

**Mytesi (crofelemer)  
Effective 02/01/2019**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

### 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  $\geq 18$  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

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