Clinical Policy: Tesamorelin (Egrifta)

Reference Number: CP.PHAR.109
Effective Date: 03/14
Last Review Date: 03/17 Revision Log

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

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for tesamorelin (Egrifta®).

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

I. Initial Approval Criteria

A. Human immunodeficiency virus (HIV) with Lipodystrophy (must meet all):

1. Age ≥ 18 years or documentation of closed epiphyses;
2. Diagnosis of HIV infection with lipodystrophy;
3. Meets clinical indicators for abdominal lipodystrophy (a or b):
   a. If female, waist circumference ≥ 88 cm;
   b. If male, waist circumference ≥ 102cm;
4. Member is currently receiving and adherent to antiretroviral therapy;
5. Member is not presently receiving therapy with growth hormone, insulin-like growth factors or any of their analogs;
6. Prescribed dose of Egrifta does not exceed 2 mg once daily;
7. At the time of request, member has none of the following contraindications:
   a. Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation, or head trauma;
   b. Active malignancy (either newly diagnosed or recurrent) and/or receiving treatment for a malignancy;
   c. Pregnancy.

Approval Duration: 6 months

II. Continued Approval

A. HIV with Lipodystrophy (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Documentation of positive response 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. Member is not presently receiving therapy with growth hormone, insulin-like growth factors or any of their analogs;
5. Prescribed dose of Egrifta 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; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

Background

Description/Mechanism of Action:

Tesamorelin, as the acetate salt, is an analog of human growth hormone-releasing factor (GRF). In vitro, tesamorelin binds and stimulates human GRF receptors with similar potency as the endogenous GRF. Growth Hormone-Releasing Factor (GRF), also known as growth hormone-releasing hormone (GHRH), is a hypothalamic peptide that acts on the pituitary somatotroph cells to stimulate the synthesis and pulsatile release of endogenous growth hormone (GH), which is both anabolic and lipolytic. GH exerts its effects by interacting with specific receptors on a variety of target cells, including chondrocytes, osteoblasts, myocytes, hepatocytes, and adipocytes, resulting in a host of pharmacodynamic effects. Some, but not all these effects, are primarily mediated by IGF-1 produced in the liver and in peripheral tissues.

Formulations:

Tesamorelin for injection) is supplied in a vial containing 2 mg of tesamorelin as a lyophilized powder. The diluent (Sterile Water for Injection, 10 mL) is provided in a separate vial.

FDA Approved Indication:

Egrifta is a GRF analog/subcutaneous injection indicated for:

- Reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

Limitations 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.

Appendices

Appendix A: Abbreviation Key

GH: growth hormone
GRF: growth hormone releasing factor
GRH: gonadotropin-releasing hormone
HIV: human immunodeficiency virus
IGF: insulin like growth factor
CT: Computed tomography

Reviews, Revisions, and Approvals	Date	Approval Date
Policy Developed	02/14	03/14
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

References

1. Egrifta Prescribing Information. Montreal, Quebec, Canada: Theratechnoligies Inc.; June 2015. Available at http://www.egrifta.com. Accessed January 26, 2016.
2. Lean ME, Han TS, Morrison CE. Waist circumference as a measure for indicating need for weight management. BMJ 1995; 311:158.

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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.