# Egrifta (tesamorelin)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization<br>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 $kg/m^2$ (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 ≥ 95 cm and waist-to-hip ratio ≥ 0.94;
    **OR**
    B. Documentation is provided that for females, waist circumference ≥ 94 cm and waist-to-hip ratio ≥ 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 for the following:

I. Individual has disruption of the hypothalamic-pituitary axis; **OR**

II. Individual has active malignancy; **OR**
III. 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: June 2, 2025
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 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 June 2, 2025.
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.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.