



## Pharmacy Drug Policy & Procedure

<b>Policy Name:</b>	<b>Mytesi (crofelemer)</b>	<b>Policy#:</b>	<b>2042P</b>
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### Purpose of the Policy

The purpose of this policy is to define coverage criteria for Mytesi (crofelemer).

### Statement of the Policy

Health Alliance Medical Plans will approve the use of Mytesi (crofelemer) if the following criteria are met.

### Criteria

#### 1. Coverage Criteria

- 1.1 Member is greater than 17 years of age
- 1.2 Member currently on antiretroviral therapy for the treatment of HIV/AIDS
- 1.3 Diagnosis of noninfectious diarrhea for at least one month
- 1.4 Symptoms persist despite use with an anti-motility drug (e.g., loperamide or diphenoxylate/atropine [Lomotil])

#### 2. Duration of Treatment

- 2.1 Initial approval: 12 months
- 2.2 Extension of treatment: 12 months with documentation of improvement of symptoms

### CPT Codes

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### HCPCS Codes

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### References

1. Mytesi (crofelemer) [prescribing information]. San Francisco, CA: Napo Pharmaceuticals Inc; November 2020.
2. Macarthur RD, Hawkins TN, Brown SJ, 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.
3. Clay PG, Crutchley RD. Noninfectious diarrhea in HIV seropositive individuals: a review of prevalence rates, etiology, and management in the era of combination antiretroviral therapy. Infect Dis Ther. 2014;3(2):103-122
4. Nwachukwu CE, Okebe JU. Antimotility agents for chronic diarrhoea in people with HIV/AIDS. Cochrane Database Syst Rev 2008; :CD005644.

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#### DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.