UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1034-13
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
Effective Date	5/1/2025

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 Myesi.[1]

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Mytesi** will be approved based on **all** of the following criteria:

   a. Diagnosis of HIV/AIDS associated diarrhea

   -AND-

   b. Patient is on antiretroviral therapy

Authorization will be issued for 12 months.

B. Reauthorization

1. **Mytesi** will be approved based on the following criterion:

   a. Documentation of positive clinical response to Mytesi therapy

Authorization will be issued for 12 months.

[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.

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.