



MEDICATION POLICY

Generic Name: Tesamorelin

Therapeutic Class or Brand Name: Egrifta®

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 2/1/13

Date Last Reviewed/Revised: 10/6/16

GPI Code: 3015008510

Prior Authorization Criteria (may be considered medically necessary when criteria I through V are met):

- I. The patient is infected with human immunodeficiency virus (HIV).
- II. There is excess accumulation of abdominal fat due to HIV-associated lipodystrophy and criteria A or B is met:
 - A. The patient is male and criteria 1 and 2 are met:
 1. Waist circumference is greater than 37.4 inches (95 cm).
 2. Waist-to-hip ratio is greater than 0.94.
 - B. The patient is female and criteria 1 and 2 are met:
 1. Waist circumference is greater than 37 inches (94 cm).
 2. Waist-to-hip ratio is greater than 0.88.
- III. Documentation in chart notes that the excess accumulation of abdominal fat has impaired function, such as significantly limiting instrumental activities of daily living (for example, meal preparation, household chores). Intermittent occupational tasks that are not required as a daily part of job functioning are not considered instrumental activities of daily living.
- IV. Lateral (side view) photographs including the abdomen are required with the submitted clinical description.
- V. Minimum age requirement: 18 years old.

Exclusion Criteria:

- The patient has a disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation or head trauma.
- The patient has an active malignancy.
- The patient is pregnant.

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.



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Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Quantities of up to 60 of the 1mg vials OR 30 of the 2mg vials per 30 days.

Approval Length:

- **Authorization:** 6 months.
- **Re-Authorization:** 1 year. An updated letter or progress notes indicating a decrease in waist circumference and that the patient's functional impairment resolved or improved.

Appendix:

N/A

References:

1. <http://blue.regence.com/trgmedpol/drugs/dru233.pdf>.
2. [Medi-Span.](#)
3. [http://www.egrifta.com/Pdfs/EGRIFTA_PI_1mg%20\(version%20F\)_06-2015.pdf](http://www.egrifta.com/Pdfs/EGRIFTA_PI_1mg%20(version%20F)_06-2015.pdf).

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Historical Tracking Of Changes Made To Policy	
10/6/2016	<ol style="list-style-type: none"> Updated “http://www.egrifta.com/Pdfs/EGRIFTA_PI_8.5x11.pdf” to “http://www.egrifta.com/Pdfs/EGRIFTA_PI_1mg%20(version%20F)_06-2015.pdf” under References.
4/14/2015	<ol style="list-style-type: none"> Changed “Quantities of up to 30 vials (one vial contains 2 mg of tesamorelin) per 30 days” to “Quantities of up to 60 of the 1mg vials OR 30 of the 2mg vials per 30 days” under Quantity/Days Supply Restrictions. Updated “http://www.egrifta.com/Pdfs/egrifta2mgpi.pdf” to “http://www.egrifta.com/Pdfs/EGRIFTA_PI_8.5x11.pdf” under References.
12/2/2013	<ol style="list-style-type: none"> Adapted policy to new format. Added GPI Code. Changed wording from “There is excess accumulation of abdominal fat due to HIV-associated lipodystrophy with the following gender-specific measures: For males: Waist circumference greater than 37.4 inches (95 cm) AND Waist-to-hip ratio greater than 0.94; For females: Waist circumference greater than 37 inches (94 cm) AND Waist-to-hip ratio greater than 0.88” to “There is excess accumulation of abdominal fat due to HIV-associated lipodystrophy and criteria A or B is met: A. The patient is male and criteria 1 and 2 are met: 1. Waist circumference is greater than 37.4 inches (95 cm), 2. Waist-to-hip ratio is greater than 0.94; B. The patient is female and criteria 1 and 2 are met: 1. Waist circumference is greater than 37 inches (94 cm), 2. Waist-to-hip ratio is greater than 0.88” under Prior Authorization Criteria. Added “Minimum age requirement: 18 years old” to Prior Authorization Criteria. Added “The patient has a disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation or head trauma; The patient has an active malignancy; The patient is pregnant” to Exclusion Criteria. Changed Quantity/Days Supply Restrictions from “Authorized in quantities of up to 60, 1-mg vials per month” to “Quantities of up to 30 vials (one vial contains 2 mg of tesamorelin) per 30 days”. Updated references to include Medi-Span and Egrifta package insert.

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