Tesamorelin (Egrifta SV®)

Place of Service

Self-Administration (May be requested from the pharmacy benefit)

HCPCS: J3490

NDC 62064-241-30

Condition(s) listed in policy (see criteria for details)

HIV-associated lipodystrophy

AHFS therapeutic class: Growth Hormone Releasing Factor

Mechanism of action: Tesamorelin increases the release of both GH and IGF-1, thus producing both lipolytic and anabolic pharmacologic effects

(1) Special Instructions and Pertinent Information

If member has a Prescription Benefit, please refer cases to Pharmacy Services for prior authorization.

If covered under the Medical Benefit, please submit clinical information for prior authorization review via fax. Please include medical rationale why medication cannot be home self-administered.

(2) Prior Authorization/Medical Review is required for the following condition(s) All requests for Egrita SV[®] (tesamorelin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

HIV-associated lipodystrophy

- 1. Patient is ≥18 years of age, AND
- 2. Prescribed by or in consultation with an HIV specialist (e.g., endocrinologist, infectious disease specialist), **AND**
- 3. Drug will not be used in combination with any form of growth hormone (somatropin) or IGF-1 (mecasermin), AND
- 4. One of the following:
 - a. Through 10/29/2022: CT scan results demonstrate excess visceral fat accumulation, or
 - b. Meets the following waist circumference <u>and</u> waist-to-hip ratio, based on patient's gender:

	Waist Circumference	Waist to Hip
Men	≥ 37.4 inches (95 cm)	<u>></u> 0.94
Women	≥ 37 inches (94 cm)	<u>></u> 0.88

Covered Doses

Up to 1.4 mg SC every day

Commercial

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Effective: 08/31/2022

Coverage Period

Initial authorization: 3 months <u>Reauthorization</u>: 6 months if patient has achieved and maintained improvement in waist circumference, and patient has been compliant with medication

ICD-10:

B20 plus E88.1

(3) The following condition(s) <u>DO NOT</u> require Prior Authorization/Preservice All requests for Egrita[®] (tesamorelin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

5) Additional Information

How supplied:

2 mg single-dose vial (lyophilized powder with a diluent of 10 mL vial of Sterile Water for Injection)

(6) References

- AHFS[®]. Available by subscription at <u>http://www.lexi.com</u>
- DrugDex[®]. Available by subscription at <u>http://www.micromedexsolutions.com</u>
- Egrifta SV® (tesamorelin) [Prescribing Information]. Montreal, Quebec, Canada: Theratechnologies Inc.; 10/2019.

(7) Policy Update

Date of last review: 3Q2022 Date of next review: 3Q2023 Changes from previous policy version:

• Section (2): HIV-associated lipodystrophy –

 Effective 10/30/2022, will remove qualifying criteria of CT scan that shows visceral fat accumulation

Rationale: Provider can provide waist circumference measurement

 Removed management of malignancy status, intact hypothalamic-pituitary-adrenal axis, and lifestyle modifications
Rationale: Low potential for misuse BSC Drug Coverage Criteria to Determine Medical Necessity Reviewed by P&T Committee

Commercial

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