



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Growth Hormone Releasing Factors, Select Agents PDL Edit
<b>First Implementation Date:</b>	December 5, 2007
<b>Revised Date:</b>	October 5, 2023
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## 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.

<b>Program-Specific Information:</b>	<b>Preferred Agents</b>	<b>Non-Preferred Agents</b>
	• Increlex®	• Egrifta SV®

- Type of Criteria:**
- |   |   |
|---|---|
| <input type="checkbox"/> Increased risk of ADE              | <input checked="" type="checkbox"/> Preferred Drug List |
| <input checked="" type="checkbox"/> Appropriate Indications | <input type="checkbox"/> Clinical Edit                  |
- Data Sources:**
- |  |   |
|--|---|
| <input type="checkbox"/> Only Administrative Databases | <input checked="" type="checkbox"/> 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  $\leq$  -3, basal IGF-1 SDS  $\leq$  -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:

Drug Description	Generic Equivalent	Max Dosing Limitation
EGRIFTA SV 2 MG VIAL	TESAMORELIN ACETATE	1 vial per day

## Required Documentation

Laboratory Results:       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

- Evidence-Based Medicine and Fiscal Analysis: “Therapeutic Class Review: ENDOCRINE AND METABOLIC AGENTS: Growth Hormones & Growth Hormone Release Factors, Select Agents”, Gainwell Technologies; Last updated April 28, 2023.
- Evidence-Based Medicine Analysis: “Growth Hormones and Growth Factors”, UMKC-DIC; February 2023.
- NCBI. “Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency. <https://www.ncbi.nlm.nih.gov/pubmed/27884013>. Accessed 20 April 2020.
- Egrifta SV [package insert]. Montreal, Quebec, Canada: Theratechnologies; July 2019.
- Increlex [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals Inc; December 2019.
- USPDI, Micromedex; 2023.
- Clinical Pharmacology [online]. Tampa (FL): Elsevier. 2023.