Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
# Mytesi (crofelemer) Step Therapy

*Effective: June 9, 2026*

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|---|---|
| **Guideline Type** | ☐ Prior Authorization<br>☐ Non-Formulary<br>☒ Step-Therapy<br>☐ 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

**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 – Approved Indications**

**Mytesi (crofelemer)** is an anti-diarrheal indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy.

## Clinical Guideline Coverage Criteria

***Note***: Prescriptions that meet the initial step therapy requirements will adjudicate **automatically** at the point of service. If the patient does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan for patients who do not meet the step therapy criteria at the point of service.

**Please refer to the table below for medications subject to this policy:**

| **Drug** | |
|---|---|
| **Step-1** | |
| Anti-retroviral therapy | Covered as listed on formulary |
| **Step-2** | |
| Mytesi (crofelemer) | Requires prior use of a drug on Step-1 |

**Automated Step Therapy Coverage Criteria**

The following stepped approach applies to coverage of the Step-2 medications by the plan:

**Step 1:** Medications on Step-1 are covered as listed on the formulary without prior authorization

**Step 2:** The plan may cover Step-2 medications if the following criteria are met:

a. The patient has had a trial of one (1) Step-1 or Step-2 medication within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by the plan.

**Coverage Criteria for Patients not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale**

The plan may cover medications on Step-2 if the following criteria are met:

1. Medication requested is for the symptomatic relief of non-infectious diarrhea in an adult patient who is currently on anti-retroviral therapy

## Limitations

None

## Codes

None

## References

1. Mytesi (crofelemer) [prescribing information]. San Francisco, CA: Napo Pharmaceuticals, Inc.; November 2020.

## Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- June 13, 2023: No changes
- June 11, 2024: No changes
- June 10, 2025: No changes
- June 9, 2026: Administrative update to remove CareLink from the Medical Necessity Guideline template.

## Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be 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 the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy 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 Pharmacy 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 policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.