Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs
New-to-Market Drugs

Effective: May 12, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

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

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

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

Overview

In order to promote clinically appropriate and cost-effective prescription drug use, the plan has several programs in place, one of which is the New-to-Market (NTM) Drug Evaluation Process described below:

NTM Drug Evaluation Process

Following the Food and Drug Administration (FDA) approval of new drugs, the plan makes a coverage determination following a comprehensive review by committees, such as the Pharmacy and Therapeutics (P&T) Committee, Medical Policy Approval Committee (MPAC), and physician specialists. During the evaluation period, beginning when the drug first becomes available on the market, the committees review the clinical evidence related to the safety and effectiveness of these new products.

Clinical Guideline Coverage Criteria

The Plan may authorize coverage of a medication within the NTM Drug Evaluation Process when the following criteria are met:

1. The request for coverage is for an FDA-approved indication for a use that is covered in the Member's benefit document or for a recognized off-label use of an FDA-approved prescription medication used in the treatment of cancer, HIV/AIDS, or a disabling or life-threatening chronic disease.

AND

2. Coverage is determined based on the NTM drug classification as follows:
   Step 1: Is the request for a gene therapy or genetically modified cellular therapy, such as a CAR-T therapies?
   a. If **YES**, then coverage for the NTM drug is determined by using documentation of the following:
      i. The requesting physician is a specialist in the treatment of the specific condition.
      ii. The member has a condition that is aligned with the studied population including the inclusion and exclusion criteria as indicated in the National Clinical Trial(s) found on clinicaltrials.gov and which was pivotal to the approval of the therapy.
   b. If **NO** the NTM drug is not a gene-based therapy, proceed to step 2.
   Step 2: Does the plan have existing Clinical Coverage Criteria for previously reviewed prescription medications with an FDA-approved indication that is the same indication as the NTM drug?

a. If **YES**, then coverage for the NTM drug is determined by using those criteria and by using documentation from the requesting physician showing that the Member has had a treatment failure of, or is unable to tolerate, two (2) or more alternative medications covered under the Medical Benefit.
b. If **NO** Existing Clinical Coverage Criteria, then proceed to step 3.

Step 3: Does the NTM drug have available alternative medications covered under the Medical Benefit to treat the same condition?

a. If **YES**, then coverage for the NTM drug is determined by using documentation from the requesting physician showing that the Member has had a treatment failure of, or is unable to tolerate, two (2) or more alternative medications covered under the Medical Benefit.
b. If **NO**, then proceed to step 4.

Step 4: Is the NTM drug a novel agent, defined as a "first of its kind drug" in a new class of drugs?

a. If **YES,** then coverage for the NTM drug is determined by using documentation from the requesting physician showing that all other available lines of treatment that are consistent with generally accepted principles of professional medical practice and/or with guidelines from a nationally recognized entity for the disease for which the Member is being treated, have been exhausted.

Limitations

- The duration of coverage will be limited to 12 months, or up to a complete course of therapy if less than one year as noted in the medication's FDA-approved package insert, or as deemed clinically necessary by the plan, and as may be outlined in existing clinical coverage class medical necessity guidelines.
- For excluded drug classes, refer to plan benefit documents.
- Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

Codes

None

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- September 10, 2024: Changed the title of the Medical Necessity Guideline from "New to Market (NTM) Drug Evaluation Process Under the Medical Benefit" to "New-to-Market (NTM) Drugs." Removed Tufts Health Together, Tufts Health RITogether, Tufts Health One Care, Harvard Pilgrim Health Care Stride Medicare Advantage, Tufts Health Plan Senior Care Options, Tufts Medicare Preferred HMO, and Tufts Medicare Preferred PPO from the Medical Necessity Guideline. Removed the Limitations "For NH and RI Commercial members requesting use of a medication for off-label use please see the medical necessity guidelines for off-label use" and "Coverage for any new agent indicated for the treatment of Duchenne muscular dystrophy will not be authorized for Members who are not ambulatory at the time of the request." Clarified approval duration rules. Minor wording updates. Added coverage criteria for cell or gene therapy (eff 10/1/24).
- September 19, 2024: Reviewed and Approved by Medical Policy Approval Committee (eff 10/1/24).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- May 12, 2026: No changes, template updated to remove CareLink from the Medical Necessity Guideline template. Administrative update from "Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans" to "Tufts Health Together- MassHealth Accountable Care Partnership Plans."

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.