

Clinical Pharmacy Program Guidelines for Growth Hormone, Growth Stimulating Agents – OHIO

Program	Prior Authorization
Medication	<p><u>Human Growth Hormone:</u></p> <p>Preferred Agents:</p> <p>Somatropin (Nutropin AQ[®] NuSpin[™])</p> <p>Nonpreferred Agents:</p> <p>Somatropin (Genotropin[®], Humatrope[®], Norditropin[®], NordiFlex[®], Omnitrope[®], Saizen[®], Zomacton, Zorbitive[®], and Serostim[®])</p> <p><u>Growth Stimulating Products :</u> Mecasermin (Increlex[®])</p>
Markets In Scope	Ohio

1. Background:

Somatropin is indicated for the treatment of growth hormone deficiency, short stature associated with Turner syndrome or Noonan syndrome, short-stature homeobox (SHOX) gene deficiency, growth failure due to Prader-Willi syndrome, short stature in children born small for gestational age, growth failure in children with chronic renal insufficiency up to the time of transplant, short bowel syndrome in patients receiving specialized nutritional support, and HIV-associated wasting. Somatropin is also indicated for replacement of endogenous growth hormone in adults with confirmed growth hormone deficiency.

****Please Note:** The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy.

Mecasermin is indicated for the treatment of growth failure in children with severe primary insulin-like growth factor-1 (IGF-1) deficiency or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone.

2. Coverage Criteria:

A. **Pediatric Growth Hormone Deficiency (GHD)**

Note: Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH deficiency, utilize criteria for Transition Phase Adolescent or Adult GH Deficiency.

1. **Initial Therapy**

a. **Somatropin** will be approved based on **one** of the following criteria:

(1) **Both** of the following:

1. **One** of the following:

(a) **All** of the following:

- i. Infant is < 4 months of age
- ii. Infant has growth deficiency
- iii. Prescribed by an endocrinologist

-OR-

(b) **Both** of the following:

- i. History of neonatal hypoglycemia associated with pituitary disease
- ii. Prescribed by an endocrinologist

-OR-

(c) **Both** of the following:

- i. Diagnosis of panhypopituitarism
- ii. Prescribed by an endocrinologist

-AND-

2. If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication

-OR-

(2) **All** of the following:

(a) Diagnosis of pediatric GH deficiency as confirmed by **one** of the following:

i. Projected height (as determined by extrapolating pre-treatment growth trajectory along current channel to 18-20 year mark) is > 2.0 standard deviations [SD] below midparental height utilizing age and gender growth charts related to height:

-OR-

ii. Height is > 2.25 SD below population mean (below the 1.2 percentile for age and gender) utilizing age and gender growth charts related to height

-OR-

iii. Growth velocity is > 2 SD below mean for age and gender

-OR-

iv. Delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared with chronological age)

-AND-

(b) **One** of the following:

i. **Both** of the following:

- Patient is male
- Bone age < 16 years

-OR-

ii. **Both** of the following:

- Patient is female
- Bone age < 14 years

-AND-

(c) Submission of medical records (e.g., chart notes, laboratory

values) documenting **one** of the following:

i. **Both** of the following:

- Patient has undergone **two** of the following provocative GH stimulation tests:
 - Arginine
 - Clonidine
 - Glucagon
 - Insulin
 - Levodopa
 - Growth hormone releasing hormone

-AND-

- **Both** GH response values are < 10 mcg/L

-OR-

ii. **Both** of the following:

- Patient is < 1 year of age

-AND-

- **One** of the following is below the age and gender adjusted normal range as provided by the physician's lab:
 - Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
 - Insulin Growth Factor Binding Protein-3 (IGFBP-3)

-AND-

(d) **One** of the following:

- i. Coverage will be provided up to a maximum supply limit of 0.3 mg/kg/week

-OR-

ii. **Both** of the following:

- Tanner Stage 3 or greater
- Coverage will be provided up to a maximum supply limit of 0.7 mg/kg/week

-AND-

(e) Prescribed by an endocrinologist

-AND-

(f) If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication

Authorization will be issued for 12 months.

Note: Documentation of previous height, current height and goal expected adult height will be required for renewal.

2. **Reauthorization**

a. **Somatropin** will be approved based on **all** of the following criteria:

(1) Height increase of at least 2 cm/year over the previous year documented by **both** of the following:

- (a) Previous height and date obtained
- (b) Current height and date obtained

-AND-

(2) **Both** of the following:

- (a) Expected adult height not attained
- (b) Documentation of expected adult height goal (e.g. genetic potential)

-AND-

(3) Calculated height (growth) velocity over the past 12 months

-AND-

(4) **One** of the following:

(a) **Both** of the following:

- i. Patient is male
- ii. Bone age < 16 years

-OR-

(b) **Both** of the following:

- i. Patient is female
- ii. Bone age < 14 years

-AND-

(5) **One** of the following:

(a) Coverage will be provided up to a maximum supply limit 0.3 mg/kg/week

-OR-

(b) **Both** of the following:

- i. Tanner Stage 3 or greater
- ii. Coverage will be provided up to a maximum supply limit of 0.7 mg/kg/week

-AND-

(6) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

B. Prader-Willi Syndrome

1. Initial Therapy

a. **Somatropin** will be approved based on **all of** the following criterion:

(1) Diagnosis of Prader-Willi Syndrome

-AND-

(2) Prescribed by an endocrinologist

-AND-

(3) If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication

Authorization will be issued for 12 months.

2. Reauthorization

a. **Somatropin** will be approved based on **one** of the following criteria:

(1) **Both** of the following:

(a) Evidence of positive response to therapy (eg, increase in total lean body mass, decrease in fat mass)

-AND-

(b) Prescribed by an endocrinologist

-OR-

(2) **All** of the following:

(a) Height increase of at least 2 cm/year over the previous year of treatment as documented by **both** of the following:

- i. Previous height and date obtained
- ii. Current height and date obtained

-AND-

(b) **Both** of the following:

- i. Expected adult height not attained
- ii. Documentation of expected adult height goal

-AND-

(c) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

C. Growth Failure in Children Small for Gestational Age (SGA)

1. Initial Therapy

a. **Somatropin** will be approved based on **all** of the following criteria:

(1) Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by the following criterion:

(a) Documentation that **one** of the following is below the 3rd percentile for gestational age (more than 2 SD below population mean):

- i. Birth weight
- ii. Birth length

-AND-

(2) Documentation that height remains \leq 3rd percentile (more than 2 SD below population mean)

-AND-

(3) Prescribed by an endocrinologist

-AND-

(4) If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication

Authorization will be issued for 12 months.

Note: Documentation of previous height, current height and goal expected adult height will be required for renewal.

2. Reauthorization

a. **Somatropin** will be approved based on **all** of the following criteria:

(1) Height increase of at least 2 cm/year over the previous year documented by **both** of the following:

- (a) Previous height and date obtained
- (b) Current height and date obtained

-AND-

(2) Documentation of **both** of the following:

- (a) Expected adult height not attained
- (b) Expected adult height goal

-AND-

(3) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

D. Turner Syndrome or Noonan Syndrome

1. Initial Therapy

a. **Somatropin** will be approved based on **all** of the following criteria:

(1) Diagnosis of pediatric growth failure associated with **one** of the following:

(a) **Both** of the following:

- i. Turner Syndrome (Gonadal Dysgenesis)

-AND-

ii. **Both** of the following:

- Patient is female
- Bone age < 14 years

-OR-

(b) **Both** of the following:

i. Noonan Syndrome

-AND-

ii. **One** of the following:

▪ **Both** of the following:

- Patient is male
- Bone age < 16 years

-OR-

▪ **Both** of the following:

- Patient is female
- Bone age < 14 years

-AND-

(2) Height is below the 5th percentile on growth charts for age and gender

-AND-

(3) Prescribed by an endocrinologist

-AND-

(4) If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication

Authorization will be issued for 12 months.

Note: Documentation of previous height, current height and goal expected adult height will be required for renewal.

2. Reauthorization

a. **Somatropin** will be approved based on **all** of the following criteria:

(1) Height increase of at least 2 cm/year over the previous year

documented by **both** of the following:

- (a) Previous height and date obtained
- (b) Current height and date obtained

-AND-

(2) Documentation of **both** of the following:

- (a) Expected adult height not attained
- (b) Expected adult height goal

-AND-

(3) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

E. Short-Stature Homeobox (SHOX) Gene Deficiency

1. Initial Therapy

a. **Somatropin** will be approved based on **all** of the following criteria:

(1) Diagnosis of pediatric growth failure with short-stature homeobox (SHOX) gene deficiency as confirmed by genetic testing

-AND-

(2) **One** of the following:

(a) **Both** of the following:

- i. Patient is male
- ii. Bone age < 16 years

-OR-

(b) **Both** of the following:

- i. Patient is female
- ii. Bone age < 14 years

-AND-

(3) Prescribed by an endocrinologist

-AND-

(4) If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication

Authorization will be issued for 12 months.

Note: Documentation of previous height, current height and goal expected adult height will be required for renewal.

2. Reauthorization

a. **Somatropin** will be approved based on **all** of the following criteria:

(1) Height increase of at least 2 cm/year over the previous year documented by **both** of the following:

- (a) Previous height and date obtained
- (b) Current height and date obtained

-AND-

(2) Documentation of **both** of the following:

- (a) Expected adult height not attained
- (b) Expected adult height goal

-AND-

(3) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

F. Growth Failure associated with Chronic Renal Insufficiency

1. Initial Therapy

a. **Somatropin** will be approved based on **all** of the following criteria:

(1) Diagnosis of pediatric growth failure associated with chronic

renal insufficiency

-AND-

(2) **One** of the following:

(a) **Both** of the following:

- i. Patient is male
- ii. Bone age < 16 years

-OR-

(b) **Both** of the following:

- i. Patient is female
- ii. Bone age < 14 years

-AND-

(3) Prescribed by **one** of the following:

- (a) Endocrinologist
- (b) Nephrologist

-AND-

(4) If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication

Authorization will be issued for 12 months.

Note: Documentation of previous height, current height and goal expected adult height will be required for renewal.

2. Reauthorization

a. **Somatropin** will be approved based on **all** of the following criteria:

(1) Height increase of at least 2 cm/year over the previous year documented by **both** of the following:

- (a) Previous height and date obtained
- (b) Current height and date obtained

-AND-

(2) Documentation of **both** of the following:

- (a) Expected adult height not attained
- (b) Expected adult height goal

-AND-

(3) Prescribed by **one** of the following:

- (a) Endocrinologist
- (b) Nephrologist

Authorization will be issued for 12 months.

G. Adult Growth Hormone Deficiency

1. Initial Therapy

a. **Somatropin** will be approved based on **all** of the following criteria:

(1) Diagnosis of adult GH deficiency as a result of **one** of the following:

- (a) Clinical records supporting a diagnosis of childhood-onset GHD

-OR-

(b) **Both** of the following:

- i. Adult-onset GHD

-AND-

- ii. Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

-AND-

(2) Submission of medical records (e.g., chart notes, laboratory

values) documenting **one** of the following:

(a) **Both** of the following:

i. Patient has undergone **one** of the following GH stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- Arginine & GHRH (GHRH+ARG)
- Glucagon
- Arginine (ARG)

-AND-

ii. **One** of the following peak GH values:

- ITT ≤ 5 $\mu\text{g/L}$
- GHRH+ARG (≤ 11 $\mu\text{g/L}$ if body mass index [BMI] < 25 kg/m^2 ; ≤ 8 $\mu\text{g/L}$ if BMI ≥ 25 and < 30 kg/m^2 ; ≤ 4 $\mu\text{g/L}$ if BMI ≥ 30 kg/m^2)
- Glucagon ≤ 3 $\mu\text{g/L}$
- ARG ≤ 0.4 $\mu\text{g/L}$

-OR-

(b) **Both** of the following:

i. Submission of medical records (e.g., chart notes, laboratory values) documenting deficiency of **three** of the following anterior pituitary hormones:

- Prolactin
- ACTH
- TSH
- FSH/LH

-AND-

ii. IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

-AND-

(3) **One** of the following:

(a) Diagnosis of panhypopituitarism

-OR-

(b) Other diagnosis **and** not used in combination with the following:

- i. Aromatase inhibitors [e.g., Arimidex (anastrozole), Femara (letrozole)]
- ii. Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

-AND-

(4) Coverage will be provided up to a maximum supply limit of 0.3 mg/kg/week

-AND-

(5) Prescribed by an endocrinologist

-AND-

(6) If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication

Authorization will be issued for 12 months.

2. Reauthorization

a. **Somatropin** will be approved based on the following criterion:

(1) Documentation of IGF-1/Somatomedin C level within the past 12 months

-AND-

(2) **One** of the following:

(a) Diagnosis of panhypopituitarism

-OR-

(b) Other diagnosis **and** not used in combination with the

following:

- Aromatase inhibitors [e.g., Arimidex (anastrozole), Femara (letrozole)]
- Androgens [e.g., Delatestryl (testoseterone enanthate), Depo-Testosterone (testosterone cypionate)]

-AND-

(3) Coverage will be provided up to a maximum supply limit of 0.3 mg/kg/week

-AND-

(4) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

H. Transition Phase Adolescent Patients

1. Initial Therapy

a. **Somatropin** will be approved based on **all** of the following criteria:

(1) Coverage will be provided up to a maximum supply limit of 0.3 mg/kg/week)

-AND-

(2) Documentation of **one** of the following:

- (a) Attained expected adult height
- (b) Closed epiphyses on bone radiograph

-AND-

(3) Submission of medical records (e.g., chart notes, laboratory values) documenting **one** of the following:

(a) **Both** of the following:

i. Documentation of high risk of GH deficiency due to GH deficiency in childhood from **one** of the following:

- Embryopathic/congenital defects

- Genetic mutations
- Irreversible structural hypothalamic-pituitary disease
- Panhypopituitarism
- Deficiency of **three** of the following anterior pituitary hormones:
 - ACTH
 - TSH
 - Prolactin
 - FSH/LH

-AND-

ii. **One** of the following:

- IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

-OR-

- **All** of the following:

- Patient does not have a low IGF-1/Somatomedin C level

-AND-

- Discontinued GH therapy for at least 1 month

-AND-

- Patient has undergone **one** of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- GHRH+ARG
- ARG
- Glucagon

-AND-

- **One** of the following peak GH values:

- ITT ≤ 5 $\mu\text{g/L}$
- GHRH+ARG (≤ 11 $\mu\text{g/L}$ if body mass index [BMI] < 25 kg/m^2 ; ≤ 8 $\mu\text{g/L}$ if BMI ≥ 25 and < 30 kg/m^2 ; ≤ 4 $\mu\text{g/L}$ if BMI ≥ 30 kg/m^2)
- Glucagon ≤ 3 $\mu\text{g/L}$
- ARG ≤ 0.4 $\mu\text{g/L}$

-OR-

(b) **All** of the following:

- i. At low risk of severe GH deficiency (eg, due to isolated and/or idiopathic GH deficiency)

-AND-

- ii. Discontinued GH therapy for at least 1 month

-AND-

iii. **Both** of the following:

- Patient has undergone **one** of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- GHRH+ARG
- ARG
- Glucagon

-AND-

- **One** of the following peak GH values:

- ITT ≤ 5 $\mu\text{g/L}$
- GHRH+ARG (≤ 11 $\mu\text{g/L}$ if body mass index [BMI] < 25 kg/m^2 ; ≤ 8 $\mu\text{g/L}$ if BMI ≥ 25 and < 30 kg/m^2 ; ≤ 4 $\mu\text{g/L}$ if BMI ≥ 30 kg/m^2)
- Glucagon ≤ 3 $\mu\text{g/L}$
- ARG ≤ 0.4 $\mu\text{g/L}$

-AND-

(4) Prescribed by an endocrinologist

-AND-

- (5) If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication

Authorization will be issued for 12 months.

2. Reauthorization

- a. **Somatropin** will be approved based on the following criterion:

- (1) Documentation of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)

-AND-

- (2) Coverage will be provided up to a maximum supply limit of 0.3 mg/kg/week)

-AND-

- (3) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

I. Human Immunodeficiency Virus (HIV)-Associated Cachexia (Serostim only)

1. Initial Therapy

- a. **Serostim** will be approved based on **all** of the following criteria:

- (1) Diagnosis of HIV-associated wasting syndrome or cachexia

-AND-

- (2) Documentation of **one** of the following:

- (a) Unintentional weight loss of > 10% over the last 12 months
(b) Unintentional weight loss of > 7.5% over the last 6 months
(c) Loss of 5% body cell mass (BCM) within 6 months
(d) Body mass index (BMI) < 20 kg/m²

(e) **One** of the following:

i. **All** of the following

- Patient is male
- BCM < 35% of total body weight
- BMI < 27 kg/m²

-OR-

ii. **All** of the following:

- Patient is female
- BCM < 23% of total body weight
- BMI < 27 kg/m²

-AND-

(3) A nutritional evaluation has been completed since onset of wasting first occurred

-AND-

(4) Patient has not had weight loss as a result of other underlying treatable conditions (e.g., depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi's sarcoma limited to skin or mucous membranes)

-AND-

(5) Patient's anti-retroviral therapy has been optimized to decrease the viral load

Authorization will be issued for 3 months.

2. Reauthorization

a. **Serostim** will be approved based on **both** of the following criteria:

(1) Evidence of positive response to therapy (i.e., $\geq 2\%$ increase in body weight and/or BCM)

-AND-

(2) **One** of the following targets or goals has not been achieved:

- (a) Weight
- (b) BCM
- (c) BMI

Authorization will be issued for 6 months.

J. Short Bowel Syndrome (Zorbtive only)

1. **Zorbtive** will be approved based on **all** of the following criteria:

- a. Diagnosis of Short Bowel Syndrome

-AND-

- b. Patient is currently receiving specialized nutritional support (e.g., intravenous parenteral nutrition, fluid, and micronutrient supplements)

-AND-

- c. Patient has not previously received 4 weeks of treatment with Zorbtive

Authorization will be issued for 4 weeks.

Note: Treatment with Zorbtive will not be authorized beyond 4 weeks. Administration for more than 4 weeks has not been adequately studied.

K. Severe Primary IGF-1 Deficiency / Growth Hormone Gene Deletion (Increlex only)

1. **Initial Therapy**

a. **Increlex** will be approved based on **one** of the following criteria:

(1) Documentation of **all** of the following:

- (a) Diagnosis of severe primary IGF-1 deficiency

-AND-

- (b) Height standard deviation score ≤ -3.0

-AND-

(c) Basal IGF-1 standard deviation score ≤ -3.0

-AND-

(d) Normal or elevated growth hormone levels

-AND-

(e) Documentation of open epiphyses on last bone radiograph

-AND-

(f) The patient will not be treated with concurrent growth hormone therapy

-AND-

(g) Prescribed by an endocrinologist

-OR-

(2) **All** of the following:

(a) Diagnosis of growth hormone gene deletion and has developed neutralizing antibodies to growth hormone

-AND-

(b) Documentation of open epiphyses on last bone radiograph

-AND-

(c) The patient will not be treated with concurrent growth hormone therapy

-AND-

(d) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

Note: Documentation of previous height, current height and goal expected adult height will be required for renewal.

2. Reauthorization

a. **Increlex** will be approved based on **all** of the following criteria:

(1) Height increase of at least 2 cm/year over the previous year of treatment as documented by **both** of the following:

- (a) Previous height and date obtained
- (b) Current height and date obtained

-AND-

(2) Documentation of **both** of the following:

- (a) Expected adult height not obtained
- (b) Expected adult height goal

-AND-

(3) Patient is not treated with concurrent growth hormone therapy

-AND-

(4) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

***Educational Statement:** Documentation of previous height, current height and goal expected adult height will be required for renewal.

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Program	Prior Authorization –Growth Hormone, Growth Stimulating Agents
Change Control	
Date	Change
2/2018	Ohio specific policy created for 4/1/18 since Ohio will be moving to a Single PDL later in 2018.