

Mytesi (crofelemer)
Effective 02/20/2019

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Exceptions	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029

Overview

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

Coverage Guidelines

Authorization may be granted when the following criteria are met:

1. Patient is ≥ 18 years of age **AND**
2. Patient has a diagnosis of human immunodeficiency virus (HIV) or acquired immunodeficiency disease (AIDS) and is actively receiving anti-retroviral therapy which has resulted in a non-infectious form of diarrhea **AND**
3. Patient has experienced an inadequate response or intolerance to treatment with both loperamide and diphenoxylate w/atropine.

Continuation of Therapy

1. Patient continues to actively receive anti-retroviral therapy **AND**
2. Symptom improvement per physician assessment

Limitations

1. Approvals will be granted for 12 months.

References

1. Mytesi (crofelemer) [prescribing information]. San Francisco, CA: Napo Pharmaceuticals Inc; June 2016
2. Feasey NA, Healey P, Gordon MA. Review article: the aetiology, investigation and management of diarrhea in the HIV-positive patient. *Aliment Pharmacol Ther.* 2011;34(6):587-603.
3. MacArthur RD, Hawkins TN, Brown SJ, LaMarca A, Clay PG, Barrett AC, et al. Efficacy and safety of crofelemer for noninfectious diarrhea in HIV-seropositive individuals (ADVENT Trial): A randomized, double-blind, placebo-controlled, two-stage study. *HIV Clin Trials* 2013; 14(6):261-273.

4. US Food and Drug Administration. FDA News Release. FDA approves first anti-diarrheal drug for HIV/AIDS patients. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm333701.htm>
5. Crofelemer: a review of its use in the management of non-infectious diarrhoea in adult patients with HIV/AIDS on antiretroviral therapy. Frampton JE. *Drugs*. 2013 Jul;73(10):1121-9. doi: 10.1007/s40265-013-0083-6. Review.

Review History

00/00/14 – Implemented

02/23/15 - Reviewed

02/22/16 - Reviewed

02/27/17 - Reviewed

02/26/18 – Updated (renamed Mytesi)

02/20/19 – Updated

09/21/22 – Reviewed at Sept P&T; Separated Comm/Exch vs MH policy; no clinical updates.

