UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1039-17
Program	Prior Authorization/Notification – Human Growth Hormone, Growth Stimulating Products
Medication	Human Growth Hormone: Somatropin (Genotropin®*, Humatrope®*, Norditropin®, NordiFlex®*, Nutropin AQ NuSpin®, Omnitrope®, Saizen®*, Zomacton®*, Zorbtive®, and Serostim®), Skytrofa™, (lonapegsomatropin-tcgd), Sogroya®*(somapacitan-beco), Ngenla™ (somatrogon-ghla) Growth Stimulating Products: Mecasermin (Increlex®)
P&T Approval Date	4/2008, 4/2009, 10/13/2009, 7/13/2010, 7/2011, 8/2012, 8/2013, 2/2014, 8/2014, 8/2015, 1/2016, 12/2016, 11/2017, 11/2018, 12/2019, 4/2020, 6/2021, 1/2022, 5/2022, 7/2022, 7/2023, 11/2023, 2/2024
Effective Date	3/15/2024

1. **Background:**
Somatropin is indicated for the treatment of growth hormone deficiency (GHD), 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 (GH) in adults with confirmed GHD.

Skytrofa™ (lonapegsomatropin-tcgd) is indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous GH.

Sogroya®*(somapacitan-beco) is indicated for the treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous GD. It is also indicated for the replacement of endogenous GD in adults with GHD.

Ngenla™ (somatrogon-ghla), is indicated for the treatment of pediatric patients aged 3 years and older who have growth failure due to inadequate secretion of endogenous GH.

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

Coverage Information
Since short stature in the absence of defined pathology is not a sickness or injury, growth hormone is not a covered health service for these indications. The standard UnitedHealthcare Pharmacy Rider explicitly excludes coverage of growth hormone for short stature caused by heredity and not by a diagnosed medical condition.

Coverage for somatropin (Genotropin*, Humatrope*, Norditropin, NordiFlex*, Nutropin AQ NuSpin, Omnitrope, Saizen*, and Zomacton*), Skytrofa, Sogroya*, Ngenla, and mecasermin (Increlex) will be provided for members who meet the following criteria:

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) **One** of the following:

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

i. Infant is < 4 months of age
ii. Infant has growth deficiency

-OR-

(b) History of neonatal hypoglycemia associated with pituitary disease

-OR-

(c) Diagnosis of panhypopituitarism

-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 IV
- Bone age < 16 years measured in the past 12 months

-OR-

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

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

-AND-

(c) **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)

b. **Ngenla, Skytrofa, and Sogroya*** will be approved based on **one** of the following criteria:

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

(a) History of neonatal hypoglycemia associated with pituitary disease

-OR-

(b) Diagnosis of panhypopituitarism

-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 IV

- Bone age < 16 years measured in the past 12 months

-OR-

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

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

-AND-

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

i. Patient has undergone **two** of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa
- Growth hormone releasing hormone

-AND-

ii. **Both** GH response values are < 10 mcg/L

-AND-

(d) Patient weighs 11.5 kg or greater

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, Ngenla, Skytrofa, and Sogroya*** will be approved based on **both** 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) **Both** of the following:

(a) Expected adult height not attained
(b) Documentation of expected adult height goal

Authorization will be issued for 12 months.

B. Prader-Willi Syndrome

1. **Initial Therapy**

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

(1) Diagnosis of Prader-Willi Syndrome

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

-OR-

(2) **Both** 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

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 **both** 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) **One** of the following is below the 3rd percentile for gestational age (≥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) Height remains ≤ 3rd percentile (≥2 SD below population mean):

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 **both** 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) **Both** of the following:

(a) Expected adult height not attained
(b) Documentation of expected adult height goal

Authorization will be issued for 12 months.

D. Turner Syndrome or Noonan Syndrome

1. **Initial Therapy**

a. **Somatropin** will be approved based on **both** 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. Documentation of **both** of the following:

- Patient is female
- **One** of the following
  - Tanner stage less than IV
  - Bone age < 14 years measured in the past 12 months

-OR-

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

i. Noonan Syndrome

-AND-

ii. Documentation of **one** of the following:

- Patient is male and **one** of the following:
  - Tanner stage less than IV
  - Bone age < 16 years measured in the past 12 months

-OR-

- Patient is female and **one** of the following:
  - Tanner stage less than IV
  - 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

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 **both** 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) **Both** of the following:

(a) Expected adult height not attained
(b) Documentation of expected adult height goal

Authorization will be issued for 12 months.

E. Short-Stature Homeobox (SHOX) Gene Deficiency

1. **Initial Therapy**

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

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

-AND-

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

(a) Patient is male and **one** of the following:

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

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 **both** 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) **Both** of the following:

(a) Expected adult height not attained
(b) Documentation of expected adult height goal

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 **both** of the following criteria:

(1) Diagnosis of pediatric growth failure associated with chronic renal insufficiency

-AND-

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

(a) Patient is male and **one** of the following:

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

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 **both** 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) **Both** of the following:

(a) Expected adult height not attained
(b) Documentation of expected adult height goal

Authorization will be issued for 12 months.

G. Adult Growth Hormone Deficiency

1. **Initial Therapy**

a. **Somatropin and Sogroya*** 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) **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. Documented 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 (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Evidence of ongoing monitoring as demonstrated by documentation within the

past 12 months of an IGF-1/Somatomedin C level

-AND-

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

i. Diagnosis of panhypopituitarism

-OR-

ii. 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)]

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) **One** of the following:

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

-AND-

(2) **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 ~~a~~ **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

Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

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) **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) Nutritional evaluation 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) 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. Idiopathic Short Stature (for the state of Maryland only)

1. **Initial Therapy**

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

      (1) Diagnosis of idiopathic short stature

      -AND-

      (2) Diagnostic evaluation has excluded other causes associated with short stature (e.g., growth-hormone deficiency, chronic renal insufficiency, etc.)

      -AND-

      (3) Documentation of height ≤ -2.25 SD score (SDS) below the corresponding mean height for age and gender

      -AND-

      (4) Documentation of growth velocity less than 25th percentile for bone age

      -AND-

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

         (a) Patient is male and **one** of the following:

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

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 **both** of the following criteria:

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

(a) Expected adult height not attained
(b) Documentation of expected adult height goal

Authorization will be issued for 12 months.

L. 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) **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

-OR-

b. **All** of the following:

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

-AND-

(2) Documentation of open epiphyses on last bone radiograph

-AND-

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

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 **both** 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) **Both** of the following:

(a) Expected adult height not obtained
(b) Documentation of expected adult height goal

-AND-

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

Authorization will be issued for 12 months.

* Genotropin, Humatrope, NordiFlex, Saizen, Sogroya, and Zomacton are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

Essential versus Nonessential Use
The Patient Protection and Affordable Care Act (PPACA) of 2010 includes a mandate that prohibits annual dollar maximum limits for "essential" benefits. A strict definition of "essential" was not provided in PPACA or in federal health care regulations published as of the date this program was revised. UnitedHealthcare defines an "essential" use of growth hormone as therapy to treat a deficiency as part of chronic disease management. Other uses such as replacement therapy in a disorder where a deficiency is not noted are considered "nonessential."

This information applies to groups with benefit caps in place for growth hormone therapy. If the diagnosis is considered an essential use of the medication, the cap will not apply. For these cases, an override for the cap amount will be entered at the same time the authorization (if criteria met) is entered for the medication. If the diagnosis is a nonessential use of the medication, then only the authorization for the medication will be entered.

Diagnosis	
Pediatric growth hormone deficiency	Essential
Growth failure in children small for gestational age	Nonessential
Growth failure due to chronic renal insufficiency	Nonessential
Growth failure due to Turner Syndrome	Nonessential
Growth failure due to Noonan Syndrome	Nonessential
Growth failure due to short-stature homeobox (SHOX) gene deficiency	Nonessential
Prader-Willi Syndrome	Nonessential
Adult growth hormone deficiency	Essential
Transition phase adolescent patients	Essential
HIV-associated wasting syndrome/cachexia	Essential
Short bowel syndrome	Essential
Severe primary IGF-1 deficiency	Essential
Idiopathic short stature (not currently covered per criteria)	Nonessential

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.

4. References:

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7. Genotropin [package insert]. New York, NY: Pharmacia & Upjohn Company; April 2019.
8. Deal CL, Tony M, Höybye C, et al. Growth hormone research society workshop summary: consensus guidelines for recombinant human growth hormone therapy in prader-willi syndrome. J Clin Endocrinol Metab. 2013 Jun;98(6):E1072-87.
9. HIV Clinical Resource. General nutrition, weight lost and wasting syndrome. Available at http://www.hivguidelines.org/clinical-guidelines/adults/general-nutrition-weight-loss-and-wasting-syndrome/. Accessed June 29, 2012.
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Program	Prior Authorization/Notification – Human Growth Hormone, Growth Stimulating Products
Change Control	
8/2013	Annual review with clarification of transitional phase adolescent and SGA criteria. Updated formatting and references.
2/2014	Modified bone age and height requirement to align with Lawson-Wilkins pediatric guidelines. Added correct dosing to be utilized per PI to both adult and children. Added not to be used in combination with androgens and aromatase inhibitors to adult criteria.
8/2014	Added concomitant use requirement to Increlex reauthorization criteria.
8/2015	Added requirement for SL dosing maximum to pediatric GHD, adult GHD, transitional, and ISS. Removed Tev-Tropin and added Zomacton.
1/2016	Removal of SL dosing maximum criterion reference from 8/2015 update.
12/2016	Updated criteria for diagnosis of pediatric GH deficiency. Updated references.
11/2017	Annual review. Updated references.
11/2018	Annual review. Added macrilen (macimorelin) as an option for the diagnosis of adult growth hormone deficiency and updated references.
12/2019	Annual review. Updated bone age requirement and references.
4/2020	Added requirement for state of California.
6/2021	Annual review. No change of clinical criteria. Updated references.
1/2022	Removed Nutropin AQ which is no longer commercially available. Added coverage criteria for new product, Skytrofa. Updated background and references.
5/2022	Updated requirement for idiopathic short stature to only include Maryland.
7/2022	Removed exclusion notation from Norditropin.
7/2023	Annual review. Updated references.
11/2023	Added coverage criteria for Ngenla and Sogroya. Removed Skytrofa and added Sogroya to exclusion footnote. Updated background and references.
2/2024	Removed Omnitrope from exclusion footnote.