

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1027-6
Program	Prior Authorization/Notification
Medication	Egrifita® (tesamorelin for injection)
P&T Approval Date	5/2011, 5/2012, 5/2013, 4/2014, 4/2015, 2/2016, 2/2017, 2/2018
Effective Date	5/1/2018; Oxford only: 5/1/2018

1. Background:

Egrifita (tesamorelin) is a growth hormone releasing factor analog indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. Since the long-term cardiovascular safety and potential long-term cardiovascular benefit of Egrifita treatment have not been studied and are not known, careful consideration should be given whether to continue Egrifita 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. Egrifita is not indicated for weight loss management (weight neutral effect). There is no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking tesamorelin.¹⁻⁴

Coverage for Egrifita will be provided for patients who meet the following criteria:

2. Coverage Criteria:

A. Initial Authorization

1. Egrifita will be approved based on the following criterion:

- a. Diagnosis of HIV-associated lipodystrophy

Authorization will be issued for 6 months.

B. Reauthorization

1. Egrifita will be approved based on the following criterion:

- a. Documentation of positive clinical response (e.g., improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance) while on Egrifita therapy.

Authorization will be issued for 6 months.

3. Additional Clinical Rules:

- Supply limits may be in place.

4. References:

1. Egrifta [prescribing information]. Montreal, Quebec, Canada. Theratechnologies, Inc. June 2015.
2. Falutz J, Potvin D, Mamputu J, et al. Effects of tesamorelin, a growth hormone-releasing factor analog, in HIV-infected patients with abdominal fat accumulation: a randomized placebo-controlled trial with a safety extension. *J Acquir Immune Defic Syndr.* 2010;53:311-322.
3. Falutz J, Allas S, Blot K, Potvin D, et al. Metabolic effects of a growth hormone-releasing factor in patients with HIV. *N Engl J Med.* 2007;357:2359-2370.
4. Stanley T, Falutz J, Marsolais C, et al. Reduction in visceral adiposity is associated with an improved metabolic profile in HIV-infected patients receiving tesamorelin. *Clin Infect Dis.* 2012 Jun;54(11):1642-51.

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Change Control	
4/2014	Annual review with age assessment resulting in no change in clinical coverage. Updated references.
4/2015	Annual review with no change in clinical coverage. Updated references.
2/2016	Annual review. Modified initial coverage criteria to require only a diagnosis. Updated references.
2/2017	Annual review. No change in clinical coverage.
2/2018	Annual review. No change in clinical coverage.