UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 2025 P 2016-20
Program	Prior Authorization/Medical Necessity
Medication	Human Growth Hormone: Somatropin (Genotropin®*, Humatrope®*, Norditropin®, Nutropin AQ® NuSpin®*, Omnitrope®, Saizen®*, Serostim®, Zomacton®*, Zorbtive®), Skytrofa™ (lonapegsomatropin-tcgd), Sogroya®*(somapacitan-beco), Ngenla™ (somatrogon-ghla) Growth Stimulating Products: Mecasermin (Increlex®)
P&T Approval Date	2/2014, 8/2014, 5/2015, 8/2015, 6/2016, 12/2016, 11/2017, 11/2018, 12/2019, 4/2020, 7/2021, 1/2022, 5/2022, 7/2022, 7/2023, 11/2023, 2/2024, 10/2024, 2/2025
Effective Date	9/14/2025

1. **Background:**
Somatropin (Genotropin®*, Humatrope®*, Norditropin®, Nutropin AQ NuSpin®*, Omnitrope®, Saizen®*, Zomacton®*) is indicated for the treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone (GH), growth hormone deficiency (GHD), short stature associated with Turner syndrome or Noonan syndrome, idiopathic short stature (ISS), short-stature or growth failure in short stature homeobox-containing gene homeobox (SHOX) gene deficiency, growth failure due to Prader-Willi syndrome, short stature in children born small for gestational age (SGA) with no catch-up growth by 2 years to 4 years of age, and chronic kidney disease (CKD) up to the time of renal transplantation., 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 GH deficiency (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.

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.

Serostim® (somatropin) is indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance.

Zorbtive® (somatropin) is indicated for the treatment of short bowel syndrome in adult patients receiving specialized nutritional support.

Increlex® (mecasermin) is indicated for the treatment of growth failure in pediatric patients 2 years of age and older with severe primary insulin-like growth factor-1 (IGF-1) deficiency or with GH gene deletion who 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, Nutropin AQ NuSpin*, Omnitrope, Saizen*, Serostim, Zomacton, Zorbtive), Ngenla, Skytrofa, Sogroya*, and Increlex will be provided for members who meet the following criteria:

2. Coverage Criteria:

A. Congenital Growth Hormone Deficiency (GHD)

1. **Initial Therapy**

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

(1) Infant is < 12 months of age

-AND-

(2) Submission of medical records documenting evidence of growth failure confirmed by **all** of the following:

(a) Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
(b) Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
(c) Calculated growth velocity

-AND-

(3) Submission of medical records documenting **one** of the following:

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

i. Hyopothalmic-pituitary defect (e.g., ectopic posterior pituitary, empty sella, hypoplastic pituitary, major congenital malformation, optic nerve hypoplasia, tumor or irradiation)
ii. Deficiency of at least one additional pituitary hormone

-OR-

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

i. Neonatal hypoglycemia and/or micropenis
ii. Serum GH concentration ≤ 5 µg/L in the first 28 days of life

iii. Deficiency of at least one additional pituitary hormone
iv. Classical imaging triad (i.e., ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk)

-AND-

(4) Submission of medical records documenting **one** of the following is below the age and gender adjusted normal range as provided by the physician's lab:

(a) Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
(b) Insulin Growth Factor Binding Protein-3 (IGFBP-3)

-AND-

(5) Prescribed by an endocrinologist

-AND-

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

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Submission of medical records documenting a height increase of at least 2 cm/year over the previous year confirmed by **all** of the following:

(a) Previous length/height and date obtained
(b) Current length/height and date obtained
(c) Calculated growth velocity
(d) Growth chart for length/height for age and gender

-AND-

(2) Submission of medical records documenting **both** of the following:

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

-AND-

(3) Prescribed by an endocrinologist

-AND-

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

Authorization will be issued for 12 months.

B. **Pediatric Growth Hormone Deficiency (GHD)**
Note: 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, Ngenla, Skytrofa, and Sogroya*** will be approved based on **all** of the following criteria:

(1) Submission of medical records documenting a diagnosis of pediatric GH deficiency

-AND-

(2) Submission of medical records documenting evidence of growth failure confirmed by **all** of the following:

(a) Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
(b) Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
(c) Calculated growth velocity

-AND-

(3) Submission of medical records documenting open epiphyses in the last 12 months

-AND-

(4) Submission of medical records documenting Tanner stage ≤ 4

-AND-

(5) Submission of medical records documenting **both** of the following:

(a) Patient has undergone **two** of the following provocative GH stimulation tests:

i. Arginine
ii. Clonidine
iii. Glucagon
iv. Insulin
v. Levodopa

-AND-

(b) Peak GH responses to each agent is < 10 mcg/L

-AND-

(6) If patient has a history of malignancy, **one** of the following:

(a) Patient is in remission
(b) Patient has been stable for at least 12 months

-AND-

(7) Prescribed by an endocrinologist

-AND-

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

(a) If the request is for Ngenla, request does not exceed a maximum supply limit of 0.66 mg/kg/week

-OR-

(b) If the request is for Somatropin, Skytrofa, or Sogroya, **one** of the following:

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

-OR-

ii. **All** of the following:

- **One** of the following:
  - Poor catch-up growth while on standard dosing

-OR-

  - IGF-1 < 2 standard deviations from the mean while on standard dosing

-AND-

- Tanner Stage 2 or greater

-AND-

- Request does not exceed a maximum supply limit of

0.7 mg/kg/week

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Submission of medical records documenting a height increase of at least 2 cm/year over the previous year confirmed by **all** of the following:

(a) Previous length/height and date obtained
(b) Current length/height and date obtained
(c) Calculated growth velocity
(d) Growth chart for length/height for age and gender

-AND-

(2) Submission of medical records documenting **both** of the following:

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

-AND-

(3) Prescribed by an endocrinologist

-AND-

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

(a) If the request is for **Ngenla**, request does not exceed a maximum supply limit of 0.66 mg/kg/week

-OR-

(b) If the request is for **Somatropin**, **Skytrofa**, or **Sogroya***, **one** of the following:

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

-OR-

iii. **All** of the following:

- **One** of the following:

- Poor catch-up growth while on standard dosing

-OR-

- IGF-1 < 2 standard deviations from the mean while on standard dosing

-AND-

- Tanner Stage 2 or greater

-AND-

- Request does not exceed a maximum supply limit of 0.7 mg/kg/week

Authorization will be issued for 12 months.

C. Transition Phase Adolescent Patients

Note: Use this criteria for patients diagnosed with GHD in childhood during the transition period from puberty to adulthood (the period from mid to late teens until 6 to 7 years after achievement of adult height).

1. **Initial Therapy**

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

(1) Submission of medical records documenting **one** of the following:

(a) Genetic mutation

-OR-

(b) Deficiency of **three** of the following anterior pituitary hormones:

i. ACTH
ii. TSH
iii. Prolactin
iv. FSH/LH

-OR-

(c) Irreversible structural hypothalamic-pituitary disease

-OR-

(d) Panhypopituitarism

-AND-

(2) Submission of medical records documenting **one** of the following:

(a) IGF-1 level is below the age and gender adjusted normal range as provided by the physician's lab

-OR-

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

i. Patient has undergone **one** of the following GH stimulation tests after discontinuation of therapy for at least 1 month:
- Insulin tolerance test (ITT)
- GH-releasing hormone-arginine test (GHRH+ARG)
- Glucagon stimulation test (GST)
- Macimorelin

-AND-

ii. **One** of the following peak GH values:
- ITT ≤ 5.1 µg/L
- GHRH+ARG ≤ 11 µg/L
- Glucagon ≤ 3 µg/L
- Macimorelin ≤ 2.8 ng/mL

-AND-

(3) Prescribed by an endocrinologist

-AND-

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

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

-OR-

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

i. **One** of the following:

- Poor catch-up growth while on standard dosing

-OR-

- IGF-1 < 2 standard deviations from the mean while on standard dosing

-AND-

ii. Tanner Stage 2 or greater

-AND-

iii. Request does not exceed a maximum supply limit of 0.7 mg/kg/week

Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

-AND-

(2) Prescribed by an endocrinologist

-AND-

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

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

-OR-

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

i. **One** of the following:

- Poor catch up growth while on standard dosing

-OR-

- IGF-1 < 2 standard deviations from the mean while on standard dosing

-AND-

ii. Tanner Stage 2 or greater

-AND-

iii. Request does not exceed a maximum supply limit of 0.7

mg/kg/week

Authorization will be issued for 12 months.

D. Adult Growth Hormone Deficiency

1. **Initial Therapy**

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

(1) Submission of medical records documenting a diagnosis of adult growth hormone deficiency (GHD) as a result of **one** of the following:

(a) Known hypothalamic or pituitary disease
(b) Panhypopituitarism
(c) History of GHD in childhood

-AND-

(2) Submission of medical records documenting **one** of the following:

(a) IGF-1 level is below the age and gender adjusted normal range as provided by the physician's lab

-OR-

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

i. Patient does not have a low IGF-1

-AND-

ii. Patient has undergone **one** of the following GH stimulation tests:
- GH-releasing hormone-arginine test (GHRH+ARG)
- Glucagon stimulation test (GST)
- Macimorelin

-AND-

iii. **One** of the following peak GH values:
- GHRH+ARG ≤ 11 µg/L
- Glucagon ≤ 3 ng/mL
- Macimorelin ≤ 2.8 ng/mL

-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) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Submission of medical records documenting an IGF-1 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:

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

-AND-

(3) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

E. Prader-Willi Syndrome

1. **Initial Therapy**

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

(1) Submission of medical records documenting **both** of the following:

(a) Diagnosis of Prader-Willi Syndrome

-AND-

(b) Diagnosis confirmed by genetic testing

-AND-

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

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

i. Patient is < 18 years of age

-AND-

ii. Submission of medical records documenting evidence of growth failure confirmed by **all** of the following:

- Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
- Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
- Calculated growth velocity

-OR-

(b) Patient is ≥ 18 years of age

-AND-

(3) Patient does not have **any** of the following:
(a) Active malignancy
(b) Severe obesity (weight >225 percent of ideal body weight)
(c) Severe respiratory impairment

-AND-

(4) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

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

i. Patient is < 18 years of age

-AND-

ii. Submission of medical records documenting a height increase of at least 2 cm/year over the previous year of treatment as documented by **all** of the following:

- Previous length/height and date obtained
- Current length/height and date obtained
- Calculated growth velocity
- Growth charts for length/height for age and gender

-AND-

iii. Submission of medical records documenting **both** of the following:
- Expected adult height not attained
- Documentation of expected adult height goal

-OR-

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

i. Patient is ≥ 18 years of age

-AND-

ii. Submission of medical records documenting positive response to therapy (e.g., reduction in fat mass, increase in lean body mass, improved strength and exercise tolerance)

-AND-

(2) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

F. 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) Submission of medical records documenting a diagnosis of growth

failure associated with SGA

-AND-

(3) Submission of medical records documenting diagnosis has been confirmed by **all** of the following:

(a) Growth charts for length/height and weight for age and gender

-AND-

(b) Documentation that one of the following is ≥ 2 SD below mean for gestational age:

i. Birth weight
ii. Birth length

-AND-

(c) Documentation that current length/height remains ≥ 2 SD below mean for age and gender at 2 to 3 years of age

-AND-

(d) Calculated growth velocity

-AND-

(3) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Submission of medical records documenting a height increase of at least 2 cm/year over the previous year confirmed by **all** of the following:

(a) Previous length/height and date obtained
(b) Current length/height and date obtained
(c) Calculated growth velocity
(d) Growth chart for length/height for age and gender

-AND-

(2) Submission of medical records documenting **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.

G. Turner Syndrome or Noonan Syndrome

1. **Initial Therapy**

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

(1) Submission of medical records documenting **one** of the following:

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

i. Diagnosis of Turner Syndrome
ii. Diagnosis confirmed by genetic testing

-OR-

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

i. Diagnosis of Noonan Syndrome
ii. Diagnosis confirmed by the presence of clinical features consistent with Noonan Syndrome (e.g., distinct facial features such as high forehead, hypertelorism, down slanting palpebral fissures with high arched eyebrows, epicanthic folds, full upper lip with a depressed nasal bridge, low set ears, blue irises, ptosis and neck webbing, pulmonary valve stenosis, hypertrophic cardiomyopathy, pectus carinatum/excavatum, mild developmental delay, cryptorchidism, lymphatic dysplasia)

-AND-

(2) Submission of medical records documenting **all** of the following:

(a) Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
(b) Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
(c) Calculated growth velocity

-AND-

(d) Submission of medical records documenting open epiphyses in the last 12 months

-AND-

(e) Submission of medical records documenting Tanner staging ≤ 4

-AND-

(f) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Submission of medical records documenting a height increase of at least 2 cm/year over the previous year documented by **all** of the following:

(a) Previous length/height and date obtained
(b) Current length/height and date obtained
(c) Calculated growth velocity
(d) Growth chart for height for age and gender

-AND-

(2) Submission of medical records documenting **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.

H. Short-Stature Homeobox (SHOX) Gene Deficiency

1. **Initial Therapy**

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

(1) Submission of medical records documenting **both** of the following:

(a) Diagnosis of short-stature homeobox (SHOX) gene deficiency

-AND-

(b) Diagnosis confirmed by genetic testing

-AND-

(2) Submission of medical records documenting **all** of the following:

(a) Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
(b) Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
(c) Calculated growth velocity

-AND-

(3) Submission of medical records documenting open epiphyses in the last 12 months

-AND-

(4) Submission of medical records documenting Tanner stage ≤ 4

-AND-

(5) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Submission of medical records documenting a height increase of at least 2 cm/year over the previous confirmed by **all** of the following:

(a) Previous length/height and date obtained
(b) Current length/height and date obtained
(c) Calculated growth velocity
(d) Growth chart for height for age and gender

-AND-

(2) Submission of medical records documenting **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.

I. Growth Failure associated with Chronic Renal Insufficiency

1. **Initial Therapy**

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

(1) Submission of medical records documenting **all** of the following:

(a) Diagnosis of chronic renal insufficiency

-AND-

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

i. Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
ii. Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
iii. Calculated growth velocity

-AND-

(c) Documentation of open epiphyses in the last 12 months

-AND-

(d) Tanner stage ≤ 4

-AND-

(2) Patient has not yet had a renal transplant

-AND-

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

(a) Endocrinologist
(b) Nephrologist

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Submission of medical records documenting a height increase of at least 2 cm/year over the previous year confirmed by **all** of the following:

(a) Previous length/height and date obtained
(b) Current length/height and date obtained
(c) Calculated growth velocity
(d) Growth chart for height for age and gender

-AND-

(2) Submission of medical records documenting **both** of the following:

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

-AND-

(4) Patient has not yet had a renal transplant

-AND-

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

(a) Endocrinologist
(b) Nephrologist

Authorization will be issued for 12 months.

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

1. **Initial Therapy**

a. **Serostim** will be approved based on submission of medical records documenting **all** of the following criteria:

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

-AND-

(2) Involuntary weight loss of ≥10%

-AND-

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

(a) Chronic diarrhea (2 loose stools daily for more than 30 days)

-OR-

(b) **Both** of the following:
i. Chronic weakness

ii. Fever

-AND-

(4) Symptoms lasting ≥ 30 days (intermittent or constant)

-AND-

(5) Absence of a concurrent condition other than HIV infection that may cause these findings (e.g., depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy except for Kaposi's sarcoma limited to skin or mucous membranes)

-AND-

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

-AND-

(7) 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 submission of medical records documenting **both** of the following criteria:

(1) Documentation of a positive response to therapy (i.e., ≥ 2% increase in body weight and/or body cell mass)

-AND-

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

(a) Weight
(b) Body cell mass (BCM)
(c) Body mass index (BMI)

Authorization will be issued for 6 months.

K. Short Bowel Syndrome (Zorbtive only)

1. **Zorbtive** will be approved based on submission of medical records documenting **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.

L. 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) Submission of medical records documenting **all** of the following:

(a) Diagnosis of idiopathic short stature

-AND-

(b) Diagnostic evaluation has excluded other causes associated with short stature (e.g., skeletal dysplasia, genetic conditions associated with short stature, rapid tempo puberty, precocious puberty, celiac disease, inflammatory bowel disease, renal failure, hepatic failure, rheumatoid arthritis, systemic lupus, etc.)

-AND-

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

i. Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
ii. Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
iii. Calculated growth velocity

-AND-

(d) Documentation of open epiphyses in the last 12 months

-AND-

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

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

-OR-

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

i. **One** of the following:

- Poor catch-up growth on standard dosing

-OR-

- IGF-1 < 2 SD from the mean while on standard dosing

-AND-

ii. Tanner Stage 2 or greater

-AND-

iii. Request does not exceed a maximum supply limit of 0.7 mg/kg/week

-AND-

(3) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Submission of medical records documenting a height increase at least 2 cm/year over the previous year of treatment as confirmed by **all** of the following:

(a) Previous length/height and date obtained
(b) Current length/height and date obtained
(c) Calculated growth velocity
(d) Growth chart for height for age and gender

-AND-

(2) Submission of medical records documenting **both** of the following:

(a) Expected adult height not attained

(b) Expected adult height goal

-AND-

(3) **<u>One</u>** of the following:

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

-OR-

(b) **<u>All</u>** of the following:

i. **<u>One</u>** of the following:

- Poor catch up growth while on standard dosing

-OR-

- IGF < 2 standard deviations from the mean while on standard dosing

-AND-

ii. Tanner Stage 2 or greater

-AND-

iii. Request does not exceed a maximum supply limit of 0.7 mg/kg/week

-AND-

(4) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

M. <u>Severe Primary IGF-1 Deficiency / Growth Hormone Gene Deletion (Increlex only)</u>

1. **<u>Initial Therapy</u>**

a. **Increlex** will be approved based on **<u>all</u>** of the following criteria:

(1) Submission of medical records documenting all of the following:

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

-AND-

(b) Documentation of height below -3.0 SD mean for age and gender

-AND-

(c) Documentation of IGF-1 below -3.0 SD mean for age and gender

-AND-

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

i. Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
ii. Calculated growth velocity

-AND-

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

i. Patient is unresponsive to a trial of growth hormone therapy

-OR-

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

- Very low or undetectable level of GHBP
- Very low or undetectable level of *GHR* mutations known to cause Laron syndrome/GH insensitivity syndrome
- *GH1* gene deletion (GHD type 1A)
- GH-neutralizing antibodies
- *STT5b* gene mutation
- *IGF-1* gene deletion or mutation

-AND-

(2) Other causes of low IGF-I levels have been ruled out (e.g., growth hormone deficiency, undernutrition, hepatic disease)

-AND-

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

-AND-

(4) Prescribed by an endocrinologist

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Submission of medical records documenting a height increase of at least 2 cm/year over the previous year of treatment as confirmed by **all** of the following:

(a) Previous length/height and date obtained
(b) Current length/height and date obtained
(c) Calculated growth velocity
(d) Growth chart for height for age and gender

-AND-

(2) Submission of medical records documenting **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.

*Genotropin, Humatrope, Nutropin, 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:

1. Genotropin [package insert]. New York, NY: Pharmacia & Upjohn Company; August 2024.
2. Humatrope [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2023.
3. Norditropin [package insert]. Plainsboro, NJ: Novo Nordisk Pharmaceuticals, Inc.; March 2020.
4. Nutropin AQ, Nutropin AQ NuSpin [package insert]. South San Francisco, CA: Genentech, Inc.; December 2016.
5. Omnitrope [package insert]. Princeton, NJ: Sandoz, Inc.; March 2024.
6. Saizen [package insert]. Rockland, MA: EMD Serono, Inc.; February 2020.
7. Zomacton [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; April 2024
8. Ngenla [package insert]. New York, NY: Pfizer, Inc.; June 2023.
9. Skytrofa [package insert]. Palo Alto, CA: Acendis Pharma Endocrinology, Inc.; May 2024.
10. Sogroya [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; April 2023.
11. Serostim [package insert]. Rockland, MA: EMD Serono, Inc.; June 2019.
12. Zorbtive [package insert]. Rockland, MA: EMD Serono, Inc.; September 2019.
13. Increlex [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; March 2024.
14. Stagi S, Tufano M, Chiti N, et al. Management of Neonatal Isolated and Combined Growth Hormone Deficiency: Current Status. *Int J Mol Sci*. 2023;24(12):10114.
15. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use in Growth Hormone-Deficient Adults and Transition Patients—2009 Update. Endocr Pract. 2009;15(Suppl 2):1-29.
16. Grimberg A, DiVall SA, Polychronakos C, et al. 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. *Horm Res Paediatr*. 2016;86(6):361-397.
17. 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.

18. Butler MG, Miller JL, Forster JL. Prader-Willi Syndrome - Clinical Genetics, Diagnosis and Treatment Approaches: An Update. *Curr Pediatr Rev*. 2019;15(4):207-244.
19. Hokken-Koelega ACS, van der Steen M, Boguszewski MCS, Cianfarani S, Dahlgren J, Horikawa R, Mericq V, Rapaport R, Alherbish A, Braslavsky D, Charmandari E, Chernausek SD, Cutfield WS, Dauber A, Deeb A, Goedegebuure WJ, Hofman PL, Isganatis E, Jorge AA, Kanaka-Gantenbein C, Kashimada K, Khadilkar V, Luo XP, Mathai S, Nakano Y, Yau M. International Consensus Guideline on Small for Gestational Age: Etiology and Management From Infancy to Early Adulthood. Endocr Rev. 2023 May 8;44(3):539-565
20. Gravholt CH, Andersen NH, Christin-Maitre S, et al. Clinical practice guidelines for the care of girls and women with Turner syndrome. *Eur J Endocrinol*. 2024;190(6):G53-G151.
21. Allanson JE. Noonan syndrome. *J Med Genet.* 1987; 24:9.
22. van der Burgt I, Berends E, Lommen E, et al. Clinical and molecular studies in a large Dutch family with Noonan syndrome. *Am J Med Genet.* 1994; 53:187.
23. Dahlgren J, Noordam C. Growth, Endocrine Features, and Growth Hormone Treatment in Noonan Syndrome. *J Clin Med*. 2022;11(7):2034.
24. Blum WF, Crowe BJ, Quigley CA, et al. Growth hormone is effective in treatment of short stature associated with short stature homeobox-containing gene deficiency: Two-year results of a randomized, controlled, multicenter trial. *J Clin Endocrinol Metab*. 2007;92(1):219-228.
25. Blum WF, Ross JL, Zimmermann AG, et al. GH treatment to final height produces similar height gains in patients with SHOX deficiency and Turner syndrome: results of a multicenter trial [published correction appears in J Clin Endocrinol Metab. 2013 Dec;98(12):4992]. *J Clin Endocrinol Metab*. 2013;98(8):E1383-E1392.
26. Molitch ME, Clemmons DR, Malozowski S, et al. Evaluation and Treatment of Adult Growth Hormone Deficiency: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2011 Jun;96(6):1587-609.
27. Yuen KCJ, Biller BMK, Radovick S, et al. American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) Guidelines for Management of Growth Hormone Deficiency in Adults and Patients Transitioning from Pediatric to Adult Care. Endocr Pract. 2019;25.
28. Nemechek PM, Polsky B, Gottlieb MS. Treatment guidelines for HIV-associated wasting. Mayo Clin Proc. 2000 Apr;75(4):386-94.
29. Polsky B, Kotler D, Steinhart C. HIV-associated wasting in the HAART era: guidelines for assessment, diagnosis and treatment. AIDS Patient Care STDS. 2001;15(8):411-23.
30. Gelato M, McNurlan M, Freedland E. Role of recombinant human growth hormone in HIV-associated wasting and cachexia: pathophysiology and rationale for treatment. *Clin Ther*. 2007;29(11):2269-2288.
31. Chou JH, Roumiantsev S, Singh R. PediTools Electronic Growth Chart Calculators: Applications in Clinical Care, Research, and Quality Improvement. J Med Internet Res. 2020 Jan 30;22(1):e16204.

Program	Prior Authorization/Medical Necessity - Human Growth Hormone and Growth Stimulating Products
Change Control	
2/2014	Developed new medical necessity criteria through revised criteria to include dosing, specialist prescriber and no combination therapy for adult GHD.
8/2014	Clarified medical record requirement language.
5/2015	Added dosing charts for ped & adult GHD. Removed Tev-tropin.
8/2015	Added Zomacton. Removed dosing charts and added requirement for

	SL dosing maximum to pediatric GHD, adult GHD, transitional, and ISS Updated formatting.
6/2016	Added Tanner Stage 3 to pediatric GHD as a requirement for dosing up to a maximum of 0.7 mg/kg/week. Added bone age and growth velocity to pediatric GHD and ISS. Clarified expected adult height.
12/2016	Revised medical record requirement language and clarified criteria for diagnosis of pediatric GH deficiency.
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, supply limits, and references.
4/2020	Added requirement for state of California.
7/2021	Annual review. No change to clinical criteria. Updated references.
1/2022	Removed Nutropin and Nutropin AQ which are no longer commercially available. Added coverage criteria for new product, Skytrofa, for pediatric GHD. Updated background and references.
5/2022	Updated requirement for idiopathic short stature to only include Maryland.
7/2022	Removed exclusion notation from Norditropin. Added Norditropin as additional step therapy for Skytrofa.
7/2023	Annual review. Updated references.
11/2023	Added coverage criteria for Ngenla and Sogroya. Removed drug-specific dosing requirements from coverage criteria. Removed Skytrofa and added Sogroya to exclusion footnote. Updated background and references.
2/2024	Removed Omnitrope from exclusion footnote.
10/2024	Added Nutropin to exclusion footnote.
2/2025	Annual review. Updated authorization criteria to align with the most current treatment guidelines for all indications. Removed Nordiflex from program which has been discontinued. Updated background and references.
8/2025 - supplemental	Supplemental update to include levodopa as acceptable GH stimulation test for pediatric GHD.