Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Egrifta (tesamorelin)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2011 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Egrifta (tesamorelin).

Egrifta (tesamorelin) is a growth-hormone releasing factor analog indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. The prescribing information for Egrifta (tesamorelin) notes 3 limitations of use: long-term cardiovascular benefit and safety have not been studied; tesamorelin is not indicated for weight loss management (weight neutral effect); and there are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta (tesamorelin).

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications.

This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Egrifta (tesamorelin), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a physician who specializes in the treatment of HIV/AIDS
- Must be age 18 years or older
- Must have a diagnosis of lipodystrophy with excess abdominal fat
    - Male member must have a waist circumference of at least 95cm (37.4in) and a waist to hip ratio of at least 0.94
    - Female member must have a waist circumference of at least 94cm (37in) and a waist to hip ratio of at least 0.88
    - Baseline waist circumference and waist to hip ratio must be provided
- Must have an underlying diagnosis of HIV infection
- Must be stable on an antiretroviral regimen for at least 8 weeks prior to beginning tesamorelin (Egrifta)
- Must have a recent (within 6 months) baseline evaluation of the following:
    - Fasting Blood Glucose (FBG)
    - IGF-1
- Must not have disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation, or head trauma
- Must not have active malignancy or history of malignancy
- Must have a baseline negative pregnancy test prior to initiation of therapy if female member of childbearing potential
- Must have a prior adequate trial and failure of physician-directed exercise and diet modifications as directed by a dietician/nutritionist. Chart documentation of modification is required.
- Must have lypodystrophy associated with depression as evidenced by chart documentation
    - Tesamorelin (Egrifta) is not approved for lipodystrophy that is purely cosmetic in nature

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals if the following criteria are met:

- Must have chart documentation showing stabilization or improvement of depression
- Must have decreases from baseline in both waist circumference and waist to hip ratio
- Must have no active malignancy or history of malignancy
- Must have chart documentation showing that FBG and IGF-1 levels are being monitored

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Egrifta [package insert]. Rockland, MA: EMD Serono. November 2010.
2. Falutz J, Potvin D, Mamputu JC, et al. Effects of Tesamorelin, a Growth Hormone-Releasing Factor, in HIV-Infected Patients With Abdominal Fat Accumulation: A Randomized Placebo-Controlled Trial With a Safety Extension. *J Acquir Immune Defic Syndr* 2010;00:1-12.
3. Falutz J, Allas S, Blot K, et al. Metabolic Effects of a Growth Hormone-Releasing Factor in Patients with HIV. *N Eng J Med* 2007;357:2359-2370.
4. Falutz J, Allas S, Mamputu JC, et al. Long-term safety and effects of tesamorelin, a growth hormone-releasing factor analogue, in HIV patients with abdominal fat accumulation. *AIDS* 2008;22:1719-1728.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*