Generic Name: Somatropin, somapacitan-beco, somatrogon-ghla, lonapegsomatropin-tcgd

Therapeutic Class or Brand Name: Growth Hormone

Applicable Drugs: Norditropin, Genotropin, Sogroya, Ngenla, Serostim, Omnitrope, Humatrope, Nutropin AQ, Zomacton, Skytrofa

Preferred: Norditropin, Genotropin, Sogroya, Ngenla

Non-preferred: Serostim, Omnitrope, Humatrope, Nutropin AQ, Zomacton, Skytrofa

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 7/30/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of one of the following conditions A through F AND must meet ALL criteria listed under applicable diagnosis.

A. Growth Hormone Deficiency (GHD) in Pediatrics

i. Documented biochemical growth hormone deficiency by meeting ONE of the criteria 1 through 4:

1. Two growth hormone (GH) stimulation tests below 10 ng/mL (mcg/L).

a. Documentation of sex steroid priming before GH stimulation test in prepubertal boys older than 11 years and prepubertal girls older than 10 years, with adult height prognosis within 2 standard deviations (SDS) below the reference mean for the patient's age and gender.

2. Hypothalamic-pituitary defect (e.g., ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk, tumor, or irradiation) AND deficiency of at least one additional pituitary hormone.

3. Multiple pituitary hormone deficiencies (MPHDs) exist (at least two others in addition to GHD).

4. Congenital GHD (GH levels < 5 ng/mL (mcg/L) detected during an acute episode of hypoglycemia).

ii. Initial bone age confirming open growth plates.

iii. Short stature/growth failure (subnormal growth rate) by meeting ONE of the criteria 1, 2, or 3:

1. Height is below the 3rd percentile for age and gender.

2. Height is below the 5th percentile and untreated growth velocity is below the 25th percentile for age and gender (with at least 1 year of growth data).
3. If pediatric GHD criteria under i4 are met, short stature/growth failure is not needed.

iv. Other causes for short stature have been ruled out (e.g., growth-inhibiting medication, endocrine disorders, psychosocial short stature).

B. GHD in Transition Period Adolescents or Adults

i. Documented persistent biochemical childhood onset or adult onset GHD by meeting ONE of the criteria 1, 2, 3, or 4:

1. Hypothalamic-pituitary congenital/genetic defect or organic hypothalamic-pituitary disease (e.g., craniopharyngioma, pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation) and meets criteria a and b:
    a. ≥ 3 MPHDs (at least two others in addition to GHD).
    b. Serum IGF-1 level (> 2.0 SDS below the mean for age and gender).
2. Organic GHD with 0 to 2 pituitary hormone deficiencies and meets criteria a and b:
    a. Serum IGF-1 > 0 SDS below the mean for age and gender.
    b. GH provocative stimulation test (with insulin, macimorelin, or glucagon) with a measured peak level as indicated for the respective provocation agent (Table 1) at least 1 month following the discontinuation of GH therapy.
3. Idiopathic childhood onset GHD and meets criteria a and b:
    a. Serum IGF-1 level (> 0 SDS below the age and gender-adjusted normal range).
    b. GH provocative stimulation test (with insulin, macimorelin, or glucagon) with a measured peak level as indicated for respective provocation agent (Table 1) at least 1 month following the discontinuation of GH therapy.
4. Adult onset GHD and meets criteria a through c:
    a. History of hypothalamic-pituitary tumors, surgery, cranial irradiation, empty sella, pituitary apoplexy, traumatic brain injury, subarachnoid hemorrhage, autoimmune hypophysitis, or Rathke's cleft cyst.
    b. Serum IGF-1 level (> 0 SDS below the mean for age and gender).

c. GH provocative stimulation test (with insulin, macimorelin, or glucagon) with a measured peak level as indicated for respective provocation agent (Table 1).

ii. If the patient is a transition period adolescent, there must also be documentation of all the following 1 through 3:

1. Closed epiphyses on bone radiograph.
2. Patient has attained expected adult height.
3. Patient does not have disorders other than GHD for which GH treatment is indicated (e.g., Prader-Willi syndrome (PWS), children born small for gestational age (SGA), Turner syndrome, Noonan syndrome, chronic kidney disease (CKD)).

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

i. Minimum age requirement: 2 years old.

ii. Documentation that the patient was born SGA, defined as birth weight and/or length ≥ 2 SDS below the mean for gestational age and gender (including infants born with intrauterine growth restriction or Russell-Silver Syndrome resulting in SGA).

iii. Short stature/growth failure (subnormal growth rate) by 2 to 4 years of age with height ≥ 2 SDS below the mean for age and gender.

iv. Other causes for short stature have been ruled out (e.g., growth-inhibiting medications, endocrine disorders, psychosocial short stature).

v. Documented initial bone age confirming open growth plates.

D. Growth Failure Associated with a Genetic Condition in Pediatrics

i. Documented diagnosis of one of the following 1 through 4:

1. Prader-Willi Syndrome (PWS) confirmed by genetic testing.
2. Turner Syndrome confirmed by karyotype analysis.
3. Noonan Syndrome confirmed by genetic testing and/or characteristic clinical features.
4. Short Stature Homeobox-containing Gene (SHOX) Deficiency confirmed by genetic testing.

ii. Short stature/growth failure (subnormal growth rate) with height ≥ 2 SDS below the mean for age and gender.

iii. Documented initial bone age confirming open growth plate.

E. Growth Failure Associated with Chronic Kidney Disease (CKD) in Pediatrics

i. Documented diagnosis of CKD with estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m^2.

ii. Short stature/growth failure (subnormal growth rate) with height below the 5th percentile and untreated growth velocity below the 25th percentile for age and gender (with at least 1 year of growth data).

iii. Documented initial bone age confirming open growth plates.

F. Human Immunodeficiency Virus (HIV)-associated Wasting or Cachexia in Adults

i. Documented diagnosis of HIV and concomitant use of antiretroviral therapy.

ii. Unintentional weight loss of ≥ 10% from baseline, weight less than 90% of the lower limit of ideal body weight, OR body mass index (BMI) of less than 20 kg/m^2.

iii. Documented nutritional evaluation and failure to respond adequately to a high-calorie diet.

II. Treatment must be prescribed by or in consultation with a pediatric endocrinologist, pediatric nephrologist, endocrinologist, gastroenterologist, or infectious disease specialist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure.
- Children with PWS who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment.
- Active malignancy.
- Active proliferative or severe non-proliferative diabetic retinopathy.
- Children with closed epiphyses (except for GHD in adolescents during the transition period).

OTHER CRITERIA

- Short Bowel Syndrome (SBS) in Adults
  - Documented diagnosis of SBS and concomitant specialized nutritional support.
  - Documented ability to ingest solid food.
  - Documented dependence on parenteral nutrition at least five days per week to provide at ≥ 3,000 calories per week.
  - Documented chart notes indicating dietary needs and goals have been addressed.
  - Request is for Zorbtive and fulfills Prior Authorization Criteria II, III, and IV.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- The quantity is limited to a maximum of a 30-day supply per fill.

APPROVAL LENGTH

- **Authorization:**
  - GHD in Transition Period Adolescents or Adults: Up to 12 months
  - CKD in Pediatrics: Up to 12 months or until time of renal transplantation, whichever is shorter
  - SBS in Adults: One time for up to 4 weeks
  - HIV-related Wasting in Adults: Up to 12 weeks
  - All other diagnoses in Pediatrics: Up to 12 months or until maximum bone age is met, whichever is shorter
    - Males: maximum bone age of 16 years
    - Females: maximum bone age of 14 years
- **Re-Authorization:**
  - GHD in Adults: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.
  - SBS in Adults: N/A
  - HIV-related Wasting in Adults: An additional 12 weeks of therapy may be approved in patients who still meet current medical necessity criteria and demonstrate weight gain with the initial 12 weeks of therapy.
  - All other diagnoses in Pediatrics (including GHD): An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the patient's growth velocity is > 2.5 cm/year. Must also include documentation of the following (if applicable):
    - Bone age must be obtained annually when chronological age reaches 15 years for males or 13 years for females. Therapy must not exceed a bone age of 16 years for males or 14 years for females.
    - If the diagnosis is chronic kidney disease (CKD), the patient must still have an eGFR < 60 ml/min/1.73 m^2.

APPENDIX

Table 1. GH Stimulation Test Peak Cutoffs by Provocation Test Type.

GH Provocation Test	Peak GH Cut-Off Range for GHD in the Transition Period
ITT	≤ 5 ng/mL
Macimorelin	≤ 2.8 ng/mL

GST	BMI < 25 kg/m^2:	≤ 3.0 ng/mL
	BMI 25 to 30 kg/m^2:	≤ 3.0 ng/mL with a high pre-test probability
	BMI 25 to 30 kg/m^2:	≤ 1.0 ng/mL with a low pre-test probability
	BMI > 30 kg/m^2:	≤ 1.0 ng/mL

Abbreviations: BMI, body mass index; GH, growth hormone, GHD, growth hormone deficiency, GST, glucagon stimulation test; ITT, insulin tolerance test.

Table 2. GH Products by FDA-approved Pediatric Indications

GH Product (brand)	GHD	PWS	SGA	Turner Syndrome	SHOX Deficiency	Noonan Syndrome	CKD
Genotropin	X	X	X	X			
Humatrope	X		X	X	X		
Ngenla	X						
Norditropin	X	X	X	X		X	
Nutropin AQ	X			X			X
Omnitrope	X	X	X	X			
Sogroya	X						
Skytrofa	X						
Zomacton	X		X	X	X		

Abbreviations: CKD, chronic kidney disease stages 3-5; GHD, growth hormone deficiency, GHD; PWS, Prader-Willi Syndrome; SGA, small for gestational age with no catch-up growth by 2 to 4 years; SHOX, short stature homeobox-containing gene.

Table 3. GH Products by FDA-approved Adult Indications

GH Product (brand)	Adult GHD	HIV-related Wasting	Short Bowel Syndrome
Genotropin	X		
Humatrope	X		
Norditropin	X		
Nutropin AQ	X		
Omnitrope	X		
Serostim		X	
Sogroya	X		
Skytrofa	X		
Zomacton	X		
Zorbtive			X

Abbreviations: HIV, human immunodeficiency virus; GHD, growth hormone deficiency.

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