Harvard Pilgrim Health Care | TUFTS Health Plan

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

Effective: January 1, 2026

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

Public Plans Products

☒ 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

References

1. Center for Biologics Evaluation and Research. Regenerative Medicine Advanced Therapy Designation. U.S. Food and Drug Administration. July 21, 2023. Accessed July 15, 2024. https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/regenerative-medicine-advanced-therapy-designation.

Approval And Revision History

September 10, 2024: Reviewed by Pharmacy and Therapeutics Committee (P&T)

September 19, 2024: Reviewed by the Medical Policy Approval Committee (MPAC)

September 2024: Reviewed and Approved by the Joint Medical Policy and Health Care Services Utilization Management Committee review (eff 10/1/24)

Subsequent endorsement date(s) and changes made:

- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

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.