Medical Necessity Guidelines: Lower Limb Prosthetic Devices (including Microprocessor Controlled Knee and Foot/Ankle)

Effective: January 25, 2021

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	**Yes ☒ No ☐**

Applies to:

COMMERCIAL Products

☒ Tufts Health Plan Commercial products; Fax: 617.972.9409

☒ Tufts Health Freedom Plan products; Fax: 617.972.9409

- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

TUFTS HEALTH PUBLIC PLANS Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax:888.415.9055

☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404

☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304

*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

SENIOR Products

- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List
- Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

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.

CLINICAL COVERAGE CRITERIA

Tufts Health Plan requires prior authorization for all new and replacement lower limb prostheses, or part thereof. Tufts Health 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 Tufts Health 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 all initial and replacement 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 Prosthesis

Tufts Health Plan may authorize coverage of initial lower limb prosthesis when **all** the following criteria are met:

1. The requested prosthesis or component(s) is the most appropriate, least intensive, medically necessary model that adequately meets the medical needs of the Member (MGL 176G § 4S).
2. Member will reach or maintain a predicted improved functional state, with the use of the prescribed prosthesis within a reasonable and predictable period of time.
3. Member is motivated and has the potential to become a functional ambulator.
4. 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.
5. 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
        1) A solid ankle-cushion heel (SACH) foot is considered appropriate in most circumstances for persons whose functional level is 1 or above.
        2) An external keel SACH foot or single axis ankle/foot is considered appropriate in most circumstances for persons whose functional level is 1 or above.
        3) A flexible-keel foot or multi-axial ankle/foot is considered appropriate in most circumstances for persons whose functional level is 2 or above.
        4) A flex foot system, energy storing foot, multi-axial ankle/foot, dynamic response, or flex-walk system or equal is considered appropriate in most circumstances for persons whose functional level is 3 or above.
    b. Knee Components (For coverage guidelines related to microprocessor knee components see below)
        1) A fluid, pneumatic, or electronic knee is considered appropriate in most circumstances for persons whose functional level is 3 or above.
        2) A single axis constant friction knee and other basic knee systems are considered appropriate in most circumstances for persons whose functional level is 1 or above.
    c. Ankle Components

1) An axial rotation unit is considered appropriate in most circumstances for persons whose functional level is 2 or above.

d. Sockets

1) Tufts Health Plan will cover up to two (2) test (diagnostic) sockets for an individual prosthesis. Additional documentation of medical necessity is required for more than two test sockets.

Microprocessor Controlled Prosthetic Knee as Initial Prosthesis:

Tufts Health 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 a healthy, active K3-K4 adult with a trans-femoral, knee-articulation or hip disarticulation amputation.
2. Functional assessment indicates member has the potential to ambulate independently with requested MPK in a reasonable and predictable period of time.
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.
4. Documentation sufficiently demonstrates the reasonable likelihood of member meeting Microprocessor Controlled Prosthetic Knee criteria below.

Microprocessor Controlled Prosthetic Knee

Tufts Health Plan may authorize coverage of a microprocessor knee component when **ALL** the following criteria are met:

1. Member is a healthy, active K3-K4 adult with a trans-femoral, knee-articulation or hip disarticulation amputation.
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
   b. Daily necessary ambulation on outdoor uneven terrain
   c. Daily necessary repetitive use of stairs beyond usual routine limited home or workplace
   d. Daily necessary ambulatory speed greater than normal or usual speed
3. Documentation of **all**:
   a. Member is in excellent physical condition, has a high exercise capacity, and has no cardiovascular, neuromuscular, musculoskeletal or cognitive conditions that could adversely affect the ability to use this prosthesis.
   b. 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 with swing and stance control.
   c. Has undergone evaluation by a trained prosthetic clinician with expertise in the evaluation and fitting of members for this device.
   d. If member has received a lower limb prosthesis with a knee component other than a microprocessor-controlled knee component in the past, they have demonstrated successful use for at least one year and this current prosthetic knee no longer fulfills ambulatory and functional needs of the member.
   e. Member has adequate strength and balance required to activate the knee unit.
   f. Member has cognitive ability required to master control, operation and maintenance of requested MPK.

Microprocessor Controlled Prosthetic Foot/Ankle (MPFA): Initial or Replacement

Tufts Health 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.
2. Member has undergone evaluation by a trained prosthetic clinician with expertise in the evaluation and fitting of individuals for this device.
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 components will not meet member's daily ambulatory and functional requirements.

   OR

   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.
5. Daily necessary ambulation on inclines/declines (e.g. slopes, ramps).
6. Daily necessary repetitive use of stairs beyond usual routine limited home or workplace.
7. Member has cognitive ability required to master control, operation and maintenance of requested foot/ankle microprocessor.

Replacement Prosthesis all products

A replacement is the removal and substitution of a component of a prosthesis that has a HCPCS definition.

Tufts Health Plan may authorize the replacement of lower limb prosthesis or the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the replacement device, or replacement part of such a device, is necessary when the following criteria are met:

1. There is a change in the physiological condition or functional level of the Member, which justifies a new prosthesis or replacement part(s)
   OR
2. There is an irreparable change in the condition of the device, or in a part of the device **and** the component or prosthesis in need of replacement is not covered under warranty.

Tufts Health Plan may cover the replacement of sockets when there is adequate documentation of functional and/or physiological need, including but not limited to: changes in the residual limb; functional need changes, or irreparable damage or wear/tear due to excessive weight or prosthetic demands of very active amputees.

In addition to the above, the following replacement criteria are applicable to Tufts Health Commercial, Tufts Freedom Plan, Tufts Health Direct, and Tufts Health RITogether products only:

1. The condition of the device, or the part of the device, requires repairs, and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.
2. The component or prosthesis is not in need of replacement as a result of improper use.

LIMITATIONS – GENERAL

- Tufts Health Plan will not authorize a prosthesis for a Member whose potential functional level is 0.
- Tufts Health will not authorize prosthesis for a Member with intolerance to test socket fitting and/or wear due to residual limb issues, including but not limited to intractable pain, joint contractures and skin/wound complications, as such intolerance will likely predict a poor outcome with a permanent prosthetic.
- Tufts Health Plan will not cover lower limb adjustable sockets.
- Tufts Health 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.
- Tufts Health Plan will not cover additional or duplicate prosthesis or prosthetic component(s).
- Tufts Health Plan will not cover repair or replacement of a spare, backup or duplicate prosthesis or prosthetic component(s).
- Tufts Health Plan will not cover any of the following items, as they are not considered medically necessary:
  - Swim prosthesis
  - Shower prosthesis
  - Devices intended for sports, recreation and/or work related purposes
  - Test (diagnostic) sockets for immediate prostheses
  - More than two of the same socket inserts per individual prosthesis at the same time
  - Vacuum-assisted socket system (VASS™)
  - Artificial limbs or parts thereof for cosmetic purposes only, including, but not limited to, nonfunctional prosthetics, nonfunctional prosthetic covers and toe prostheses.
  - Tufts Health Plan will not cover powered knee flexion/extension component (L5859) and power assist ankle-foot or ankle system (L5969) as they are considered to be experimental and investigational according to the Tufts Health 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.

ADDITIONAL LIMITATIONS – MICROPROCESSOR KNEE AND MICROPROCESSOR FOOT/ANKLE

Tufts Health 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:

- Amputees with the following functional levels : K0 , K1 or K2.
- Significant deformity of the remaining limb exists, impairing ability to stride.
- Member is unable to tolerate the weight of the microprocessor unit.
- Significant hip flexion contracture of affected residual limb preventing correct knee alignment and MPK activation as per manufacturer's recommendations.
- Prosthesis will be utilized in environment contraindicated for microprocessor components, including excessive sand, debris, water and saltwater.
- Genium X2 microprocessor-controlled knee prosthetic device and Genium X3 waterproof microprocessor-controlled knee prosthetic device as there is a less intensive level of service and more cost-effective alternative which can be safely and effectively provided.
- Microprocessor foot/ankle components which include powered (power assist motor) ankle dorsiflexion/extension.

CODES

The following HCPCS/CPT code(s) require prior authorization:

Code	Description
L5000 – L5020, L5050 – L5060, L5100 – L5105, L5150 – L5160, L5200 – L5230, L5250 – L5270, L5280 – L5341, L5500 – L5505, L5510 – L5600, L5610 – L5617, L5618 – L5629, L5630 – L5653, L5654 – L5699, L5700 – L5707, L5710 – L5782, L5785 – L5795, L5810 – L5858, L5910-5968, L5970-L5973, L5974-L5999	Lower limb prosthetics
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

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APPROVAL HISTORY

January 3, 2007: Reviewed by the Clinical Coverage Criteria Committee, new criteria.

Subsequent endorsement date(s) and changes made:

- February 28, 2007: Reviewed and renewed, without changes
- February 27, 2008: Reviewed and renewed, without changes
- March 26, 2008: Reviewed and renewed, without changes
- October 8, 2008: Special Information box added to MNG format.
- March 16, 2009: Limitation for noncoverage of cosmetic, nonfunctional prostheses added.
- March 2010: Reviewed by MASPAC, Medical Policy-Medical Affairs. Microprocessor knee component criteria added as they are now covered; ankle microprocessor limitation added these components are still considered experimental.
- April 2011: Reviewed by MSPAC, without changes
- January 1, 2012: New CPT code added
- April 11, 2012: Reviewed and renewed at Integrated Medical Policy Advisory Committee (IMPAC), no changes.
- October 9, 2013: Reviewed at IMPAC. Microprocessor knee weight guidelines removed from limitations.
- December 19, 2013: New AMA CPT code L5969 added effective January 1, 2014
- September 17, 2014: Adopted by Tufts Health Plan – Network Health Commercial Plans and Tufts Health Plan – Network Health Medicaid Plans.

- December 10, 2014: Reviewed at IMPAC, approved for effective date April 1, 2015. Added to coverage guideline verification of K-level by AMPPRO and/or AMPnoPRO score from Amputee Mobility Predictor tool.
- July 31, 2015. Link to Amputee Mobility Predictor tool removed.
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- December 9, 2015: Reviewed by IMPAC. For effective date of July 1, 2016, intolerance to socket fitting and/or wear due to residual limb issues will be added to limitations section.
- April 13, 2016: Reviewed by IMPAC. Clarification to language for test socket intolerance limitation.
- December 14, 2016: Reviewed by IMPAC. For effective date April 1, 2017, lower limb adjustable sockets added to limitations
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017.
- November 8, 2017: Reviewed by IMPAC. For effective date April 1, 2018, Genium X2 and X3 microprocessor-controlled knee prosthetic devices will be added to limitations section.
- December 19, 2017: Minor MNG title change.
- October 10, 2018: Reviewed by IMPAC, renewed without changes
- October, 2018: Template and disclaimer updated
- March 20, 2019: Reviewed at IMPAC. For effective date July 1, 2019, criteria added for MPK as initial prosthesis. Additional MPK criteria added. Clarification of replacement criteria applicable to Tufts Health Commercial, Tufts Freedom Plan, Tufts Health Direct, and Tufts Health RITogether products only. Additions to general and MPK limitations sections.
- May 30, 2019: Clarification of replacement criteria. No additional criteria required of replacement due to change in the physiological condition or functional level.
- June 19, 2019: Reviewed at IMPAC. For effective date October 1, 2019, powered knee flexion/extension (L5859) and power assist ankle, foot/ankle system (L5969) prosthetic components are not covered as they are considered investigational.
- October 16, 2019: Reviewed by IMPAC, renewed without changes.
- January 15, 2020: Reviewed at IMPAC. For effective date July 1, 2020, limitations added. Upgrade or enhancement of member's current prosthesis, an additional or duplicate prosthesis and repair/replacement of a spare, backup or duplicate prosthesis will not be covered.
- April 2, 2020: Fax number for Unify updated
- October 21, 2020: Reviewed by IMPAC, renewed without changes
- December 16, 2020: Reviewed at IMPAC. For effective date January 25, 2021, added coverage guidelines for microprocessor-controlled foot/ankle (L5973). Coverage criteria allows choice of functional mobility prediction tools to verify functional K level.

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.

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.