Pharmacy Medical Necessity Guidelines: Mytesi™ (crofelemer)

Effective: April 1, 2019

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These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**
- Tufts Health Plan Commercial products – large group plans
- Tufts Health Plan Commercial products – small group and individual plans
- Tufts Health Freedom Plan products – large group plans
  - CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization
- Tufts Health Public Plans Products
  - Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
  - Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
- Tufts Health RITogether – A Rhode Island Medicaid Plan

**Fax Numbers:**
- RXUM: 617.673.0988

**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, pancreatic 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)

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

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.
- 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.

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.

Provider Services

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