SmartPA Criteria Proposal

Drug/Drug Class:	Growth Hormones & Growth Hormone Releasing Factors, Select Agents PDL Edit
First Implementation Date:	December 5, 2007
Proposed Date:	June 17, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐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® 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	Non-Preferred Agents
• Egrifta SV® • Increlex®	• Egrifta®

Type of Criteria:

☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☒ **Preferred Drug List**
☐ **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

- 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 ~~and blood glucose~~ 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 ~~funduscopic examination~~, 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 ~~laboratory values (i.e. blood glucose,~~ 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 funduscopic examinations~~ current blood glucose levels and X-rays for participants ≥ 15 years as necessary

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- 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)
- Claim exceeds maximum dosing limitation for the following:

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

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.
3. Evidence-Based Medicine and Fiscal Analysis: “Growth Hormones and Growth Factors - Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; June 2021.
4. Evidence-Based Medicine Analysis: “Growth Hormones and Growth Factors”, UMKC-DIC; April 2021.
5. 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.
6. Egrifta SV [package insert]. Montreal, Quebec, Canada: Theratechnologies; October 2019.
7. Increlex [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals Inc; December 2019.