

**Clinical Policy: Tesamorelin (Egrifta)**

Reference Number: CP.PHAR.109

Effective Date: 03.01.14

Last Review Date: 11.17

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Tesamorelin (Egrifta<sup>®</sup>) is a growth hormone releasing factor analog.

**FDA approved indication**

Egrifta is indicated for the reduction of excess abdominal fat in human immunodeficiency virus (HIV)-infected patients with lipodystrophy.

Limitations of use:

- Long-term cardiovascular benefit and safety of Egrifta have not been studied.
- 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 (which may include office chart notes and lab results) supporting that member has met all approval criteria*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Egrifta is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria****A. Human Immunodeficiency Virus with Lipodystrophy (must meet all):**

1. Diagnosis of HIV infection with lipodystrophy;
2. Age  $\geq$  18 years or documentation of closed epiphyses;
3. 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. At the time of request, member has none of the following contraindications:
  - a. Pregnancy;
6. Dose does not exceed 2 mg once daily.

**Approval duration: 6 months**

**B. Other diagnoses/indications**

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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**II. Continued Therapy**

**A. Human Immunodeficiency Virus 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 (e.g., waist circumference or computed tomography (CT) scan shows reduction in visceral adipose tissue since therapy initiation and no unacceptable toxicity);
3. Member is currently receiving and adherent to antiretroviral therapy;
4. If request is for a dose increase, new dose does not exceed 2 mg once daily.

**Approval duration: 12 months**

**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 CP.PHAR.57 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 – CP.PHAR.57 or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

ART: antiretroviral therapy

CT: computed tomography

FDA: Food and Drug Administration

HIV: human immunodeficiency virus

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
HIV infection with lipodystrophy	2 mg injected subcutaneously once daily	2 mg/day

**VI. Product Availability**

Vial: 1 mg

**VII. References**

1. Egrifta Prescribing Information. Montreal, Quebec, Canada: Theratechnologies Inc.; June 2015. Available at <http://www.egrifta.com>. Accessed July 26, 2017.
2. Lean ME, Han TS, Morrison CE. Waist circumference as a measure for indicating need for weight management. *BMJ* 1995; 311:158.

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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. - 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.	07.01.17	11.17

**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.

## CLINICAL POLICY

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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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