

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

*FHK- Florida Healthy Kids

Egrifta (tesamorelin)

Override(s)	Approval Duration
Prior Authorization	Initial: 6 Months
Quantity Limit	Continuation: 1 Year

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

APPROVAL CRITERIA

Requests for Egrifta (tesamorelin) may be approved if the following criteria are met:

- I. An initial 6-month course of Egrifta (tesamorelin) injections may be approved when used for reduction of excess abdominal visceral adipose tissue (VAT) in HIV-infected individuals with lipodystrophy when all of the following criteria are met:
 - A. Individual is an adult age 18 or older; **AND**
 - B. Individual's Body Mass Index (BMI) is greater than 20 kg/m²; **AND**
 - C. Individual's waist circumference and a waist-to-hip ratio are both at least 2.5 standard deviations above normal based on age and gender; **AND**
 - D. Individual's Fasting Blood Glucose (FBG) is less than 150 mg/dL (8.33 mmol/L); **AND**
 - E. Individual does not have a history of type 1 diabetes or insulin-treated type 2 diabetes; **AND**
 - F. Individual does not have an active malignancy (e.g. a potential cancer which is being evaluated or a diagnosed cancer which is being treated); **AND**
 - G. Individual is not currently pregnant or breast-feeding.

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.

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

*FHK- Florida Healthy Kids

- II. Continuation of Egrifta (tesamorelin) injections may be approved for individuals when there is a clear response in reduction of visceral adipose tissue measured by waist circumference or computed tomography (CT) scan.

Egrifta (tesamorelin) injection **may not be approved** when:

- A. Being used for HIV-associated abdominal lipodystrophy which does not meet the criteria above; **OR**
- B. Individual has lipodystrophy of anatomic sites aside from the abdomen; **OR**
- A. Lipodystrophy is not associated with HIV infection; **OR**
- B. Individual meets reconstructive criteria above for an initial course, but do not show a clear response as judged by the degree of reduction in visceral adipose tissue measured by waist circumference or CT scan; **OR**
- C. Being used for weight loss management; **OR**
- D. Individual has a history of disruption of the hypothalamic-pituitary (HPA) axis due to hypophysectomy, hypopituitarism, pituitary tumor, pituitary surgery, head irradiation, or head trauma; **OR**
- E. All other conditions not addressed above.

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

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed January 30, 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

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.