

Clinical Pharmacy Program Guidelines for Mytesi

Program	Prior Authorization
Medication	Mytesi™ (crofelemer)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

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.¹

Members will be required to meet the coverage criteria below.

2. Coverage Criteria:

<p>A. <u>Authorization</u></p> <p>1. Mytesi will be approved based on the following criteria:</p> <p style="margin-left: 40px;">a. Diagnosis of HIV/AIDS associated diarrhea</p> <p>Authorization will be issued for 12 months.</p>
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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. References:

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

Program	Prior Authorization –Mytesi (crofelemer)
Change Control	
Date	Change
3/2013	New Guideline
6/2015	Annual review, no changes to clinical criteria
10/2016	Updated clinical criteria to align with Employer and Individual’s notification policy and updated policy template
2/2017	Program updated to reflect change in brand name from Fulyzaq to Mytesi. No change in clinical coverage. Updated reference.
3/2017	Changed initial authorization duration to 12 months.
9/2017	Removed requirement that patient be on antiretroviral therapy. Removed reauthorization criteria to allow for Dx to Rx implementation.
2/2018	Annual review. No change to criteria.
2/2019	Annual review. Updated reference.
2/2020	Annual review. No changes to criteria.
2/2021	Annual review. No change in clinical coverage. Updated reference.