

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Egrifra (tesamorelin)

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

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

APPROVAL CRITERIA

Initial therapy with Egrifra (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. Individual has lipodystrophy associated with HIV (human immunodeficiency virus); **AND**
- III. Individual is using to reduce excess abdominal visceral adipose tissue (VAT); **AND**
- IV. Individual has a body mass index (BMI) greater than 20 kg/m² (Falutz 2010); **AND**
- V. Individual has a waist circumference and a waist-to-hip ratio of one of the following (Falutz 2010):
 - A. For males, waist circumference ≥ 95 cm and waist-to-hip ratio ≥ 0.94;
 - OR**
 - B. 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); **AND**
- IX. Individual is not currently pregnant or breast-feeding.

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

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 26, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. 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 October 26, 2018.
6. 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.
7. 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.

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