Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

HIV Pre-Exposure Prophylaxis (PrEP) Medications

Effective: March 10, 2026

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

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 MCO Plan and 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

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956

☐ 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

Food and Drug Administration (FDA) Approved Indications:

- **Yeztugo (lenacapavir sodium)** is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition. Individuals must have a negative HIV-1 test prior to initiating Yeztugo.

Clinical Guideline Coverage Criteria

Initial Coverage Criteria:

The Plan may cover Yeztugo when all the following clinical criteria is met:

1. Yeztugo is being requested for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition

AND

2. The patient has tried and failed or has a contraindication, to or clinical intolerance to, or compliance related concern with taking oral emtricitabine/tenofovir disoproxil fumarate 200-300 mg (generic Truvada)

Note: Per RI HB6725, prior authorization requirement of Yeztugo for the treatment of PrEP for Rhode Island groups is not required. Prior authorization is required for all other groups in all other states.

Reauthorization Criteria:

Reauthorization may be granted when **ALL** of the following clinical criteria are met:

1. The Member meets initial approval criteria

AND

2. The Member has maintained a positive clinical response and remains HIV-1 negative

Limitations

- Initial approval duration will be for a period of 12 months. Reauthorizations will be for a duration of an additional 12 months.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0738	injection, lenacapavir, 1 mg
J0752	oral, lenacapavir, 300 mg

References:

1. Apretude (cabotegravir) [prescribing information]. Research Triangle Park, NC: ViiV Healthcare; December 2023.
2. Yeztugo (lenacapavir sodium) [prescribing information]. Gilead Sciences, Inc. Foster City, CA; June 2025.

Approval And Revision History

May 17, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)

June 13, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees effective January 1, 2023
- Administrative update: April 2023 added Medical Benefit Drugs to title, updated MATogether and RITogether fax numbers to 617-673-0939
- May 17, 2023: Annual review, no change, effective July 1, 2023
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- June 11, 2024: No change
- September 10, 2024: Effective January 1, 2025, remove PA requirement for THP and HPHC Commercial to accommodate RI HB7625.
- November 12, 2024: Effective January 1, 2025, add back PA requirement for all Commercial groups, with the exception of RI FI, to support RI HB 7625. Added a note clarify prior authorization is not required for RI FI Commercial groups.
- May 13, 2024: Effective 5/19/25, remove PA requirement for ME Commercial groups, and clarified PA is not required for all RI Commercial groups.
- October 14, 2025: Changed name of MNG from Apretude to HIV Pre-Exposure Prophylaxis (PrEP) Medications. Added coverage criteria for Yeztugo.
- March 10, 2026: No clinical changes. Separated Commercial and Direct from RITogether MNG. Removed Apretude from MNG, as no PA is required. Administrative update to remove Carelink from the guidline template.

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.