

Clinical Policy: Tesamorelin (Egrifta SV)

Reference Number: CP.PHAR.109

Effective Date: 03.01.14

Last Review Date: 08.20

Line of Business: Commercial, HIM, 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.

It is the policy of health plans affiliated with Centene Corporation[®] that Egrifta SV is **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 lipodystrophy;
2. Age \geq 18 years or documentation of closed epiphyses;
3. Member meets clinical indicators for abdominal lipodystrophy (a or b):
 - a. If female, waist circumference \geq 88 cm;
 - b. If male, waist circumference \geq 102 cm;
4. Member is currently receiving and adherent to antiretroviral therapy;
5. Dose does not exceed 1.4 mg per day.

Approval duration:

Medicaid/HIM – 6 months

Commercial – 6 months or to member's renewal date, whichever is longer

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit 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 per day.

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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 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.PHAR.21 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 (either newly diagnosed or recurrent): any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with Egrifta/Egrifta SV

- Pregnancy: During pregnancy, visceral adipose tissue increases due to normal metabolic and hormonal changes. Modifying this physiologic change of pregnancy with Egrifta/Egrifta SV offers no known benefit and could result in fetal harm. If pregnancy occurs, discontinue Egrifta/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	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 April 20, 2020.
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
Converted policy to new template. Criteria: removed upper age limit as not an absolute contraindication; added max dosage; indicators changed from hip-to-waist to waist circumference. Appendices: added abbreviation key; removed appendices A and B (clinical indicators for abdominal lipodystrophy and contraindications) and incorporated into criteria.	02.16	03.16
Open epiphyses added in addition to age requirement as contraindication. Removed certain safety criteria, but retained contraindications per PI. Continued therapy duration extended to 12 months. Added formulations.	02.17	03.17
- Removed member is not presently receiving therapy with growth hormone, insulin-like growth factors or any of their analogs; It was part of the exclusion criteria in the pivotal study but is not list as a contraindications and does not meet our current safety policy. - Removed Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head	07.01.17	11.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
irradiation, or head trauma and Active malignancy (either newly diagnosed or recurrent) and/or receiving treatment for a malignancy per updated safety policy.		
3Q 2018 annual review: policies combined for Centene Medicaid, HIM (new) and Commercial lines of business; no significant changes from previously approved corporate policy; Medicaid: removed adherence to current antiretroviral therapy on re-auth; Commercial: age ≥ 18 or documentation of closed epiphyses added per PI, minimum waist circumference modified from 95/94 cm to 102/88 cm in men/women and requirement for waist-to-hip ratio removed per Lean et al and specialist feedback, pregnancy contraindication added per safety guidance endorsed by Centene Medical Affairs; 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

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.

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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.

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