Generic Name: tesamorelin

Applicable Drugs: Egrifta SV®

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 12/13/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

I. Clinical and laboratory documentation of ALL the following (A through D):

A. Age: ≥ 18 years old.

B. Diagnosis of human immunodeficiency virus-associated lipodystrophy and criteria i or ii is met:

i. Male: Waist circumference ≥ 37.4 inches (95 cm) **AND** waist-to-hip ratio ≥ 0.94.

ii. Female: Waist circumference ≥ 37 inches (94 cm) **AND** waist-to-hip ratio is ≥ 0.88.

C. Excess accumulation of abdominal fat has impaired function, significantly limiting instrumental activities of daily living (IADL) (e.g., meal preparation, household chores). Intermittent occupational tasks that are not required as a daily part of job functioning are not considered IADL.

D. Patient has been stable on an antiretroviral regimen for at least 8 weeks.

E. Lateral (side view) photographs including the abdomen are required with the submitted clinical description.

II. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

III. Drug is prescribed by or in consultation with an endocrinologist or a physician specializing in the treatment of HIV infection (e.g. infectious disease specialist).

IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation or head trauma.
- Active malignancy.
- Pregnancy/lactation.
- Renal impairment.

- Hepatic impairment.
- Acute critical illness.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Thirty 2 mg 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 is resolved or improved. Letter or notes must be accompanied by at least one IGF-1 level within the past 6 months and documentation that IGF-1 levels are not elevated (e.g., >3 standard deviation score).

APPENDIX

N/A

REFERENCES

1. Egrifta SV. Prescribing information. Theratechnologies, Inc; 2024. Accessed December 13, 2024. https://www.egriftasv.com/documents/Prescribing-Information.pdf
2. 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):311-22. doi: 10.1097/QAI.0b013e3181cbdaff