

SmartPA Criteria Proposal

Drug/Drug Class:	Growth Hormones, Somatropin Agents Edit
First Implementation Date:	December 5, 2007
Proposed Date:	June 18, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input checked="" 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. Serostim[®] is used to increase lean body mass and body weight in HIV patients with wasting or cachexia, and Zorbtive[™] is indicated in adult patients diagnosed with short bowel syndrome. 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
	<ul style="list-style-type: none"> • Genotropin[®] • Genotropin MiniQuick[®] • Norditropin[®] FlexPro[®] 	<ul style="list-style-type: none"> • Humatrope[®] • Nutropin AQ[®] NuSpin[®] • Omnitrope[®] • Saizen[®] • Serostim[®] • Zomacton[®] • Zorbtive[®]

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, Somatropin Agents
- Age range: All appropriate MO HealthNet participants

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**
- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents as indicated:
 - Documented trial period for preferred agents
 - Documented ADE/ADR to preferred agents **AND**
- Participants ≥ 18 years of age:
 - Approvable diagnoses:
 - Growth hormone deficiency:
 - **Low serum insulin-like growth factor I (IGF-I) defined as below -3 SDS AND**
 - Failure of 1 GH stimulation test:
 - Insulin Tolerance Test (ITT) **OR**
 - GH Stimulation Panel (i.e. with arginine, glucagons, propranolol, or levodopa) **OR**
 - Serum IGF-I concentration (if ITT contraindicated) **OR**
 - Equivalent Diagnostic Test (subject to clinical review)
 - Cardiomyopathy: clinical consultant review required **OR**
 - Short bowel syndrome: clinical consultant review required **OR**
 - HIV with wasting or cachexia:
 - Participant is currently receiving and compliant to antiretroviral therapy (90/120 days) **AND**
 - **Documentation of unintentional weight loss of more than 5% body weight in the past 6 months AND**
 - Documentation of baseline height and weight demonstrating a BMI $< 20\text{g}/\text{m}^2$ **AND**
 - **Adequate therapeutic trial (defined as at least 1 month of therapy) of dronabinol or megestrol acetate or documented contraindication/intolerance**
- Participants < 18 years of age:
 - **Growth failure defined as one of the following:**
 - **Height SDS more than 3 SDS below the mean for chronological age and sex OR**
 - **Height SDS between -2 and -3 below the mean for chronological age and sex AND growth velocity measured over 1 year below 25th percentile for age and sex OR**
 - **Growth velocity measured over 1 year -2 SDS below the mean for age and sex AND**
 - **Documented gender-specific delayed bone age AND**
 - **Approvable diagnoses:**
 - **Growth hormone deficiency:**
 - **Low serum insulin-like growth factor I (IGF-I) defined as below -3 SDS AND**
 - **Failure of 1 GH stimulation test:**
 - **Insulin Tolerance Test (ITT) OR**
 - **GH Stimulation Panel (i.e. with arginine, glucagons, propranolol, or levodopa) OR**
 - **Serum IGF-I concentration (if ITT contraindicated) OR**
 - **Equivalent Diagnostic Test (subject to clinical review) OR**
 - **Children currently aged 2 - 4 years who were born small for gestational age: clinical consultant review OR**
 - **Chronic renal insufficiency/chronic kidney disease (CKD): lack of renal transplant in the past year OR**
 - **Prader-Willi syndrome confirmed with genetic testing OR**

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- Turner Syndrome confirmed by chromosome analysis OR
- Noonan syndrome confirmed with genetic testing OR
- Short stature homeobox-containing gene (SHOX) deficiency confirmed with genetic testing OR
- Idiopathic short stature with lack of other identifiable causes of subnormal growth (i.e. hypothyroidism, chronic illness, undernutrition or genetic disorders): clinical consultant review
 - For Serostim: clinical consultant review required for use in pediatrics
- 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, BMI) AND
 - Documentation of current fundoscopic examinations and X-rays as necessary AND
 - Documentation of benefit of therapy as demonstrated by growth monitoring, or improvement/ stabilization in BMI AND
 - Documentation of polysomnography as necessary

Denial Criteria

- Therapy will be denied if no approval criteria are met
- Documentation of active malignancy (diagnosis or inferred with chemotherapy/radiation)
- Claim exceeds maximum dosing limitation for the following:

SEROSTIM 4 MG VIAL		
SEROSTIM 5 MG VIAL		
SEROSTIM 6 MG VIAL		
ZORBTIVE 8.8 MG VIAL		

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

3 months

References

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