Pharmacy Policy Bulletin: J-0490 Egrifta(tesamorelin) – Commercial and Healthcare Reform	
Number: J-0490	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0490-012	**Original Date:** 12/01/2010
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Egrifta SV (tesamorelin for injection) • Egrifta WR (tesamorelin for injection)
FDA-Approved Indication(s):	• Reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy

Background:	• Egrifta (tesamorelin for injection) is a self-administered, subcutaneous growth hormone-releasing factor (GHRF) analog. GHRF is a hypothalamic peptide that acts on the pituitary somatotroph cells to stimulate the synthesis and pulsatile release of endogenous growth hormone, which is both anabolic and lipolytic and allows for the reduction of excess abdominal fat in human immunodeficiency virus (HIV) associated lipodystrophy. • The efficacy and safety of Egrifta was studied in patients 18 to 65 years of age stable on an antiretroviral regimen for at least 8 weeks with defined parameters of ≥ 95 cm waist circumference and ≥ 0.94 waist to hip ratio for men and ≥ 94 cm and ≥ 0.88 for women, respectively, and fasting blood glucose (FBG) < 150 mg/dL. • Waist circumference (WC) and waist-to-hip ratio (WHR) are all independent predictors of cardio-metabolic risk and important in HIV/acquired immunodeficiency syndrome (AIDS) patients on antiretroviral therapy at risk of increased visceral adiposity. • HIV-associated lipodystrophy is defined as a redistribution of adipose tissue and can present as fat accumulation (lipohypertrophy) or fat loss (lipoatrophy). The exact cause of HIV-associated lipodystrophy is unknown, but it is thought to be a result of the underlying mechanism associated with the HIV infection and the metabolic changes associated with antiretroviral drugs. Thymidine analog nucleoside reverse transcriptase inhibitors (NRTI), such as zidovudine and stavudine are often associated with lipoatrophy, while lipohypertrophy is often associated with protease inhibitors (PI). Of note, discontinuing NRTIs may prevent progression of the disease but studies have not shown discontinuation of

	PIs to reverse fat accumulation. Lipodystrophy can lead to the development of insulin resistance, hyperlipidemia, and endothelial dysfunction. • HIV-associated lipodystrophy is diagnosed based on physical appearance and it is recommended to monitor waist measurements, serial weight, and body mass index (BMI) measurements, a routine fasting lipid panel, and routine testing for glucose metabolism. • Treatment is dependent on patient presentation and may include lifestyle interventions, alternative antiretroviral therapy, thiazolidinediones, metformin, and surgical interventions. Egrifta SV and Egrifta WR are the only FDA-approved treatment options available. • Prescribing Considerations: ○ Long-term cardiovascular safety of Egrifta SV and Egrifta WR has not been established. Consider risk/benefit of continuation of treatment in patients who have not had a reduction in visceral adipose tissue. ○ Egrifta SV and Egrifta WR are not indicated for weight loss management as it has a weight neutral effect. ○ There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta SV or Egrifta WR. ○ Safety and effectiveness have not been established in children. There is no information on the use of Egrifta SV or Egrifta WR in patients greater than 65 years of age. ○ Glucose intolerance or diabetes mellitus may develop with Egrifta SV or Egrifta WR use. Evaluate glucose prior to and during therapy. ○ If patients treated with Egrifta SV or Egrifta WR develop glucose intolerance or diabetes, consider discontinuing in patients who do not show a clear efficacy response. ○ Egrifta SV and Egrifta WR are contraindicated in patients with disruption of hypothalamic-pituitary axis, active malignancy, and pregnancy. ○ Egrifta SV and Egrifta WR are not substitutable with each other. ○ These two formulations and strengths have differences in the dosage, the number of vials required to prepare a dose, reconstitution instructions, and storage requirements.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Egrifta SV or Egrifta WR may be approved when all of the following criteria are met **(A. through D.)**:

A. The member is between the ages of 18 and 65 years.

B. The member has a diagnosis of human immunodeficiency virus (HIV) infection (ICD-10: B20) and meets all of the following criteria **(1. and 2.)**:
- **1.** The member has been receiving antiretroviral therapy for a minimum of 8 weeks.
- **2.** The member continues to receive antiretroviral therapy.

C. The member has abdominal lipodystrophy (ICD-10: E88.1) supported by one (1) of the following criteria **(1. or 2.)**:
- **1.** If the member is a male, all of the following criteria are met **(a. and b.)**:
  - **a.** The member has a waist circumference ≥ 95 cm.
  - **b.** The member has a waist to hip ratio ≥ 0.94.
- **2.** If the member is a female, all of the following criteria are met **(a. and b.)**:
  - **a.** The member has a waist circumference ≥ 94 cm.
  - **b.** The member has a waist to hip ratio ≥ 0.88.

D. The member's fasting blood glucose is < 150 mg/dL.

II. Reauthorization

When a benefit, reauthorization of Egrifta SV or Egrifta WR may be approved when all of the following criteria are met **(A. and B.)**:

A. The member continues to receive antiretroviral therapy for HIV infection.

B. The member has experienced a reduction in visceral adipose tissue (for example, reduction in minimum waist circumference, waist to hip ratio, or reduction in BMI from baseline).

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.

Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Egrifta SV [package insert]. Quebec, Canada: Theratechnologies Inc.; February 2024.
2. Egrifta WR [package insert]. Quebec, Canada: Theratechnologies Inc.; March 2025.
3. Dimala CA, Ngu RC, Kadia BM, Tianyi FL, Choukem SP. Markers of adiposity in HIV/AIDS patients: Agreement between waist circumference, waist-to-hip ratio, waist-to-height ratio and body mass index. *PLoS One*. 2018;13(3):e0194653.
4. Guzman N, Vijayan V. HIV-associated Lipodystrophy. National Library of Medicine. 2022.