

## Pharmacy Medical Necessity Guidelines: Egrifta® (tesamorelin)

Effective: January 14, 2020

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><b>Commercial Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans</li> <li><input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans</li> <li><input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans</li> <li><input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans</li> <li>• CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</li> </ul> <p><b>Tufts Health Public Plans Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)</li> <li><input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans</li> <li><input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan</li> </ul>		<p><b>Fax Numbers:</b></p> <p>RXUM: 617.673.0988</p>	

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

### 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.

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.

### 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

1. Egrifta (tesamorelin) [package insert]. Rockland, MA: EMD Serono Inc.; July 2018.
2. Falutz J, Allas S, Blot K, et al. Metabolic effects of a growth hormone-releasing factor in patients with HIV. *N Engl J Med.* 2007; 357(23):2359-70.
3. Falutz J, Allas S, Kotler D, et al. A placebo-controlled, dose-ranging study of a growth hormone releasing factor in HIV-infected patients with abdominal fat accumulation. *AIDS.* 2005; 19(12):1279-87.
4. Falutz J, Allas S, Mamputu JC, et al. Long-term safety and effects of tesamorelin, a growth hormone-releasing factor analogue, in HIV patients with abdominal fat accumulation. *AIDS.* 2008; 22(14):1719-28.
5. Falutz J, Potvin D, Mamputu JC, et al. Effects of tesamorelin, a growth hormone-releasing factor, in HIV-infected patients with abdominal fat accumulation: a randomized placebo-controlled trial with a safety extension. *J Acquir Immune Defic Syndr.* 2010; 53(3):311-22.
6. Mahy M, Stover J, Stannecki K, et al. Estimating the impact of antiretroviral therapy: regional and global estimates of life-years gained among adults. *Sex Transm Infect.* 2010; 86 Suppl 2:ii67-71.
7. Moyle G, Moutschen M, Martinez E, et al. Epidemiology, assessment, and management of excess abdominal fat in persons with HIV infection. *AIDS Rev.* 2010; 12(1):3-14.

8. Stanley TL, Feldpausch MN, Oh J, et al. Effect of tesamorelin on visceral fat and liver fat in HIV-infected patients with abdominal fat accumulation: a randomized clinical trial. *JAMA*. 2014 Jul 23-30; 312(4):380-9.
9. Thompson MA, Aberg JA, Cahn P, et al. Antiretroviral treatment of adult HIV infection: 2010 recommendations of the International AIDS Society – USA Panel. *JAMA*. 2010;304(3):321-33.
10. Villarroya F, Domingo P, Giralt M. Drug-induced lipotoxicity: lipodystrophy associated with HIV-1 infection and antiretroviral treatment. *Biochim Biophys Acta*. 2010;1801(3):392-9.

#### **APPROVAL HISTORY**

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

Subsequent endorsement date(s) and changes made:

1. April 10, 2012: No changes.
2. March 12, 2013: No changes.
3. March 11, 2014: No changes.
4. March 10, 2015: No changes.
5. January 1, 2016: Administrative change to rebranded template
6. March 8, 2016: No changes.
7. March 14, 2017: No changes.
8. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
9. February 13, 2018: No changes.
10. February 12, 2019: Administrative update changing title of Medical Necessity Guideline to “Egrifta (tesamorelin)” from “Egrifta (tesamorelin) injection.”
11. January 14, 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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