



Prior Authorization Approval Criteria

Egrifta (tesamorelin)

Generic name:	tesamorelin
Brand name:	Egrifta
Medication class:	Growth Hormone–Releasing Factors
FDA-approved uses:	reduction of excess abdominal fat in HIV-associated lipodystrophy
Available dosage forms:	single-use vials containing tesamorelin 1 mg as a lyophilized powder and mannitol 50 mg. It is supplied in a package consisting of 1 “medication” box containing 60 vials of tesamorelin 1 mg and 1 “injection” box containing 30 single-use 10 mL vials of diluent, thirty 3 mL disposable syringes, and needles sufficient for a 30-day supply. Two tesamorelin vials are necessary for a single dose.
Usual dose:	2 mg subcutaneously once daily
Approximate monthly cost: (based on AWP 2011)	\$2356.80/ Month
Duration of therapy:	to be determined based on response. Long term safety data beyond 1 year has not been established.

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Patient must have HIV- associated lipodystrophy with excess abdominal fat.
- Must provide baseline waist circumference.
- Must provide baseline A1c, glucose and IGF-1 levels.
- Must provide baseline lipid and TG levels
- Must not have an active malignancy

Criteria for continuation of therapy:

- Long-term cardiovascular (CV) safety and potential long-term CV benefit of tesamorelin have not been studied; therefore, careful consideration should be given to whether to continue therapy in patients who do not show a response to tesamorelin as measured by a reduction in visceral adipose tissue (VAT) by waist circumference or computed tomography (CT) scan. Studies did ct scan.
- Must show improvement in waist circumference
- Must show improvement in lipid and TG levels

Caution:

- Increase in IGF-1
- Increase in glucose levels

Monitoring:

- Patients should be monitored for therapeutic response, including monitoring of the lipid and glucose profile, and for adverse events, including hypersensitivity reactions.

Contraindication:

- Tesamorelin is contraindicated in patients with disruption of the hypothalamic-pituitary axis caused by hypophysectomy, hypopituitarism or pituitary tumor/surgery, head irradiation, or head trauma; as well as in patients with active malignancy, pregnancy, or known hypersensitivity to tesamorelin or mannitol.

Not approved if:

- Have any contraindications to the use of Egrifta.
- Does not meet the above stated criteria.

Special considerations:

- Tesamorelin is a GHRF analog that has been shown to reduce central adiposity in patients with HIV infection and to improve some lipid parameters, primarily triglycerides. It has not been proven to reduce the risk of negative outcomes associated with lipohypertrophy or to improve compliance with antiretroviral therapy by improving self-image. In addition, long-term safety beyond 1 year has not been established.
- Treatment options in patients developing lipohypertrophy have included lifestyle modification; stopping or switching HIV medications, metformin, testosterone, growth hormone, or the growth hormone–releasing hormone (GHRH) analog tesamorelin; and surgery.
- Fat volumes return to baseline when the drug is stopped
- In the short term, tesamorelin sharply increased the risk of diabetes.
- Its long term effects are not known.
- Increase in insulin like growth factor-1 (theoretical risk of malignancy)
- The drug is available only thru a restricted access program (www.egrifta.com/AxisCenter.aspx).
- Basically improve self image in patients, other benefits, if any are unknown.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 06/08/11