

ALASKA MEDICAID
Prior Authorization Criteria

**Mytesi®
(crofelemer)**

FDA INDICATIONS AND USAGE¹

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

APPROVAL CRITERIA^{1,2}

1. Patient is 18 years of age or older **AND;**
2. Patient has a diagnosis of HIV/AIDS confirmed by history of antiretroviral claims within the last 90 days **AND;**
3. Patient is experiencing diarrhea (i.e., one or more watery stools daily for 5 out of 7 days per week) **AND;**
4. Secondary causes of diarrhea (i.e., irritable bowel syndrome, gluten and lactose intolerance, traveler's diarrhea, functional diarrhea, and antiretroviral therapy associated diarrhea) have been ruled out by complete and appropriate physical and historical examination **AND;**
5. Patient has tried and failed or has a contraindication to both loperamide and atropine-diphenoxylate.

DENIAL CRITERIA¹

1. Failure to meet approval criteria.

CAUTIONS¹

- Consider infectious etiologies of diarrhea before starting treatment to reduce the risk of inappropriate therapy and worsening disease.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Re-authorization: up to 12 months

QUANTITY LIMITS

- 60 – 125mg tablets per 30 days

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REFERENCES / FOOTNOTES:

1. Mytesi (crofelemer) [prescribing information]. San Francisco, CA: Napo Pharmaceuticals, Inc.; November 2020.
2. MacArthur RD, DuPont HL. Etiology and pharmacologic management of noninfectious diarrhea in HIV-infected individuals in the highly active antiretroviral therapy era. *Clin Infect Dis*. 2012b;55(6):860-7.
3. Framptom JE. Crofelemer: a review of its use in the management of non-infectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy. *Drugs*. 2013 Jul;73(10):1121-9.