

**Generic Name:** Tesamorelin

**Applicable Drugs:** Egriftra SV™

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 2/1/2013

**Date Last Reviewed / Revised:** 9/19/2023

## 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:  $\geq 18$  years old.
  - B. Diagnosis of human immunodeficiency virus-associated lipodystrophy and criteria i or ii is met:
    - i. Male: Waist circumference  $\geq 37.4$  inches (95 cm) **AND** waist-to-hip ratio  $\geq 0.94$ .
    - ii. Female: Waist circumference  $\geq 37$  inches (94 cm) **AND** waist-to-hip ratio is  $\geq 0.88$ .
  - 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. Lateral (side view) photographs including the abdomen are required with the submitted clinical description.
- II. Medication is prescribed in accordance with FDA labeling.
- III. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure 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. 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.0b013e3181cbda1f
2. Egrifita SV. Prescribing information. Theratechnologies, Inc; 2019. Accessed September 19, 2023. [https://www.egrifitasv.com/pdf/Prescribing\\_Info\\_en.pdf](https://www.egrifitasv.com/pdf/Prescribing_Info_en.pdf)

**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 judgement in providing the most appropriate care for their patients.