

Clinical Policy: Tesamorelin (Egrifta)

Reference Number: CP.PHAR.109

Effective Date: 03.01.14

Last Review Date: 08.19

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[®]) is a growth hormone releasing factor analog.

FDA Approved Indication(s)

Egrifta 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 treatment have not been studied and are not known, careful consideration should be given whether to continue Egrifta 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 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.

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 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 2 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 2 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

- Pregnancy: During pregnancy, visceral adipose tissue increases due to normal metabolic and hormonal changes. Modifying this physiologic change of pregnancy with Egrifta offers no known benefit and could result in fetal harm. If pregnancy occurs, discontinue Egrifta therapy
- Known hypersensitivity to tesamorelin and/or mannitol
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HIV infection with lipodystrophy	2 mg SC QD	2 mg/day

VI. Product Availability

Vial: 1 mg (1 mg/mL when reconstituted)

VII. References

1. Egrifta Prescribing Information. Montreal, Quebec, Canada: Theratechnologies Inc.; July 2018. Available at <http://www.egrifta.com>. Accessed April 22, 2019.
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
Added information for nursing mothers Appendix A re-titled from "Definition of Lipodystrophy" to "Clinical Indicators of Lipodystrophy." Updated algorithm to specify HIV-associated lipodystrophy Updated algorithm to verify absence of all contraindications Added Appendix B: Contraindications for Use of Egrifta	02.15	03.15
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.	07.01.17	11.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
- Removed Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head 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 \geq 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

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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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