When services may be Medically Necessary when criteria are met:

HCPCS	
L5000-L5020	Partial foot prostheses [includes codes L5000, L5010, L5020]
L5050-L5060	Ankle prostheses [includes codes L5050, L5060]
L5100-L5105	Below knee prostheses [includes codes L5100, L5105]
L5150-L5160	Knee disarticulation (or through knee) prostheses [includes codes L5150, L5160]
L5200-L5230	Above knee prostheses [includes codes L5200, L5210, L5220, L5230]
L5250-L5270	Hip disarticulation prostheses [includes codes L5250, L5270]
L5280	Hemipelvectomy, Canadian type: molded socket, hip joint, single axis constant friction knee, shin, SACH foot
L5301	Below knee, molded socket, shin, each foot, endoskeletal system

L5312	Knee disarticulation (or through knee), molded socket, single axis knee, pylon, SACH foot, endoskeletal system
L5321	Above knee, molded socket, open end, SACH foot, endoskeletal system, single axis knee
L5331	Hip disarticulation, Canadian type, molded socket, endoskeletal system, hip joint, single axis knee, SACH foot
L5341	Hemipelvectomy, Canadian type, molded socket, endoskeletal system, hip joint, single axis knee, SACH foot
L5400-L5460	Immediate post surgical or early fitting prostheses [includes codes L5400, L5410, L5420, L5430, L5450, L5460]
L5500-L5505	Initial prostheses [includes codes L5500, L5505]
L5510-L5600	Preparatory prostheses [includes codes L5510, L5520, L5530, L5535, L5540, L5560, L5570, L5580, L5585, L5590, L5595, L5600]

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Additions/Repair/Accessories
When services may be Medically Necessary when criteria are met:

HCPCS	
K1022	Addition to lower extremity prosthesis, endoskeletal, knee disarticulation, above knee, hip disarticulation, positional rotation unit, any type
L5610-L5617	Additions to lower extremity prostheses [includes codes L5610, L5611, L5613, L5614, L5616, L5617]
L5618-L5629	Additions to lower extremity prostheses, test sockets [includes codes L5618, L5620, L5622, L5624, L5626, L5628, L5629]
L5630-L5653	Additions to lower extremity prostheses, socket variations [includes codes L5630, L5631, L5632, L5634, L5636, L5637, L5638, L5639, L5640, L5642, L5643, L5644, L5645, L5646, L5647, L5648, L5649, L5650, L5651, L5652, L5653]

L5654-L5699	Additions to lower extremity prostheses, socket inserts and suspension [includes codes L5654, L5655, L5656, L5658, L5661, L5665, L5666, L5668, L5670, L5671, L5672, L5673, L5676, L5677, L5678, L5679, L5680, L5681, L5682, L5683, L5684, L5685, L5686, L5688, L5690, L5692, L5694, L5695, L5696, L5697, L5698, L5699]
L5700-L5707	Replacements for lower extremity prostheses [includes codes L5700, L5701, L5702, L5703, L5704, L5705, L5706, L5707]
L5710-L5795	Additions to lower extremity prostheses, exoskeletal knee-shin system [includes codes L5710, L5711, L5712, L5714, L5716, L5718, L5722, L5724, L5726, L5728, L5780, L5781, L5782, L5785, L5790, L5795]
L5810-L5848	Additions to lower extremity prostheses, endoskeletal knee-shin system [includes codes L5810, L5811, L5812, L5814, L5816, L5818, L5822, L5824, L5826, L5828, L5830, L5840, L5845, L5848]
L5850	Addition, endoskeletal system, above knee or hip disarticulation
L5855	Addition, endoskeletal system, hip disarticulation
L5910-L5966	Additions to lower extremity prostheses, endoskeletal system [includes codes L5910, L5920, L5925, L5930, L5940, L5950, L5960, L5961, L5962, L5964, L5966]
L5968-L5990	Additions to lower extremity prostheses [includes codes L5968, L5970, L5971, L5972, L5974, L5975, L5976, L5978, L5979, L5980, L5981, L5982, L5984, L5985, L5986, L5987, L5988, L5990]
L5999	Addition to lower extremity prosthesis, not otherwise specified
L7510-L7520	Repair of prosthetic device [includes codes L7510, L7520]
L8400-L8410	Prosthetic sheath [includes codes L8400, L8410]
L8417	Prosthetic sheath/sock, including a gel cushion layer, below knee or above knee
L8420-L8430	Prosthetic sock, multiple ply [includes codes L8420, L8430]
L8440-L8460	Prosthetic shrinker [includes codes L8440, L8460]
L8470-L8480	Prosthetic sock, single ply [includes codes L8470, L8480]

ICD-10 Diagnosis

All diagnoses

Discussion/General Information

~~Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.~~

~~Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.~~

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Mechanical prosthetic devices are widely recognized as consistent with generally accepted standards of medical practice for individuals with extremity amputations from any cause. The need for a specific type of mechanical prosthetic limb and related components/additions is based upon demonstrated medical need, ability to utilize a particular device, and the expectations of the ordering provider regarding the likely post-treatment functional level.

Potential functional ability is based upon many factors, including but not limited to:

a. The individual's past history and level of activity (including prior prosthetic use if applicable).
b. The individual's current condition including the status of the residual limb and the nature of other medical problems.
c. The individual's likely ability for community-based ambulation.

Functional Levels, also known as 'K Levels', are used to guide the appropriateness of lower limb prosthesis (Balk, 2018). Provided below are definitions of these levels. Please note that within the functional classification hierarchy, bilateral amputees often cannot be strictly bound by functional level classifications.

Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and prosthesis does not enhance their quality of life or mobility.
Level 1: Has the ability or potential to use 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 has the ability to 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.

Hofstad and colleagues (2004) published a systematic review evaluating prosthetic ankle-foot mechanisms and the impact of daily functioning of individuals with lower limb amputation. A total of 26 studies were included, with a total of 245 individuals. The data indicated there may be a slight advantage in stride length and energy cost for individuals with transfemoral amputation utilizing the Flex-foot on level walking ground. However, the authors concluded that overall, there is insufficient evidence to conclude that one prosthetic design is superior to another, such as the Flex-foot versus the SACH (solid ankle, cushioned heel) foot.

Balk and colleagues (2018) published the results of a comparative effectiveness review of lower limb prostheses and what factors best determine the prosthetic configuration that is optimal for an individual with an amputation. The authors reviewed assessment techniques, prediction tools, and functional outcome measurement tools through 80 eligible studies with a focus on tools that are generalizable to the Medicare population. For all outcomes evaluated, the authors concluded that there is low or insufficient evidence. The studies that were available had methodological limitations, inconsistent findings, and few studies reported outcomes of interest. There is insufficient evidence to predict success and added benefit from a specific prosthesis, including components and configuration, for subgroups of amputees. Furthermore, no assessment instruments have been identified that reliably predict individual success based on prosthesis configuration.

In 2017 the Veteran's Affairs and Department of Defense (VA/DoD) published their clinical practice guideline for rehabilitation of individuals with lower limb amputation. This document provides guidance on prosthesis selection and states the following:

> There are inconclusive studies regarding differences in socket design, prosthetic foot categories, as well as advantages and disadvantages of various types of suspensions and interfaces. Each component of a prosthetic prescription should be carefully selected based on the capabilities and anticipated compliance of the user as well as the integrity and shape of the residual limb. Patient desired outcomes, patient goals, and the compatibility of the entire prosthetic system should also be a consideration when prescribing prosthetic components

Additionally, they recommend full consideration of the individual's health status when relevant to prosthetic use outcomes:

> 8. We recommend an assessment of factors that are associated with poorer outcomes following acquired limb loss, such as smoking, comorbid injuries or illnesses, psychosocial functioning, and pain.

Some prosthetics and prosthetic accessories are designed specifically for use during leisure or sporting activities such as running, biking, or swimming. Such devices provide functionality above what may be considered necessary for routine daily activities for an individual or may be beyond what may be considered clinically appropriate for an

individual. The use of a prosthetic device designed and intended specifically for use during leisure or sporting activities does not primarily serve a medical purpose. That use is thus considered not medically necessary.

Overall, the available evidence for the selection of prosthetic devices is poor, and the available recommendations emphasize a holistic approach taking multiple factors into consideration, including the individual's health and functional status, as well as potential functional abilities and use.

References

Peer Reviewed Publications:

1. Hofstad C, Linde H, Limbeek J, Postema K. Prescription of prosthetic ankle-foot mechanisms after lower limb amputation. Cochrane Database Syst Rev. 2004;(1):CD003978.
2. Lovegreen W, Murphy DP, Smith WK, et al. Lower Limb Amputation and Gait. In: Cifu DX ed, Braddom's Physical Medicine and Rehabilitation, 5th Ed. Philadelphia, PA: Elsevier, 2016: 191-223.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Balk EM, Gazula A, Markozannes G, et al. Lower limb prostheses: measurement instruments, comparison of component effects by subgroups, and long-term outcomes. Agency for Healthcare Research and Quality. 2018 September. Available at: https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-213-lower-limb-protheses-report.pdf. Accessed on August 4, 2022~~November 2, 2021~~.
2. Centers for Medicare & Medicaid Services. Activities of Daily Living. 2008. Available at: https://www.cms.gov/research-statistics-data-and-systems/research/mcbs/downloads/2008_appendix_b.pdf. Accessed on August 4, 2022.
~~2.~~3. Centers for Medicare & Medicaid Services. Health Technology Assessment. Lower Limb Prosthetic Workgroup. Consensus Document. September 2017. Available at: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/LLP_Consensus_Document.pdf. Accessed August 4, 2022~~on November 2, 2021~~.
~~3.~~4. Veteran's Affairs/ Department of Defense. VA/DoD Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation. 2017. Available at: https://www.healthquality.va.gov/guidelines/Rehab/amp/VADoDLLACPG092817.pdf. Accessed on ~~November 2,~~ August 4, 2022~~2021~~.

Clinical UM Guideline

Lower Limb Prosthesis

Index

Lower Leg
Prosthesis
SACH Foot

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	08/11/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Added new NMN statements addressing prosthetics utilized primarily for leisure or sporting activities. Updated Discussion and References sections.
Revised	11/11/2021	~~Medical Policy & Technology Assessment Committee (~~MPTAC~~)~~ review. Moved Functional Level information from Clinical Indications section to Discussion section. Updated Discussion/General Information and References sections.
	10/01/2021	Updated Coding section with 10/01/2021 HCPCS changes; added K1022.
Reviewed	11/05/2020	MPTAC review. Updated Discussion/General Information and References sections. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review.
Reviewed	01/24/2019	MPTAC review.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date."
Revised	02/02/2017	MPTAC review. Revised Replacement criteria in Clinical Indications section.
Reviewed	11/03/2016	MPTAC review. Updated formatting in Clinical Indications section. Updated references section.
Revised	11/05/2015	MPTAC review. Minor clarifications made to Clinical Indications section. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review.

Reviewed	11/14/2013	MPTAC review.
Reviewed	11/08/2012	MPTAC review. Updated References section. Updated coding section with 01/01/2012 HCPCS changes; removed code L7500 deleted 12/31/2011.
Reviewed	11/17/2011	MPTAC review. Updated Coding section with 01/01/2012 HCPCS changes; removed code L5311 deleted 12/31/2011.
Reviewed	11/18/2010	MPTAC review. Updated Coding section with 01/01/2011 HCPCS changes.
Reviewed	11/19/2009	MPTAC review.
Reviewed	11/20/2008	MPTAC review.
Reviewed	11/29/2007	MPTAC review.
Reviewed	12/07/2006	MPTAC review.
New	12/01/2005	MPTAC initial guideline development.

Pre-Merger Organizations	**Last Review Date**	**Policy/Guideline Number**	**Title**
Anthem Connecticut	09/01/2004		CT DME Coverage Guidelines, Section G: Prostheses: Upper and Lower Limb
Anthem West	10/29/2004	DME.706	West Region: Lower Limb Prostheses
Anthem MidWest	11/05/2004	DME-005	Midwest Region: Lower Limb Prosthesis
WellPoint Health Networks, Inc.		None	

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