Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

AposTherapy System

Effective: April 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	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

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

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055

☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404

☐ Tufts Health One Care Plan – A dual-eligible product; 857-304-6304

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

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

AposTherapy System is a foot- worn biomechanical device clinically proven to reduce chronic knee and low back pain. The device is designed to redistribute the load away from painful areas in the knee and back, thus decreasing pain. AposTherapy use has shown a decreased use in opioids and delayed a Member's need for surgery.

The AposTherapy device consists of a shoe-like platform and 2 convex perturbation units, called Pertupods. The Pertupods are mounted on the special shoe-like platform and located below the main weight-bearing areas of the hindfoot and forefoot regions on each foot. Pertupods and spacers made the device completely customizable to meet the Members individual needs.

The device is personally calibrated for each patient by an AposTherapy Trained Clinician (ATC), which are specially trained clinicians or physical therapists. The ATC utilizes clinical findings, computerized gait laboratory and questionnaire results, the gait pattern, and the AposTherapy methodology to calibrate the location, weight, and convexity of each Pertupod. The AposTherapy is a 4-step treatment plan including initial assessment, personalizing the device, at home treatment, and monitoring. During the at home treatment portion, members will wear the device during daily activity for up to 60 minutes a day. The goal of AposTherapy is to retrain the body to walk in a pain free pattern even when not wearing the device.

Clinical Guideline Coverage Criteria

The Plan may consider AposTherapy medically necessary for adults when all of the following criteria are met:

Knee:

1. The Member has a diagnosis of knee osteoarthritis that is confirmed by appropriate imaging and has lasted for at least 3 months; **and**
2. Member meets referral criteria for knee surgery (including total knee replacement) but prefers a less invasive treatment option; **and**
3. Member has persistent chronic knee pain that is impacting their quality of life, including limitations in activities of daily living and increased safety risks; **and**
4. Member has persistent pain that is not controlled despite conservative pain management, including but not limited to:
    a. Therapeutic Exercise Program, including strengthening, flexibility, and balance training
    b. Physical Therapy/ Manual Therapy
    c. Pharmaceutical treatment options (ie NSAIDs, topical steroids, intra- articular (knee) injections as appropriate)
    d. Weight loss efforts as appropriate

Low back:

1. The Member has a diagnosis of chronic low back pain that has persisted for more than 6 months; **and**
2. Member meets referral criteria for back surgery but prefers a less invasive treatment option; **and**
3. Chronic low back pain is impacting the member quality of life, including limitations in activities of daily living; **and**
4. Member has persistent pain that is not controlled despite conservative pain management, including but not limited to:
    a. Therapeutic Exercise Program, including strengthening, flexibility, and balance training
    b. Physical Therapy/ Manual Therapy
    e. Pharmaceutical treatment options (ie NSAIDs, opioids, topical steroids, Intra- articular injections as appropriate)
    c. Weight loss efforts as appropriate

Limitations

1. The Plan does not consider AposTherapy Systems medically necessary for the treatment of any other diagnosis.
2. AposTherapy should not be used if the Member has:
    a. Severe balance or vertigo issues
    b. Has a history of falls
    c. Peripheral neuropathy
    d. Severe osteoporosis
    e. Active infection of the affected joint
    f. Requires the use of an assistive walking device
    g. Any other contraindication to AposTherapy not listed above as noted by the manufacturer

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

Code	Description
97799	Unlisted Rehabilitation Service or Procedure

List of ICD-10 codes for which AposTherapy may be medically necessary.

References:

1. AposHealth for knee osteoarthritis. NICE Guidance. April 11, 2023. Accessed March 13, 2025. https://www.nice.org.uk/guidance/mtg76/resources/aposhealth-for-knee-osteoarthritis-pdf-64372240535749.

2. Bartels M, Suk M. Summary of outcomes of a non-invasive biomechanical therapy for patients with knee osteoarthritis. Journal of Orthopaedic Experience & Innovation. 2022.
3. Debbi EM, Bernfeld B, Herman A, Salai M, Laufer Y, Wolf A. A Biomechanical Foot-Worn Device Improves Total Knee Arthroplasty Outcomes. The Journal of Arthroplasty 2018 1-9.
4. DeRogatis, M., Anis, H. K., Sodhi, N., Ehiorobo, J. O., Chughtai, M., Bhave, A., & Mont, M. A. (2019). Non-operative treatment options for knee osteoarthritis. *Annals of translational medicine*, *7*(Suppl 7), S245.
5. Greene A, Miles C. Surgery avoidance rates among total knee replacement candidates following a non-invasive biomechanical intervention: A retrospective cohort study. Journal of Orthopaedic Experience & Innovation. 2022.
6. Hasanoglu, A., Hsu, A., Yerra, S., et al. (2023) Incidence of Knee Surgeries Over 5 Years Among Patients with Knee osteoarthritis Treated with a Non- Invasive, Home- Based, Biomechanical Intervention. *Journal of Musculoskeletal Research;* 27(2).
7. Lee SW, Veeramachaneni R, Abou Saleh I, Morice K, Tiu T, Lo Y, Frison K, Bartels M. Footwear-Generated Dynamic Biomechanical Manipulation and Perturbation Training for Chronic Nonspecific Low Back Pain. PMR. 2018 Aug;10(8):836-842.
8. Miles C, Greene A. The effect of treatment with a non-invasive foot worn biomechanical device on subjective and objective measures in patients with knee osteoarthritis- A retrospective analysis on a UK population. BMC Musculoskeletal Disorders. 2020;21:386.
9. Reichenbach A, Felson DT, Hincapi CA, Heldner S, Butikofer L, Lenz A, da Costa BR, Bonel HM, Jones RK, Hawker GA, Juni P. Effect of Biomechanical Footwear on Knee Pain in People With Knee Osteoarthritis. The BIOTOK Randomized Clinical Trial. JAMA 2020;323(18):1802-1812.
10. Veeramachaneni R, Gitkind A, Yerra S, et al. Clinical Outcomes of a New Foot-Worn Non-Invasive Biomechanical Intervention Compared to Traditional Physical Therapy in Patients With Chronic Low Back Pain. A Randomized Clinical Trial. Global Spine Journal. 2025. Accessed January 13, 2025.

Approval And Revision History

July 22, 2024: Reviewed by the Medical Policy Approval Committee (MPAC), effective April 1, 2025

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.