UnitedHealthcare Community Plan

# Clinical Pharmacy Program Guidelines for Egrifta

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| Program | Prior Authorization/Notification |
| Medication | Egrifta (tesamorelin for injection) |
| Markets in Scope | Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New Mexico, New York, New York EPP, Ohio, Rhode Island, Washington, New Jersey, Louisiana |
| Issue Date | 6/2011 |
| Pharmacy and Therapeutics Approval Date | 2/2018 |
| Effective Date | 4/2018 |

## 1. Background:

Egrifta (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 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 is no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking tesamorelin.[1-4]

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

## 2. Coverage Criteria:

**A. Authorization**

1. **Egrifta** will be approved based on the following criterion:

   a. Diagnosis of HIV-associated lipodystrophy

   **Authorization will be issued for 12 months.**

## 3. References:


1. Egrifta [prescribing information]. Montreal, Quebec, Canada. Theratechnologies, Inc. June 2015.
2. Faultz 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** | |
| 6/2011 | New guideline |
| 6/2012 | Annual Review |
| 6/2013 | Converted policy to new UHC enterprise wide formatting.<br>Added age requirement. No other changes to clinical criteria. |
| 3/2015 | Removed extraneous endnotes and renumbered endnotes. Added endnote to document reason for keeping age criteria. No change to criteria |
| 10/2016 | Updated policy template. Updated clinical criteria to align with Employer & Individual. |
| 2/2017 | Updated policy template |
| 3/2017 | Changed initial and reauthorization duration from 6 months to 12 months |
| 9/2017 | Removed reauthorization criteria to allow for Dx to Rx implementation |
| 2/2018 | Annual review. No change to clinical criteria. |