Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Lower Limb Prostheses

Effective: February 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the Fax numbers	Yes ☒ No ☐
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816
☒ Tufts Health Plan Commercial products; 617-972-9409

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
☒ Tufts Health Together – MassHealth Accountable Care Partnership Plans; 888-415-9055
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
☒ Tufts Health One Care – A dual-eligible product; 857-304-6304

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-972-9409
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-972-9409
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-972-9409

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

A lower limb prosthesis is a device designed to replace the function of a missing lower limb.

A microprocessor is a prosthetic component which includes an internal computer and sensors. The microprocessor monitors each phase of an individual's gait pattern and makes real-time adjustments, allowing for a more efficient gait at various speeds, and increased control on varying terrain and/or increased control on slopes, ramps, and stairs.

The microprocessor knee (MPK) component specifically enables rapid adjustments in knee resistance during swing and/or stance phase control to provide real-time adjustment of resistance within the MPK unit and facilitate optimal walking patterns on all surfaces, including uneven terrain, stairs, and inclines/declines.

The microprocessor foot/ankle (MPFA) unit specifically adjusts and controls ankle/foot movement in real time in response to sensor feedback, allowing optimization of plantarflexion and dorsiflexion during stance and swing phases and adaptation to underlying terrain, inclines/declines, and stairs. Additional potential benefit of a microprocessor unit includes reduced energy expenditure during ambulation.

The Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Dual Product Eligible plan members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals and MassHealth Medical Necessity Determinations are the basis for coverage determinations. LCD - Lower Limb Prostheses (L33787) (cms.gov) is being supplemented to provide additional detail regarding medical necessity for **Tufts Health One Care**.

For the service of lower limb prostheses, evidence is sufficient for coverage. In addition to the criteria in the LCD, evidence

also supports additional criteria for microprocessors of the knee and ankle/foot to be approved for the appropriate Member. For the appropriate member, a highly complex microprocessor can allow for a better quality of life, including decreased fall risk, and increased stability, control, and speed on uneven surfaces and slopes.

The use of this supplemented criteria in the utilization management process will ensure access to evidence based clinically appropriate care. See References section below for all evidence accessed in the development of these criteria.

Clinical Guideline Coverage Criteria

The Plan requires prior authorization for select lower limb prosthetics (i.e. flex- walk systems) and microprocessor lower limb prostheses, or part thereof. The Plan will use the following as a guideline for determining the Member's level of function as part of the process to determine medical necessity. It is the expectation provider will conform to manufacture's product-specific recommendations.

According to Medicare Functional Classification Level (MFCL), an individual's functional level is a measurement of the capacity and potential of the individual to accomplish his/her expected post- rehabilitation, daily function. The functional classification is used by The Plan to establish the medical necessity of prosthetic knee, feet, and ankle components. The clinical assessments of the Member's rehabilitation potential should be based on the following classification levels:

K Level	AMPnoPRO score	AMPPro score	Description
Level K-0	0-8	N/A	Does not have the ability or potential to ambulate or transfer safely with or without assistance, and prosthesis does not enhance the quality of life or mobility.
Level K-1	9-20	15-26	Has the ability or potential to use prosthesis for transfers or ambulation on level services at fixed cadence. Typical of the limited and unlimited household ambulator.
Level K-2	21-28	27-36	Has the ability or potential for ambulation with the ability to transfer low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
Level K-3	29-36	37-42	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to transverse most environmental barriers, and may have vocational, therapeutic, or exercise activities that demands prosthetic utilization beyond simple locomotion.
Level K-4	37-43	43-47	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 a child, active adult, or athlete.

Note: For lower limb prosthetic requests, the score from the applicable functional mobility prediction tool (e.g., AMPPro, PROMIS 29) must be submitted to verify Member's K functional level

Initial Lower Limb Prostheses Authorization

The Plan may authorize coverage of initial lower limb prostheses as reasonable and medically necessary, safe and effective for the intended purpose(s) and prescribed by the attending physician (based on recommendations from an American Board for Certification (ABC) or Board of Certification (BOCP) certified prosthetic clinician) when **ALL** of the following criteria are met:

1. Covered devices must be fitted and programmed by a board-certified prosthetist [American Board of Certification (ABC) or Board of Certification (BOCP) certified prosthetic clinician] ; **and**
2. The requested prosthesis or component(s) is the most appropriate, least intensive, medically necessary model that adequately meets the medical needs of the Member; **and**
3. Member will reach or maintain a predicted improved functional state (e.g. transfers, ambulation) with the use of the prescribed prosthesis within a reasonable and predictable period of time; **and**
4. Member is motivated and has adequate cardiovascular reserve and cognitive ability to utilize the device; **and**
5. There is clinical documentation and support for the functional need of the technology or design feature of a given type of foot and/or knee; **and**
6. The component(s) or prosthesis has been prescribed by a physician, and meets the specific criteria listed for each lower limb component described below:

a. Foot Components (For coverage guidelines related to microprocessor foot components see below)
    i. A flex foot system, multi-axial ankle/foot, dynamic response, or flex- walk system or equal is considered appropriate for persons whose functional level is 3 or above.
b. Knee Components (For coverage guidelines related to microprocessor knee components see below)
    i. A single axis constant friction knee and other basic knee systems are considered appropriate for persons whose functional level is 1 or above; **or**
    ii. A fluid, pneumatic, or electronic knee is considered appropriate for persons whose functional level is 3 or above.

7. Documentation of a complete multidisciplinary assessment (e.g., medical record notes, Physical Therapy assessment, detailed written order completed by certified prosthetist and signed by the attending physician) including an evaluation by a certified prosthetic clinician with expertise in the evaluation and fitting for the requested device is required.

Microprocessor Controlled Prosthetic Knee as Initial Prosthesis:

The Plan may authorize coverage of a microprocessor knee component as initial prosthesis when criteria for initial prosthesis are met **and** when **ALL** the following criteria are met:

1. Member is an active MFCL K3-K4 individual with a trans-femoral, knee-disarticulation or hip disarticulation amputation; **and**
2. Functional assessment indicates a member has the potential to ambulate independently with requested MPK in a reasonable and predictable period of time; **and**
3. Member has no contraindications which prevent immediate training with requested MPK. Contraindications may include but are not limited to pain, delay of wound healing of residual limb, inability to fit socket, co-morbidities; **and**
4. Documentation sufficiently demonstrates the reasonable likelihood of member meeting Microprocessor Controlled Prosthetic Knee criteria below.

Microprocessor Controlled Prosthetic Knee

The Plan may authorize coverage of a microprocessor knee component when documentation confirms **ALL** of the following:

1. Member has no cardiovascular, neuromuscular, musculoskeletal, or cognitive conditions that could adversely affect the ability to successfully use requested prosthesis.
2. Member has undergone evaluation by a trained prosthetic clinician with expertise in the evaluation and fitting of members for this device.
3. Member has adequate strength and balance required to activate the knee unit.
4. Member has cognitive ability required to master control, operation, and maintenance of requested MPK
5. AND criteria for applicable MFCL is met:

<u>MPK for MFCL K3-K4</u>

The Plan may authorize coverage of a microprocessor knee component for MFCL K3-4 when **ALL** of the following criteria are met:

1. Member is an active MFCL K3-K4 adult with a trans-femoral, knee disarticulation or hip disarticulation amputation; **and**
2. Member has a documented need for and use of a microprocessor knee as the primary day to day prosthesis for **ALL** the following:
    a. Daily necessary long-distance ambulation (> 400 ft.) at variable speeds; **and**
    b. Daily necessary ambulation on outdoor uneven terrain; **and**
    c. Daily necessary repetitive use of stairs beyond usual routine limited home or workplace; **and**
    d. Daily necessary ambulatory speed greater than normal or usual speed
3. Documentation of **ALL** of the following:
    a. Member is in excellent physical condition, has a high exercise capacity; **and**
    b. Member has undergone a clinical gait analysis demonstrating the ability to ambulate at a rate faster than the member's baseline rate using a standard prosthetic application swing and stance control; **and**
    c. Current non-MPK knee no longer fulfills ambulatory and functional needs of the member

<u>MPK for MFCL K2</u>

The Plan may authorize coverage of a microprocessor knee component for MFCL K2 when **ALL** of the following criteria are met:

1. Member is an MFCL K2 individual with a unilateral trans-femoral amputation; **and**
2. Provider attests and includes documentation that a non-MPK lower limb prosthesis does not meet the member's daily ambulatory and functional requirements; **and**
3. Member's use of MPK will result in **ONE** of the following:
    a. Improved balance; **or**
    b. Decreased risk of fall(s); **or**
    c. Increased indoor ambulation; **or**
    d. Increased independence in indoor ADLs; **or**
    e. Increased community ambulation, including uneven terrain, slopes and/or ramps
4. Member has completed a trial using MPK prosthesis; **and**
5. Documented peer-reviewed outcome measures from MPK trial (e.g., 2MWT, AMP, TUG, AMPPro, Basic Amputee Mobility Score (BAMS)), support member will achieve desired ambulatory and functional goals

Microprocessor Controlled Prosthetic Foot/Ankle (MPFA): Initial

The Plan may authorize coverage of a microprocessor foot/ankle component when criteria for initial lower limb prosthesis are met **and** when **ALL** the following criteria are met:

1. Member is a transtibial amputee whose functional level is K3-K4; **and**
2. Member has undergone evaluation by a board-certified prosthetist [American Board of Certification (ABC) or Board of Certification (BOCP) certified prosthetic clinician trained prosthetic with expertise in the evaluation and fitting of individuals for this device; **and**
3. Non-microprocessor ankle/foot prosthetic components (e.g., multi-axial ankle/foot, dynamic- response foot) have been trialed and submitted clinical documentation supports that trialed component will not meet member's daily ambulatory and functional requirements, **OR**
    a. Member currently utilizes a lower limb prosthesis with a foot/ankle component other than a microprocessor-controlled foot/ankle component, and documentation supports their current prosthetic foot/ankle component no longer meets member's ambulatory daily functional requirements.
4. Daily necessary ambulation on outdoor uneven terrain; **and**
5. Daily necessary ambulation on inclines/declines (e.g., slopes, ramps); **and**
6. Daily necessary repetitive use of stairs beyond usual routine limited home or workplace; **and**
7. Member has cognitive ability required to master control, operation, and maintenance of requested foot/ankle microprocessor.

Prostheses and Prosthetic Components for Recreational Purposes

Applicable to Harvard Pilgrim Health Care members Residing in Maine or with Maine Plans, or members residing in New Hampshire or with New Hampshire Plans. Please refer to the Member's plan documents for details. For members in an individual plan, prostheses and prosthetic components for recreational purposes is not covered.

The Plan may authorize coverage of **one** additional prosthesis and/or prosthetic component for Members under 18 years of age in Maine, or under 19 years of age in New Hampshire, for recreational purposes when the following criteria are met:

1. Documentation of a complete multidisciplinary assessment (e.g., medical record notes, Physical Therapy assessment, detailed written order completed by certified prosthetist and signed by the attending physician) including an evaluation by a certified prosthetic clinician with expertise in the evaluation and fitting for the requested device is required and includes **ALL** of the following:
    a. Requested prosthesis/prosthetic component is the most appropriate and least intensive model that meets the medical needs of the Member to maximize the Member's ability to perform recreational activity (e.g., ambulate, run, bike, swim) and allow developmentally appropriate experience; **and**
    b. Physical therapy evaluation and assessment (e.g., musculoskeletal, endurance) supports the Member is able to tolerate the physical demands of desired recreational activity **and**
    c. Delivery of prosthesis by prosthetist will include education regarding any specialized maintenance and care of prosthesis/prosthetic components

Limitations

1. The Plan will not authorize a prosthesis for a Member whose potential functional level is 0.
2. The Plan will not cover upgrade or enhancement of member's current prosthesis or prosthetic component(s) when member's current prosthesis or prosthetic component(s) meets their medical and ambulatory needs and allows the Member to perform activities of daily living.
3. The Plan will not cover additional or duplicate prosthesis or prosthetic component(s).

4. The Plan will not cover repair or replacement of a spare, backup or duplicate prosthesis or prosthetic component(s).
5. The Plan will not cover any of the following items, as they are not considered medically necessary:
    a. Swim prosthesis (Note: Unless covered per "Prostheses/prosthetic components for recreational purposes" criteria)
    b. Shower prosthesis
    c. Devices intended for sports, recreation and/or work-related purposes (Note: Unless covered per "Prostheses/prosthetic components for recreational purposes" criteria)
    d. Prosthetic device/component(s)intended for athletics (e.g., high-tech competitive models)
    e. Vacuum-assisted socket system (VASS™)
    f. Artificial limbs or parts thereof for cosmetic purposes only, including, but not limited to, nonfunctional prosthetics, nonfunctional prosthetic covers and toe prostheses.
    g. The Plan will not cover powered knee flexion/extension component (L5859) and power assist ankle-foot or ankle system (L5969) as they are considered experimental and investigational according to the Plan's Evidence of Coverage definition. There is a lack of sufficient evidence in the published peer-reviewed medical literature substantiating their effectiveness in reducing disability and improving function over standard leg prostheses. Refer to Medical Necessity Guidelines: Noncovered Investigational Services.
    h. Hip flexion contracture >30
    i. Microprocessor-controlled prostheses for individuals who do not meet recommended weight or height guidelines of manufacturer
    j. Recreational prosthesis/prosthetic components for individuals who do not meet recommended weight or height guidelines of manufacturer
    k. Osseointegrated prostheses
    l. Targeted muscle innervation
    m. Myoelectric sensors can be implanted beneath the skin to improve the prosthetic function and control

Additional Limitations – Microprocessor Knee and Microprocessor Foot/Ankle
The Plan will not cover the following, as they relate to microprocessor knee and microprocessor foot/ankle prosthetic component requests, as they are not considered medically necessary:

1. Significant deformity of the remaining limb exists, impairing ability to transfer or ambulate stride.
2. Member is unable to tolerate the weight of the microprocessor unit.
3. Significant hip flexion contracture of affected residual limb preventing correct knee alignment and MPK activation as per manufacturer's recommendations.
4. Prosthesis will be utilized in environment contraindicated for microprocessor components, including excessive sand, debris, water, and saltwater.
5. Genium X2 microprocessor-controlled knee prosthetic device and Genium X3 waterproof microprocessor-controlled knee prosthetic devices when there is a less intensive MPK device which can safely and effectively meet the Member's ambulatory and functional needs.
6. Waterproof MPK devices

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

Code	Description
L5827	Endoskeletal knee-shin system, single axis, electromechanical swing and stance phase control, with or without shock absorption and stance extension damping
L5828	Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5846	Addition, endoskeletal, knee-shin system, microprocessor control feature, swing phase only
L5847	Addition, endoskeletal knee-shin system, microprocessor control feature, stance phase
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
L5857	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type
L5858	Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source

Code	Description
L5980	All lower extremity prostheses, flex foot system
L5981	All lower extremity prostheses, flex-walk system or equal
L5987	All lower extremity prostheses, shank foot system with vertical loading pylon
L5999	Lower extremity prosthesis, not otherwise specified

The following codes are considered experimental/investigational

Table 2: CPT/HCPCS Codes

Code	Description
L5859	Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)

References

1. MassHealth 130 CMR 428.000: Prosthetics Lower Limb Prosthetic Devices (including Microprocessor Controlled Knee and Foot/Ankle) Services. Accessed August 21, 2025. 130 CMR 428.000: Prosthetics Services | Mass.gov
2. Centers for Medicare & Medicaid Services; Local Coverage Determination (LCD) L33787: Lower Limb Prostheses. Accessed August 21, 2025. LCD - Lower Limb Prostheses (L33787) (cms.gov)
3. 130 CMR 409.000: Durable Medical Equipment Services Accessed August 21, 2025. 130 CMR 409.000: Durable Medical Equipment Services | Mass.gov
4. Mass. Gen. Laws § 176G-4S. Accessed August 21, 2025. General Law - Part I, Title XXII, Chapter 176G, Section 4S (malegislature.gov)
5. Coverage Guidelines for Durable Medical Equipment; Orthotic and Prosthetic Devices. The Executive Office of Health and Human Services State of Rhode Island. Accessed August 21, 2025. Coverage Guidelines For Durable Medical Equipment | Executive Office of Health and Human Services (ri.gov)
6. R.I. Gen. Laws §27-20-52. Accessed August 21, 2025. webserver.rilin.state.ri.us/Statutes/TITLE27/27-20/27-20-52.htm
7. Maine. Gen. Laws § 24_a-56-4315. Coverage of prosthetic devices. Accessed August 21, 2025 Title 24-A, §4315: Coverage of prosthetic devices (maine.gov)
8. SB177 an act relative to health insurance coverage of prosthetics for children under 19 years of age. NHLA Bill Review: Bill Text - SB177 (2024). January 20, 2023. Accessed August 21, 2025. https://bills.nhliberty.org/bills/2024/SB177/revision/37669.
9. McGrath M, Laszczak P, Zahedi S, Moser D. The influence of a microprocessor-controlled hydraulic ankle on the kinetic symmetry of trans-tibial amputees during ramp walking: A case series. J Rehabil Assist Technol Eng. 2018;5:2055668318790650. Published 2018 Oct 8.
10. Kaufman KR, Bernhardt KA, Symms K. Functional assessment and satisfaction of transfemoral amputees with low mobility (FASTK2): A clinical trial of microprocessor-controlled vs. non-microprocessor-controlled knees. Clin Biomech (Bristol, Avon). 2018;58:116-122.
11. Kuhlmann A, Krüger H, Seidinger S, Hahn A. Cost-effectiveness and budget impact of the microprocessor-controlled knee C-Leg in transfemoral amputees with and without diabetes mellitus. Eur J Health Econ. 2020;21(3):437-449.
12. Centers for Medicare & Medicaid Services Health Technology Assessment: Lower Limb Prosthetic Workgroup Consensus Document; September 2017.
13. Using a microprocessor knee (C-Leg) with appropriate foot transitioned individuals with dysvascular transfemoral amputations to higher performance levels: a longitudinal randomized clinical trial. J Neuroeng Rehabil. 2021;18(1):88. Published 2021 May 25.

Approval And Revision History

October 20, 2021: Reviewed by the Medical Policy Approval Committee (MPAC), renewed without changes

Subsequent endorsement date(s) and changes made:

- February 1, 2022: Template Update
- March 16, 2022: Reviewed by Medical Policy Approval Committee (MPAC) for integration purposes between Harvard Pilgrim Health Care and Tufts Health Plan with an effective date of June 1, 2022.
- November 16, 2022: Reviewed by MPAC, renewed without changes
- January 18, 2023: Reviewed by MPAC. For effective date June 1, 2023, clarification to replacement criteria

requirement for physiological condition/functional level change vs. irreparable change.
- September 20, 2023: Reviewed by MPAC; Language and criteria added for Prostheses and Prosthetic Components for Recreational Purposes in accordance with ME H.P. 741 – L.D. 1003 An Act to Improve Outcomes for Persons with Limb Loss effective January 1, 2024
- November 2023: Rebranded Unify to One Care and updated overview, effective January 1, 2024
- January 11, 2024: Coding updated, per AMA HCPCS®, the following code(s) removed K1014, effective January 1, 2024
- October 17, 2024: Reviewed by MPAC, updated MPK for MFCL K2 criteria #2 to remove step through mechanical knee before microprocessor knee, added language and criteria for Prostheses and Prosthetic Components for New Hampshire in accordance with SB177 an act relative to health insurance coverage of prosthetics for children under 19 years of age effective January 1, 2025
- March 2025: Per CMS HCPCS the following codes added to prior authorization: L5827 effective April 1, 2025
- August 20, 2025: Reviewed by MPAC, added code L5783 to policy effective October 1, 2025
- September 5, 2025: Fax number for Senior Care Options, Tufts Medicare Preferred HMO and Tufts Medicare Preferred PPO updated; language for Carelink removed
- November 19, 2025: Reviewed by MPAC, removed replacement prosthetic criteria, services have been removed from prior authorization; removed about 190 codes from prior authorization associated with a standard prosthetic build, services have been moved to covered, intent of MNG is to now just manage microprocessor and complex components of the prosthetic; limitation section updated, effective February 1, 2026

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.