



TESAMORELIN (Egrifita[®])

UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS: Growth Hormone Releasing Factor

BRAND (generic) NAMES: Egrifita (Tesamorelin)

One vial contains 1mg of tesamorelin; two vials are used for each 2 mg dose.

FDA-APPROVED INDICATIONS:

Reduction of excess abdominal fat in HIV-infected patients with lipodystrophy

COVERAGE AUTHORIZATION CRITERIA

Tesamorelin (Egrifita) is covered for the following conditions:

1. The patient has a diagnosis of HIV infection **AND**
2. The patient has abdominal lipodystrophy, defined as
 - a. a waist circumference of ≥ 95 cm [37.4 inches] and a waist-to-hip ratio of ≥ 0.94 for men **OR**
 - b. a waist circumference of ≥ 94 cm [37.0 inches] and ≥ 0.88 for women respectively **AND**
3. The patient has a CD4 cell count >100 cells/mm³ and a viral load $<10,000$ copies/mL **AND**
4. The patient is between 18 and 65 years of age **AND**
5. The patient is currently on anti-retroviral therapy (ART) **AND**
6. The patient has a BMI > 20 kg/m² **AND**
7. The patient does not have a disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, or pituitary tumor/surgery, head irradiation or head trauma **AND**
8. The patient does not have an active malignancy **AND**
9. The patient is not currently pregnant, planning to become pregnant or breastfeeding **AND**
10. The patient does not have a diagnosis of diabetes mellitus or a fasting blood glucose of >150 mg/dL **AND**
11. The patient is not currently being treated with growth hormone(GH), GH secretagogues, GH-releasing hormone/GH-releasing factor products, insulin-like growth factor (IGF)-1, or IGF-binding protein-3 **AND**
12. The prescribed dosage is 2 mg injected subcutaneously once daily

Warnings and Precautions

- Neoplasms: Preexisting malignancy should be inactive and its treatment complete prior to starting therapy.
- Elevated IGF-1: Monitor regularly in all patients. Consider discontinuation in patients with persistent elevations.
- Fluid retention: Symptoms may include edema, arthralgia, and carpal tunnel syndrome.
- Glucose intolerance: May develop with use. Evaluate glucose status prior to and during therapy.
- Hypersensitivity reactions (e.g., rash, urticaria): Advise patients to seek immediate medical attention if suspected.
- Injection site reactions: Advise patients to rotate sites.
- Acute critical illness: Consider discontinuation.

CONTRAINDICATIONS:

Tesamorelin is contraindicated in

- active malignancy,
- known hypersensitivity,
- pregnancy, and
- disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism or pituitary tumor/surgery, head irradiation or head trauma

DOSAGE AND ADMINISTRATION:

2 mg injected subcutaneously once daily

The recommended injection site is the abdomen. Injection sites should be rotated to different areas of the abdomen. Do not inject into scar tissue, bruises or the navel.

REFERENCES:

Tesamorelin (Egrifta) product information. Distributed by: EMD Serono, Inc., Rockland, MA 02370. 2010 http://www.egrifita.com/Pdfs/Prescribing_Information.pdf