Clinical Policy: Tesamorelin (Egrifta)

Reference Number: PA.CP.PHAR.109
Effective Date: 01/18
Last Review Date: 03/17 Revision Log

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

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness 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 Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.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 1 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

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.