

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 1034-10
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
Effective Date	5/1/2022; Oxford only: 5/1/2022

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. 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 6 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.

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.