UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Growth Hormone, Growth Stimulating Agents – Managed Medicaid

Program	Prior Authorization
Medication	**Human Growth Hormone:** **Preferred Agents:** Somatropin (Zomacton®) **Nonpreferred Agents:** Somatropin (Genotropin®, Humatrope®, Norditropin®, NordiFlex®, Nutropin®, Nutropin AQ®, Nutropin AQ® NuSpin™, Omnitrope®, Saizen®, Zorbtive®, and Serostim®) **Growth Stimulating Products :** Mecasermin (Increlex®)
Markets in Scope	CA, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York- Medicaid, New York EPP, Rhode Island, South Carolina
Issue Date	6/2009
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

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. Patient is male and **one** of the following:

- Tanner stage less than 4
- Bone age < 16 years measured in the past 12 months

-OR-

ii. Patient is female and **one** of the following:

- Tanner stage less than 4
- Bone age < 14 years measured in the past 12 months

-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. Request does not exceed a maximum supply limit of 0.3 mg/kg/week

-OR-

ii. **Both** of the following:

- Tanner Stage 3 or greater
- Request does not exceed 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) Patient is male and one of the following:

i. Tanner stage less than 4
ii. Bone age < 16 years measured in the past 12 months

-OR-

(b) Patient is female and one of the following:

i. Tanner stage less than 4
ii. Bone age < 14 years measured in the past 12 months

-AND-

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

(a) Request does not exceed a maximum supply limit 0.3 mg/kg/week

-OR-

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

i. Tanner Stage 3 or greater
ii. Request does not exceed 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 (e.g., 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 birth to 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 (greater than or equal to 2 SD below population mean):

i. Birth weight
ii. Birth length

-AND-

(b) Patient has demonstrated failure of catch up growth in the first 24 months of life

-AND-

(2) Documentation that height remains ≤ 3rd percentile (greater than or equal to 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
- **One** of the following:

- Bone age < 14 years measured in the past 12 months
- Tanner stage less than 4

-OR-

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

i. Noonan Syndrome

-AND-

ii. **One** of the following:

- Patient is male and **one** of the following:

  - Tanner stage less than 4
  - Bone age < 16 years measured in the past 12 months

-OR-

- Patient is female and **one** of the following:

  - Tanner stage less than4
  - Bone age < 14 years measured in the past 12 months

-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) Patient is male and **one** of the following:

i. Tanner stage less than 4
ii. Bone age < 16 years measured in the past 12 months

-OR-

(b) Patient is female and **one** of the following:

i. Tanner stage less than 4
ii. Bone age < 14 years measured in the past 12 months

-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) Patient is male and **one** of the following:

i. Tanner stage less than 4
ii. Bone age < 16 years measured in the past 12 months

-OR-

(b) Patient is female and **one** of the following:

i. Tanner stage less than 4
ii. Bone age < 14 years measured in the past 12 months

-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)
- Macrilen (macimorelin)

-AND-

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

- ITT ≤ 5 µg/L
- GHRH+ARG (≤ 11 µg/L if body mass index [BMI] < 25 kg/m^2; ≤ 8 µg/L if BMI ≥ 25 and < 30 kg/m^2; ≤ 4 µg/L if BMI ≥ 30 kg/m^2)
- Glucagon ≤ 3 µg/L
- ARG ≤ 0.4 µg/L
- Macimorelin < 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

-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 (anastrazole), Femara (letrazole)]
ii. Androgens [e.g., Delatestryl (testoseterone enanthate), Depo-Testosterone (testosterone cypionate)]

-AND-

(4) Request does not exceed 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 (anastrazole), Femara (letrazole)]
- Androgens [e.g., Delatestryl (testoseterone enanthate), Depo-Testosterone (testosterone cypionate)]

-AND-

(3) Request does not exceed 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) Request does not exceed 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 µg/L
  - GHRH+ARG (≤ 11 µg/L if body mass index [BMI] < 25 kg/m^2; ≤ 8 µg/L if BMI ≥ 25 and < 30 kg/m^2; ≤ 4 µg/L if BMI ≥ 30 kg/m^2)
  - Glucagon ≤ 3 µg/L
  - ARG ≤ 0.4 µg/L

-OR-

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

i. At low risk of severe GH deficiency (e.g., 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 µg/L
  - GHRH+ARG (≤ 11 µg/L if body mass index [BMI] < 25 kg/m^2; ≤ 8 µg/L if BMI ≥ 25 and < 30 kg/m^2; ≤ 4 µg/L if BMI ≥ 30 kg/m^2)
  - Glucagon ≤ 3 µg/L
  - ARG ≤ 0.4 µg/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) Request does not exceed 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/m^2
(e) **One** of the following:

i. **All** of the following

- Patient is male
- BCM < 35% of total body weight
- BMI < 27 kg/m^2

-OR-

ii. **All** of the following:

- Patient is female
- BCM < 23% of total body weight
- BMI < 27 kg/m^2

-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., ≥ 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.

3. Additional Clinical Rules:

• Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
• Supply limits may be in place.

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Program	Prior Authorization –Growth Hormone, Growth Stimulating Agents
Change Control	
Date	Change
6/2009	Criteria were taken from previously approved AmeriChoice Growth Hormone policy and Unison's RX06 Growth Hormone policy. Policy was reformatted.
9/2010	Changed Saizen to a non-preferred product and Omnitrope to a preferred product. Removed Saizen from the guidelines and replaced it with Omnitrope.
12/2010	Updated the guidelines as follows: • Added Nutropin QA NuSpin to product list and Indications. • Added low IGF-1 levels to diagnostic criteria for GH deficiency in children. • Updated diagnostic criteria for SGA. • Updated criteria for Turner Syndrome, SHOX deficiency, Noonan Syndrome (removed growth requirements from the initial therapy criteria) and • Updated re-authorization criteria for Prader-Willi Syndrome (added re-authorization requirements). • Changed criteria for growth failure associated with CRI to a separate item in the guidelines (had previously shared criteria with pediatric GH deficiency). • Updated criteria for GH deficiency in adults and added criteria for Transition patients to it. • Updated intial therapy and re-authorization criteria for HIV-associated wasting and cahcexia. Changed re-authorization approval length from 12 months to 6 months. Updated Short Bowel Syndrome criteria (removed criteria related to length of the small intestine and functioning colon).
9/2011	Annual Review
12/2011	IGF-1 level reference table provided in the Pediatric Growth Hormone Deficiency criteria [A.1.a..5.(b)] and the Growth Hormone Deficiency in Adults and Adolescents criteria [F.1.a.3. (b).(ii)]. Low IGF-1 criteria also clarified to reference the table of values provided or that which is supplied on the lab report.
12/2012	Updated clinical criteria for each indication. Added a background section for national guidelines. Updated References.

9/2013	• Updated to standard UHC format • Clarified transitional phase adolescent criteria into 2 separate criteria – 'high risk GHD' and 'low risk GHD' with no change to actual clinical criteria Clarified SGA criteria – patient should have both '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' and 'height remains ≤ 3rd percentile.' Criteria previously said 'or.'
12/2013	• Revised height below the 3rd percentile for age and gender criteria for Pediatric Growth Hormone Deficiency (GHD) to be > 2.0 standard deviations (SD) below midparental height or > 2.25 SD below population mean based on the 2003 Lawson Wilkins Pediatric Endocrinology Society guidelines for the use of growth hormone in children. • For Pediatric GHD, Turner/Noonan Syndrome, Short-Stature Homeobox (SHOX) Gene Deficiency, Growth Failure Associated with Chronic Renal Insufficiency (CRI) indications, and Idiopathic Short Stature, revised bone age for males to be < 16 years and for females to be < 14 years to more accurately reflect the bone age used in *Mauras et al.2000*. • Added criteria for Pediatric GHD requiring that pediatric GH dosing be utilized as defined by the prescribing information. • For Adult GHD, added a requirement for "clinical records supporting a diagnosis of" childhood-onset GHD, and for "clinical records documenting" the hormone deficiency cause for an adult-onset GHD diagnosis. • For Adult GHD, added initial authorization and reauthorization criteria that growth hormones not be used in combination with either aromatase inhibitors (eg, Arimidex [anastrazole], Femara [letrazole]), or androgens (eg, Delatestryl [testosterone enanthate], Depo-testosterone [testosterone cypionate]). • For Adult GHD, added initial authorization and reauthorization criteria requiring that adult GH dosing be utilized as defined by the prescribing information. • For Transition Phase Adolescent Patients, added "Continued use of adult GH dosing as defined by the prescribing information (additional information may be found in the AACE 2009 treatment guideline)" to reauthorization criteria to mirror initial authorization and to add another verification of appropriate dosing prior to approval of continuation of • Added a specialist prescriber requirement to all reauthorization criteria for all diagnoses, except HIV-associated cachexia and Short Bowel Syndrome, to be consistent with initial authorization criteria

	Added specialist prescriber requirement to Isolated Growth Hormone Deficiency in Adults criteria to mirror criteria for other indications
9/2015	Changed Preferred Product to Nutropin, all criteria sections list Nutropin as the preferred product except for Human Immunodeficiency Virus (HIV)-Associated Cachexia (Serostim) and Short Bowel Syndrome (Zorbtiv) sections. Clarified adult growth hormone deficiency criteria "not used in combination with aromatase inhibitors and androgens" will not apply to adults with growth hormone deficiency due to panhypopituitarism as part of initial and reauthorization criteria. Added "not used in combination with aromatase inhibitors and androgens" to isolated growth hormone deficiency in adults criteria.
6/2016	Policy name changed from "Growth Hormone" to "Growth Hormone, Growth Stimulating Agents" due to Increlex (mecasermin) policy and Growth Hormone policy being combined. The individual Increlex policy will be discontinued and this policy will continue to serve for reviews of Increlex. The Increlex criteria (section K) added has not changed from when Increlex was a stand-alone policy. The same clinical criteria previously approved were moved to this policy and not changed. Growth Hormone changes: **Pediatric growth hormone deficiency (section A):** • Added prescriber requirement to section A at section A.1.a.(1) because in past policy format if a member were to meet the requirements of (a), (b), or (c) the prescriber requirement would not have been required. • Update reauthorization criteria to assess bone age, dosing, and growth velocity upon reauthorization. This was previously only assessed as initial therapy authorization. **Dosing Statements** – dosing statements in sections A, G, and H updated to specify the actual weight based dose target recommended. Section A (initial and reauthorization) includes an alternative dosing target for Tanner Stage 3 or greater.
12/2016	Revised medical record requirement language and clarified criteria for diagnosis of pediatric GH deficiency.
2/2018	Added language for review of non-preferred medications. Separated preferred and non-preferred products in medications

	section. Zomacton will be preferred and Nutropin AQ NuSpin will be non-preferred starting 4/1/18. Updated references.
11/2018	Added Macrilen (macimorelin) as an option for the diagnosis of adult growth hormone deficiency. Updated references.
12/2019	Updated bone age requirements and supply limit language. Updated references.
11/2020	Updated references.