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5.30.005

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	September 8, 2011
Subject:	Egrifta SV	**Page:**	1 of 4

Last Review Date: March 7, 2025

Egrifta SV

Description

Egrifta SV (tesamorelin)

Background
Egrifta SV is approved by the FDA for HIV-associated lipodystrophy which is defined as a condition in which excess fat develops in different areas of the body, especially around the liver, stomach and other abdominal organs commonly observed in HIV-infected patients. Egrifta SV is a growth hormone releasing factor (GRF) analog that acts on pituitary cells in the brain to stimulate the production and release of endogenous growth hormone (1).

Egrifta SV stimulates growth hormone production and increases serum IGF-1. Given that IGF-1 is a growth factor and the effect of prolonged elevations in IGF-1 levels on the development or progression of malignancies is unknown, any pre-existing malignancy should be inactive, and treatment should be completed prior to initiating therapy with Egrifta SV. IGF-1 levels should be monitored closely during Egrifta SV therapy. Careful consideration should be given to discontinuing Egrifta SV in patients with persistent elevations of IGF-1 levels, particularly if the efficacy response is not robust (1).

Regulatory Status
FDA-approved indication:
Egrifta SV is a growth hormone releasing factor (GRF) analog indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy (1).

Limitations of Use: (1)

- Long-term cardiovascular benefit and safety of Egrifta SV have not been established
- Not indicated for weight loss management (weight neutral effect)
- There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta SV

Egrifta SV is contraindicated in women who are pregnant, in patients with disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor or surgery, head irradiation or head trauma, in patients with known hypersensitivity to Egrifta SV and or mannitol, and in patients with active malignancies. Egrifta SV therapy should be discontinued if pregnancy occurs; therefore, a positive pregnancy test prohibits therapy (1).

Preexisting malignancy should be inactive, and its treatment complete prior to starting Egrifta SV therapy (1).

Egrifta SV treatment may result in glucose intolerance. An increased risk of developing diabetes with Egrifta SV relative to placebo was observed. Therefore, glucose status should be carefully evaluated prior to initiating Egrifta SV treatment. Patients must have their glucose status checked routinely (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Egrifta SV may be considered **medically necessary** if the conditions indicated below are met.

Egrifta SV may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years old or older

Diagnosis

Patient must have the following:

HIV-associated lipodystrophy with excess abdominal (visceral) fat

AND ALL of the following:

1. Concomitant antiretroviral therapy
2. No evidence of active malignancy
3. Women of child-bearing age must have a negative pregnancy test

Prior – Approval *Renewal* Requirements

Age 18 years old or older

Diagnosis

Patient must have the following:

HIV-associated lipodystrophy

AND ALL of the following:

1. Concomitant antiretroviral therapy
2. No evidence of active malignancy
3. Physician confirmation of glucose monitoring
4. Visceral adipose tissue (VAT) decrease as shown by a decrease in waist circumference or CT scan
5. Women of child-bearing age must have a negative pregnancy test

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 3 months

Prior – Approval *Renewal* Limits

Duration 6 months

Rationale

Summary

Egrifta SV is approved for HIV-associated lipodystrophy in patients 18 years of age and older. It is contraindicated in women who are pregnant and preexisting malignancies. Treatment may result in glucose intolerance (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Egrifta SV while maintaining optimal therapeutic outcomes.

References

1. Egrifta SV [package insert]. Montreal, Canada: Theratechnologies Inc.; February 2022.

Policy History

Date	Action
December 2012	Annual editorial review and update
June 2014	Annual editorial review and update.
September 2015	Annual editorial review and reference update
September 2016	Annual editorial review and reference update
	Policy number change from 5.08.05 to 5.30.05
December 2017	Annual editorial review
	Addition of age requirement in renewal section
November 2018	Annual review and reference update
December 2019	Annual review and reference update
December 2020	Annual review and reference update
March 2021	Annual editorial review. Renamed policy Egrifta SV
March 2022	Annual review
March 2023	Annual review. Changed policy number to 5.30.005
June 2023	Annual review
March 2024	Annual review
June 2024	Annual review
March 2025	Annual editorial review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.