Clinical Policy: Tesamorelin (Egrifta SV, Egrifta WR)

Reference Number: PA.CP.PHAR.109
Effective Date: 01/2018
Last Review Date: 07/2025

Description
Tesamorelin (Egrifta SV®, Egrifta WR™) is a growth hormone releasing factor analog.

FDA Approved Indication(s)
Egrifta SV Egrifta WR are indicated for the reduction of excess abdominal fat in human immunodeficiency virus (HIV)-infected adult patients with lipodystrophy.

Limitation(s) of use:
- Long-term cardiovascular safety of Egrifta SV and Egrifta WR treatment have 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 and Egrifta WR.

Policy/Criteria
It is the policy of PA Health & Wellness that Egrifta SVand Egrifta WR are **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Human immunodeficiency virus (HIV) with Lipodystrophy (must meet all):
1. Diagnosis of HIV infection with lipodystropy;
2. Age ≥ 18 years;
3. Meets clinical indicators for abdominal lipodystrophy (a or b):
   a. If female, waist circumference ≥ 94 cm and waist-hip ratio ≥0.88;
   b. If male, waist circumference ≥ 95 cm and waist-hip ratio ≥ 0.94;
4. Member is currently receiving and adherent to antiretroviral therapy;
5. Dose does not exceed one of the following (a or b):
   a. Egrfita SV: 1.4 mg (1 vial) per day;
   b. Egrifta WR: 1.28 mg per day (1 vial per week).

Approval Duration: 6 months

B. Other diagnoses/indications : Refer to PA.CP.PMN.53

II. Continued Approval

A. HIV with Lipodystrophy (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA. PHARM.01) applies;
2. Member is responding positively to therapy;

3. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. Egrfita SV: 1.4 mg (1 vial) per day;
   b. Egrifta WR: 1.28 mg per day (1 vial per week).

Approval Duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA. PHARM.01) applies; or
2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HIV: human immunodeficiency virus

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s):
  - Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation or head trauma
  - Active malignancy. Any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with Egrifta SV
  - Pregnancy.
  - Known hypersensitivity to tesamorelin or excipients in Egrifta SV
- Boxed warning(s): none reported

Appendix D: General Information
- On June 15, 2020, Theratechnologies discontinued Egrifta and permanently replaced it with Egrifta SV, a smaller volume injection able to be stored at room temperature.

IV. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Tesamorelin (Egrifta SV)	1.4 mg (0.35 mL) SC QD After reconstitution and administration, any unused solution should be thrown away	1.4 mg/day
Tesamorelin (Egrifta WR)	1.28 mg (0.16 mL) SC QD One reconstituted Egrifta WR vial provides daily doses for 7 consecutive days. Discard unused solution of Egrifta WR 7 days after mixing.	1.28 mg/day

V. Product Availability

Drug Name	Availability
Tesamorelin (Egrifta SV)	Single-dose vial with powder for reconstitution: 2 mg
Tesamorelin (Egrifta WR)	Multiple-dose vial with powder for reconstitution: 11.6 mg

VI. References

1. Egrifta SV Prescribing Information. Montreal, Quebec, Canada: Theratechnologies Inc.; February 2024. Available at http://www.egriftasv.com. Accessed May 1, 2025.
2. Egrifta WR Prescribing Information. Montral, Quebec, Canada: Theratechnologies Inc.; March 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/022505s020lbl.pdf. Accessed May 1, 2025.
3. Falutz J, Mamputu JC, Potvin D, et al. Effects of tesamorelin (TH9507), a growth hormone-releasing factor analog, in human immunodeficiency virus-infected patients with excess abdominal fat: a pooled analysis of two multicenter, double-blind placebo-controlled phase 3 trials with safety extension data. *J Clin Endocrinol Metab*. 2010 Sep;95(9):4291-304. doi: 10.1210/jc.2010-0490.
4. Falutz J, Allas S, Blot K, et al. Metabolic effects of a growth hormone-releasing factor in patients with HIV. *N Engl J Med*. 2007 Dec 6;357(23):2359-70. doi: 10.1056/NEJMoa072375.

HCPCS Codes	Description
J3590	Unclassified biologics

Reviews, Revisions, and Approvals	Date
Removed adherence to current antiretroviral therapy on re-auth; pregnancy contraindication added per safety guidance endorsed by Centene Medical Affairs; references reviewed and updated.	05/2018
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/2019
3Q 2020 annual review: replaced old formulation Egrifta with new formulation Egrifta SV and updated dose; removed pregnancy contraindication from criteria as separate edits are in place to address these risks; references reviewed and updated.	07/2020
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021
3Q 2022 annual review: no significant changes; added quantity restriction (1 vial per day) to dosing requirement; updated HCPCS codes; references reviewed and updated.	07/2022
3Q 2023 annual review: no significant changes; references reviewed and updated.	07/2023
3Q 2024 annual review: revised clinical indicators for abdominal lipodystrophy criteria to require waist circumference and waist-hip ratio thresholds that reflect efficacy studies; per PI, revised FDA Approved Indications and contraindications, removed criteria allowing pediatric use in members with closed epiphyses; updated HCPCS codes; references reviewed and updated.	07/2024
3Q 2025 annual review: RT4: added newly approved Egrifta WR formulation	07/2025