

Pharmacy Medical Necessity Guidelines: Mytesi™ (crofelemer)

Effective: November 10, 2020

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| Prior Authorization Required | √ | Type of Review – Care Management | |
| Not Covered | | Type of Review – Clinical Review | √ |
| Pharmacy (RX) or Medical (MED) Benefit | Rx | Department to Review | RXUM |
| <p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan | | <p>Fax Numbers: RXUM: 617.673.0988</p> | |

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Mytesi (crofelemer) is indicated for symptomatic relief of non-infectious diarrhea in adult patients with human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) on anti-retroviral therapy.

Mytesi (crofelemer) is an anti-diarrheal and is the first drug indicated for the treatment of diarrhea in patients with HIV/AIDS. It is also the second approved botanical product. Mytesi (crofelemer) is extracted from the sap of the *Croton lechleri* plant.

Several studies have found that patients with HIV experience diarrhea at a higher rate than other populations. The management of idiopathic, noninfectious diarrhea, associated with HIV or protease inhibitor use has generally been nonspecific. Commonly used therapies include anti-motility agents (e.g., loperamide, diphenoxylate/atropine, opioids), adsorbents (e.g., bismuth subsalicylate), bulk-forming fiber supplements, calcium supplements, and at times, pancrelipase or octreotide. Data supporting the use of such agents are very limited, and randomized, controlled trials are lacking. Open-label trials of bulk-forming fiber supplements, loperamide, and calcium supplements have reported treatment response rates between 32 and 100%, though the definition of a treatment response was often subjective.

COVERAGE GUIDELINES

The plan may authorize coverage of Mytesi (crofelemer) for Members, when the **all** the following criteria are met:

1. Documented diagnosis of noninfectious diarrhea associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS)
- AND**
2. The Member has failed treatment with or is unable to tolerate at least two other commonly used generic therapies for non-infectious diarrhea, including but not limited to:
 - a) Anti-motility agents (e.g. loperamide, diphenoxylate/atropine)
 - b) Adsorbents (e.g. bismuth subsalicylate)
 - c) Bulk-forming fiber supplements
 - d) Calcium supplements

LIMITATIONS

Note: Mytesi™ has been previously marketed under name Fulyzaq. Product strength and formulation remains the same.

CODES

None

REFERENCES

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2. Cello JP, Day LW. Idiopathic AIDS enteropathy and treatment of gastrointestinal opportunistic pathogens. *Gastroenterology*. 2009;136(6):1952-65.
3. Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents. 2016 July 16. URL: aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf Available from Internet. Accessed 2016 July 21.
4. Frampton JE. Crofelemer: a review of its use in the management of non-infectious diarrhoea in adult patients with HIV/AIDS on antiretroviral therapy. *Drugs*. 2013 Jul;73(10):1121-9.
5. 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.
6. MacArthur R, Hawkins T, Brown S, 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 Nov-Dec;14(6):261-73.
7. Mytesi (crofelemer) [prescribing information]. San Francisco, CA: Napo Pharmaceuticals, Inc.; March 2018.
8. Sherman DS, Fish DN. Management of protease inhibitor-associated diarrhea. *Clin Infect Dis*. 2000;30(6):908-14.

APPROVAL HISTORY

August 6, 2013: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 12, 2014: No changes.
- August 11, 2015: No changes.
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- August 9, 2016: No changes. Effective August 15, 2016 Medical Necessity Guideline applies to Tufts Health Together.
- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
- September 12, 2017: Brand Fulyzaq has been discontinued and replaced with Mytesi™. Revision to name of the MNG, overview section and guidelines reflect this change.
- October 16, 2018: Effective 4/1/19, update criteria to require the member has had a trial and failure with, or inability to tolerate at least two other commonly used generic alternatives.
- November 12, 2019: No changes.
- November 10, 2020: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

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