**Egrifta**

**Description**

Egrifta (tesamorelin)

**Background**

Egrifta is approved by the FDA for HIV-associated lipodystrophy which is defined as a condition in which excess fat develops in different areas of the body, especially around the liver, stomach and other abdominal organs commonly observed in HIV-infected patients. Egrifta is a growth hormone releasing factor (GRF) analog that acts on pituitary cells in the brain to stimulate the production and release of endogenous growth hormone (1).

Egrifta stimulates growth hormone production and increases serum IGF-1. Given that IGF-1 is a growth factor and the effect of prolonged elevations in IGF-1 levels on the development or progression of malignancies is unknown, any pre-existing malignancy should be inactive and treatment should be completed prior to initiating therapy with Egrifta. IGF-1 levels should be monitored closely during Egrifta therapy. Careful consideration should be given to discontinuing Egrifta in patients with persistent elevations of IGF-1 levels, particularly if the efficacy response is not robust (1).

**Regulatory Status**

FDA-approved indication:
Egrifta is a growth hormone releasing factor (GRF) analog indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy (1).
Limitations of Use: (1)
- Long-term cardiovascular benefit and safety of Egrifta have not been studied
- 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

Egrifta is contraindicated in women who are pregnant, in patients with disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor or surgery, head irradiation or head trauma, in patients with known hypersensitivity to Egrifta and or mannitol, and in patients with active malignancies. Egrifta therapy should be discontinued if pregnancy occurs; therefore, a positive pregnancy test prohibits therapy (1).

Preexisting malignancy should be inactive and its treatment complete prior to starting Egrifta therapy (1).

Egrifta treatment may result in glucose intolerance. An increased risk of developing diabetes with Egrifta relative to placebo was observed. Therefore, glucose status should be carefully evaluated prior to initiating Egrifta treatment. Patients must have their glucose status checked routinely (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Egrifta may be considered medically necessary for patients 18 years of age and older who have HIV-associated lipodystrophy with excess abdominal fat and if the conditions indicated below are met.

Egrifta may be considered investigational in patients that are under the age of 18 and for all other indications.

Prior-Approval Requirements

Age 18 years old or older
Diagnosis

Patient must have the following:

HIV-associated lipodystrophy with excess abdominal (visceral) fat

AND ALL of the following:
1. Concomitant antiretroviral therapy
2. No evidence of active malignancy
3. Women of child bearing age must have a negative pregnancy test

Prior – Approval **Renewal Requirements**

**Age**

18 years old or older

**Diagnosis**

Patient must have the following:

HIV-associated lipodystrophy

AND ALL of the following:
1. Concomitant antiretroviral therapy
2. No evidence of active malignancy
3. Physician confirmation of glucose monitoring
4. Visceral adipose tissue (VAT) decrease as shown by a decrease in waist circumference or CT scan
5. Women of child bearing age must have a negative pregnancy test

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Duration**

3 months
**Prior – Approval Renewal Limits**

**Duration**
6 months

**Rationale**

**Summary**
Egrifta is approved for HIV-associated lipodystrophy in patients 18 years of age and older. It is contraindicated in women who are pregnant and preexisting malignancies. Treatment may result in glucose intolerance (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Egrifta while maintaining optimal therapeutic outcomes.

**References**

**Policy History**

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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.