

# Egrifta (tesamorelin)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 Year

Medications	Quantity Limit
Egrifta (tesamorelin)	May be subject to quantity limit

## **APPROVAL CRITERIA**

Initial therapy with Egrifta (tesamorelin) injections may be approved for **reconstructive purposes** when the following criteria are met:

- I. Individual is an adult age 18 or older (Falutz 2010); **AND**
- II. Documentation is provided that individual has lipodystrophy associated with HIV (human immunodeficiency virus) (Falutz 2010); **AND**
- III. Individual is using to reduce excess abdominal visceral adipose tissue (VAT) (Falutz 2010); **AND**
- IV. Documentation is provided that individual has a body mass index (BMI) greater than 20 kg/m<sup>2</sup> (Falutz 2010); **AND**
- V. Individual has a waist circumference and a waist-to-hip ratio of one of the following (Falutz 2010):
  - A. Documentation is provided that for males, waist circumference  $\geq$  95 cm and waist-to-hip ratio  $\geq$  0.94;
  - OR**
  - B. Documentation is provided that for females, waist circumference  $\geq$  94 cm and waist-to-hip ratio  $\geq$  0.88;

### **AND**

- VI. Fasting Blood Glucose (FBG) is less than 150 mg/dL (8.33 mmol/L) (Falutz 2010); **AND**
- VII. Individual does not have a history of type 1 diabetes or insulin-treated type 2 diabetes (Falutz 2010); **AND**
- VIII. Individual has no active malignancy (for example, a potential cancer which is being evaluated or a diagnosed cancer which is being treated) (Falutz 2010); **AND**
- IX. Individual is not currently pregnant or breast-feeding.

Continuation therapy with Egrifta (tesamorelin) injections may be approved for **reconstructive purposes** when the following criterion is met:

- I. Documentation is provided that individual has exhibited a clear response in reduction of visceral adipose tissue measured by waist circumference or computed tomography (CT) scan.

Egrifta (tesamorelin) may not be approved when the above criteria are not met and for all other indications.

## **Key References:**

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 10, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. US Department of Health and Human Services (HHS). Guide for HIV/AIDS Clinical Care. Health Resources and Services Administration, HIV/AIDS Bureau. April 2014. Available from <https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/2014guide.pdf>. Accessed April 10, 2023.
5. Falutz J, Mamputu JC, Potvin D, et al. Effects of tesamorelin (TH9507), a growth hormone-releasing factor analog, in human immunodeficiency virus-infected patients with excess abdominal fat: a pooled analysis of two multicenter, double-blind placebo-controlled phase 3 trials with safety extension data. *J Clin Endocrinol Metab.* 2010; 95(9):4291-4304.
6. 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):311-322.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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