

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1034-14
Program	Prior Authorization/Notification
Medication	Mytesi™ (crofelemer)
P&T Approval Date	2/2013, 11/2013, 2/2015, 2/2016, 2/2017, 2/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023, 2/2024, 2/2025, 2/2026
Effective Date	5/1/2026

1. Background:

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. Ruling out infectious etiologies of diarrhea is required for the appropriate use of Mytesi.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria^a:

<p>A. <u>Initial Authorization</u></p> <p>1. Mytesi will be approved based on all of the following criteria:</p> <p style="margin-left: 40px;">a. Diagnosis of HIV/AIDS associated diarrhea</p> <p style="text-align: center;">-AND-</p> <p style="margin-left: 40px;">b. Patient is on antiretroviral therapy</p> <p>Authorization will be issued for 12 months.</p> <p>B. <u>Reauthorization</u></p> <p>1. Mytesi will be approved based on the following criterion:</p> <p style="margin-left: 40px;">a. Documentation of positive clinical response to Mytesi therapy</p> <p>Authorization will be issued for 12 months.</p> <p>^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</p>

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

4. Reference:

1. Mytesi [package insert]. San Francisco, CA: Napo Pharmaceuticals, Inc; November 2020.

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Change Control	
2/2013	New criteria.
11/2013	Formatting update. Removal of dose information in Background Section. Updated reference.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
2/2015	Minor formatting.
2/2016	Annual review. Updated criteria to reflect indications and usage section of product label.
2/2017	Annual review. Program updated to reflect change in brand name from Fulyzaq to Mytesi. No change in clinical coverage. Updated reference.
2/2018	Annual review. No change in clinical coverage.
2/2019	Annual review. No change in clinical coverage. Updated reference.
2/2020	Annual review. No change in clinical coverage.
2/2021	Annual review. No change in clinical coverage. Updated reference.
2/2022	Annual review with no changes to coverage criteria. Updated background.
2/2023	Annual review with no changes to coverage criteria. Added state mandate footnote.
2/2024	Annual review with no changes to coverage criteria.
2/2025	Annual review. Updated initial authorization duration to 12 months.
2/2026	Annual review with no changes.