Pharmacy Medical Necessity Guidelines: Egrifta® (tesamorelin) injection

Effective: February 13, 2018

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

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 (FDA)-APPROVED INDICATIONS**

Egrifta (tesamorelin) is a growth hormone releasing factor analog indicated for the reduction of excess abdominal fat in human immunodeficiency virus (HIV)-infected individuals with lipodystrophy.

Limitations of use:

- Since the long-term cardiovascular safety and potential long-term cardiovascular benefit of Egrifta (tesamorelin) treatment have not been studied and are not known, careful consideration should be given whether to continue Egrifta (tesamorelin) treatment in patients who do not show a clear efficacy response as judged by the degree of reduction in visceral adipose tissue measured by waist circumference or CT scan.
- Egrifta (tesamorelin) is not indicated for weight loss management (weight neutral effect).
- There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta.

Egrifta (tesamorelin) is a subcutaneous injection intended for once-daily administration.

**COVERAGE GUIDELINES**

The plan may authorize coverage of Egrifta (tesamorelin) for Members, when the following criterion is met:

1. Documented diagnosis of lipodystrophy associated with human immunodeficiency virus (HIV)

**LIMITATIONS**

None

**CODES**

None

**REFERENCES**


**APPROVAL HISTORY**
May 10, 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- April 10, 2012: No changes
- March 12, 2013: No changes
- March 11, 2014: No changes
- March 10, 2015: No changes
- January 1, 2016: Administrative change to rebranded template
- March 8, 2016: No changes
- March 14, 2017: No changes
- February 13, 2018: 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. 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.

Provider Services