## 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 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

<table>
<thead>
<tr>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Increlex®</td>
<td>• Egrifta SV®</td>
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</tbody>
</table>

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

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

## 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
- Prescribed by or in consultation with an infectious disease specialist, endocrinologist, nephrologist, or other appropriate specialist for the disease state AND
- For 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
  - Documented gender-specific delayed bone age as necessary and baseline 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 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 bone age scan as necessary

### Denial Criteria

- Documentation of active malignancy in the past year
- For Increlex:
  - Documented diagnosis of secondary IGF-1 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>
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</thead>
<tbody>
<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

- USPDI, Micromedex; 2023.