Drug Therapy Guidelines

Egrifta® (tesamorelin)

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Applicable</th>
<th>Effective: 5/1/18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy-Formulary 1</td>
<td>x</td>
<td>Next Review: 3/19</td>
</tr>
<tr>
<td>Pharmacy-Formulary 2</td>
<td>x</td>
<td>Date of Origin: 6/11</td>
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<tr>
<td>Pharmacy-Formulary 4/AON</td>
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I. Medication Description

Egrifta is a synthetic analog of human growth hormone-releasing factor. Growth hormone-releasing factor stimulates the pituitary to synthesize and secrete growth hormone, which is anabolic and lipolytic. Growth hormone plays an important role in the formation and function of fat cells as well as the overall regulation of fat metabolism.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage for Egrifta is provided when the following criteria are met:

- Patient is infected with human immunodeficiency virus (HIV) **AND**
- Patient is between 18 and 65 years of age **AND**
- Patient has abdominal lipohypertrophy as defined by the following:
  - **Males**
    - Waist circumference of at least 95 cm (37.4 in) **AND**
    - Waist-to-hip ratio of at least 0.94
  - **Females**
    - Waist circumference of at least 94 cm (37.0 in) **AND**
    - Waist-to-hip ratio of at least 0.88

IV. Quantity Limitations

1mg vials: 60 vials per month

V. Coverage Duration

Initial coverage is granted for 6 months and may be renewed in up to 12 month intervals.
VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Absence of unacceptable toxicity from the drug **AND**
- After an initial 6 months of usage, the patient has clinical documentation of a decrease in waist circumference from baseline

VII. **Billing/Coding Information**

Egrifta is available in packages containing 60-1mg vials of drug and 1 box of diluent, syringes, and needles

VIII. **Summary of Policy Changes**

- 6/1/11: new policy
- 6/15/12: no changes
- 2/2013: 2mg vial addressed in policy
- 6/15/13: diagnosis code added, age restriction added
- 6/15/14: Removal of reference to 1mg vials (off market)
- 6/15/15: addition of 1mg vials back to policy (potentially available again)
- 7/1/15: formulary distinctions made
- 6/15/16: no policy changes; removed reference to 2mg vials (removed from market)
- 4/5/17: no policy changes
- 5/1/18: no policy changes

IX. **References**


*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.*

*The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.*

*The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*