Pharmacy Medical Necessity Guidelines: Mytesi™ (crofelemer)

Effective: September 12, 2017

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>√</th>
<th>Type of Review – Care Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Covered</td>
<td></td>
<td>Type of Review – Clinical Review</td>
</tr>
<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>RX</td>
<td>Department to Review</td>
</tr>
</tbody>
</table>

This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

**Fax Numbers:**
- RXUM: 617.673.0988

**Note:** For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

**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 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 other commonly used therapies 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.

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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.