# Clinical Policy: Tesamorelin (Egrifta SV)

Reference Number: ERX.SPA.68
Effective Date: 03.01.15
Last Review Date: 08.22
Line of Business: Commercial, Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
Tesamorelin (Egrifta SV™) is a growth hormone releasing factor analog.

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

Limitation(s) of use:
- Since the long-term cardiovascular safety and potential long-term cardiovascular benefit of Egrifta SV treatment have not been studied and are not known, careful consideration should be given whether to continue Egrifta SV treatment in patients who do not show a clear efficacy response as judged by the degree of reduction in visceral adipose tissue measured by waist circumference or CT scan.
- Egrifta SV is 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.

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Egrifta SV is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. HIV Infection with Lipodystrophy** (must meet all)**:**
1. Diagnosis of HIV infection with lipodystrophy;
2. Age ≥ 18 years or documentation of closed epiphyses;
3. Member meets clinical indicators for abdominal lipodystrophy (a or b):
   a. If female, waist circumference ≥ 88 cm;
   b. If male, waist circumference ≥ 102 cm;
4. Member is currently receiving and adherent to antiretroviral therapy;
5. Dose does not exceed 1.4 mg (1 vial) per day.

**Approval duration: 6 months**

**B. Other diagnoses/indications**
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. HIV Infection with Lipodystrophy** (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;

3. If request is for a dose increase, new dose does not exceed 1.4 mg (1 vial) per day.
**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
**Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

## IV. 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 (either newly diagnosed or recurrent): any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with Egrifta SV
  - Pregnancy: During pregnancy, visceral adipose tissue increases due to normal metabolic and hormonal changes. Modifying this physiologic change of pregnancy with Egrifta SV offers no known benefit and could result in fetal harm. If pregnancy occurs, discontinue Egrifta SV therapy
  - Known hypersensitivity to tesamorelin and/or mannitol
- 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.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| HIV infection with lipodystrophy | 1.4 mg (0.35 mL) SC QD<br><br>After reconstitution and administration, any unused solution should be thrown away | 1.4 mg/day |

## VI. Product Availability

Single-use vial with powder for reconstitution: 2 mg

## VII. References

1. Egrifta SV Prescribing Information. Montreal, Quebec, Canada: Theratechnologies Inc.; October 2019. Available at http://www.egriftasv.com. Accessed March 29, 2022.
2. Lean ME, Han TS, Morrison CE. Waist circumference as a measure for indicating need for weight management. BMJ 1995; 311:158.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 3Q 2018 annual review: no significant changes; removed adherence to current antiretroviral therapy on re-auth; references reviewed and updated. | 05.14.18 | 08.18 |
| 3Q 2019 annual review: no significant changes; removed pregnancy contraindication from criteria as separate edits are in place to address these risks; references reviewed and updated. | 04.22.19 | 08.19 |
| 3Q 2020 annual review: no significant changes; replaced old formulation Egrifta with new formulation Egrifta SV; references reviewed and updated. | 04.20.20 | 08.20 |
| 3Q 2021 annual review: no significant changes; references reviewed and updated. | 03.18.21 | 08.21 |
| 3Q 2022 annual review: no significant changes; added quantity restriction (1 vial per day) to dosing requirement; references reviewed and updated. | 03.29.22 | 08.22 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.