Clinical Policy: Tesamorelin (Egrifta SV, Egrifta WR)

Reference Number: CP.PHAR.109
Effective Date: 03.01.14
Last Review Date: 08.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

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

Description

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

FDA Approved Indication(s)

Egrifta SV and 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 they have 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.

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.

It is the policy of health plans affiliated with Centene Corporation® that Egrifta SV and Egrifta WR are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Human Immunodeficiency Virus Infection with Lipodystrophy (must meet all)**:**

1. Diagnosis of HIV infection with lipodystropy;
2. Age ≥ 18 years;
3. Member 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:
Medicaid/HIM – 6 months
Commercial – 6 months or to member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Human Immunodeficiency Virus Infection with Lipodystrophy (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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:
Medicaid/HIM – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, 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. Any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with Egrifta SV or Egrifta WR
  - Pregnancy
  - Known hypersensitivity to tesamorelin or excipients in Egrifta SV or Egrifta WR
- 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

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	1.28 mg/day

Drug Name	Dosing Regimen	Maximum Dose
	One reconstituted Egrifta WR vial provides daily doses for 7 consecutive days. Discard unused solution of Egrifta WR 7 days after mixing.	

VI. 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

VII. 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.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2021 annual review: no significant changes; added HCPCS code; references to HIM.PHAR.21 revised to HIM.PA.154; 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; updated HCPCS codes; references reviewed and updated.	03.29.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.30.22	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2023 annual review: no significant changes; updated HCPCS codes; references reviewed and updated.	04.14.23	08.23
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.	05.09.24	08.24
RT4: added newly approved Egrifta WR formulation	04.10.25	
3Q 2025 annual review: no significant changes; references reviewed and updated.	04.25.25	08.25

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.