Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Growth hormone-releasing hormone (GHRH), or somatocrinin, is primarily secreted by the arcuate nucleus of the hypothalamus and acts on the pituitary to stimulate the release of human growth hormone (hGH). hGH is then secreted and acts by binding to the hGH receptor which initiates the production of insulin-like growth-factor I (IGF-1). Growth hormone (GH), or somatotropin, was first FDA-approved in 1985 for the treatment of growth hormone deficiency. Over the past thirty-five years, indications for the use of exogenously-produced GH and GHRH have expanded to include conditions that affect not only children, but also adolescents and adults. Increlex® (mecasermin [rDNA origin]), a recombinant human insulin-like growth factor, is specifically indicated for deficiencies in IGF-1. Egrifta® and Egrifta SV® (tesamorelin), a human growth hormone-releasing factor analog, is indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy. Growth hormone therapy is consistently among the highest amounts paid per member per month out of all therapeutic classes.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

- **Preferred Agents**
  - Egrifta SV®
  - Increlex®
- **Non-Preferred Agents**
  - Egrifta®

Type of Criteria: ☒ Preferred Drug List
☐ Increased risk of ADE
☒ Appropriate Indications
☐ Clinical Edit

Data Sources: ☒ Databases + Prescriber-Supplied
☐ Only Administrative Databases

Setting & Population:

- Drug class for review: Growth Hormones & Growth Hormone Releasing Factors, Select Agents
- Age range: All appropriate MO HealthNet participants aged 2 years or older
Approval Criteria

- Documented compliance on current therapy regimen OR
- Prescribed by or in consultation with an infectious disease specialist, endocrinologist, nephrologist or other appropriate specialist for the disease state AND
- For Egrifta and Egrifta SV:
  - Participant aged 18 years or older AND
  - Documented diagnosis of HIV AND
  - Participant is currently receiving and compliant to antiretroviral therapy (90/120 days) AND
  - Documented diagnosis of excess abdominal fat lipodystrophy AND
  - Participant is currently not pregnant AND
  - Baseline IGF-1 levels OR
- For Increlex:
  - Participant aged 2 years or older AND
  - Documented diagnosis:
    - Growth failure with severe primary IGF-1 deficiency as defined by height SDS ≤ -3, basal IGF-1 SDS ≤ -3, and normal or elevated growth hormone OR
    - Growth hormone gene deletion with development of neutralizing antibodies to GH AND
  - Baseline X-rays for participants ≥ 15 years as necessary and blood glucose levels
- Initial approval is for 3 months, renewal of prior authorization may be up to 12 months with documentation of the following:
  - Documentation of current (i.e. IGF-1 levels) AND
  - Documentation of benefit of therapy as demonstrated by growth monitoring or reduction in excessive abdominal fat AND
  - For Increlex only: Documentation of current blood glucose levels and X-rays for participants ≥ 15 years as necessary

Denial Criteria

- Documentation of active malignancy in the past year
- For Increlex:
  - Presence of epiphyseal closure determined by X-ray
  - Documented diagnosis of secondary IGF-I deficiency (i.e. malnutrition, hypothyroidism, chronic treatment with pharmacological doses of anti-inflammatory steroids)
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

<table>
<thead>
<tr>
<th>Drug Description</th>
<th>Generic Equivalent</th>
<th>Max Dosing Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>EGRIFTA 1 MG VIAL</td>
<td>TESAMORELIN ACETATE</td>
<td>2 vials per day</td>
</tr>
<tr>
<td>EGRIFTA SV 2 MG VIAL</td>
<td>TESAMORELIN ACETATE</td>
<td>1 vial per day</td>
</tr>
</tbody>
</table>

Required Documentation

- Laboratory Results: [X]
- Progress Notes: [ ]
- MedWatch Form: [ ]
- Other: [ ]

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL
Default Approval Period

For initial approval: 3 months
For continued approval: 12 months

References

1. USPDI, Micromedex; 2021.
2. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.