

Generic Name: Somatropin, somapacitan-beco (adult)

Therapeutic Class or Brand Name: Growth Hormone (adult)

Applicable Drugs (if Therapeutic Class):
Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Sogroya, Zomacton, Zorbtive

Preferred: Genotropin, Norditropin, Sogroya

Non-preferred: Humatrope, Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton, Zorbtive

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 1/1/2025

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of one of the following conditions A through D AND must meet criteria listed under applicable diagnosis:
 - A. Childhood-onset growth hormone deficiency (GHD) with persistent biochemical GHD into adulthood and ONE of the criteria 1, 2, or 3 is met:
 1. Documented congenital defects, genetic defects, and organic hypothalamic-pituitary disease (e.g., craniopharyngioma, pituitary hypoplasia, ectopic posterior pituitary, or previous cranial irradiation) with ≥ 3 multiple pituitary hormone deficiencies (MPHDs) (at least two others in addition to GHD) and one serum IGF-1 level (> 2.0 SDS below the mean for the patient's age and gender).
 2. Documented organic hypothalamic-pituitary disease (e.g., craniopharyngioma, pituitary hypoplasia, ectopic posterior pituitary, or previous cranial irradiation) with 0 to 2 pituitary hormone deficiencies, one serum IGF-1 (> 0 SDS below the mean for the patient's age and gender), and one 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.
 3. Documented idiopathic childhood GHD with one serum IGF-1 level (> 0 SDS below the age and gender-adjusted normal range) and one 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.
 - B. Adult-onset GHD and ONE of the criteria 1, 2, or 3 is met:
 1. Documented organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with ≥ 3 MPHDs (at least two others in addition to GHD) and one low serum IGF-1 level (> 2.0 SDS below the mean for the patient's age and gender).

2. Documented organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with 0 to 2 pituitary hormone deficiencies, one serum IGF-1 (> 0 SDS below the mean for the patient's age and gender), and one GH provocative stimulation test (with insulin, macimorelin, clonidine, or glucagon) with a measured peak level as indicated for respective provocation agent (Table 1.)
 3. Documented history of hypothalamic-pituitary tumors, surgery, cranial irradiation, empty sella, pituitary apoplexy, traumatic brain injury, subarachnoid hemorrhage, autoimmune hypophysitis, or Rathke's cleft cyst, one serum IGF-1 (> 0 SDS below the mean for the patient's age and gender), and one GH provocative stimulation test (with insulin, macimorelin, or glucagon) with a measured peak level as indicated for respective provocation agent (Table 1.)
- C. Short Bowel Syndrome (SBS) and criteria 1 through 3 are met:
1. Ability to ingest solid food.
 2. Dependent on parenteral nutrition at least five days per week to provide at least 3,000 calories per week.
 3. Chart notes to indicate dietary needs and goals have been addressed.
- D. Acquired immunodeficiency syndrome (AIDS) Wasting Syndrome and criteria 1 through 4 are met:
1. Documented diagnosis of AIDS.
 2. The patient must be currently taking antiretroviral medications.
 3. Documented weight loss of at least 10% from baseline weight OR a body mass index (BMI) of less than 20.
 4. Documentation that the patient has had an adequate nutritional evaluation and has failed to respond adequately to a high-calorie diet.
- II. Treatment must be prescribed by or in consultation with an endocrinologist, gastroenterologist, or infectious disease specialist.
- III. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Acute Critical Illness due to complications following open heart surgery, abdominal surgery, or multiple accidental trauma or those with acute respiratory failure.
- Active Malignancy.
- Active Proliferative or Severe Non-Proliferative Diabetic Retinopathy.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

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

APPROVAL LENGTH

- **Authorization:**
 - SBS: One time for up to 4 weeks.
 - AIDS-related wasting: Up to 12 weeks.
 - Growth hormone deficiency: Up to 12 months.
- **Re-Authorization:**
 - SBS: N/A
 - AIDS-related wasting: 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.
 - Growth hormone deficiency: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

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

GH provocation test	Peak GH cutoff range for Adult GHD
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 adult indications.

GH product (brand)	Adult GHD	AIDS-Related Wasting	Short bowel syndrome
Genotropin	X		
Humatrope	X		
Norditropin	X		
Nutropin AQ	X		
Omnitrope	X		
Saizen	X		
Serostim		X	

Sogroya	X		
Zomacton	X		
Zorbtive			X

Abbreviations: AIDS, acquired immunodeficiency syndrome; GHD, growth hormone deficiency.

REFERENCES

1. Yuen, K.C.J., et. al. American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Growth Hormone Deficiency in Adults and Patients Transitioning from Pediatric to Adult Care. *Endocr Pract.* 2019; 25(11), 1191-1232. doi: 10.4158/GL-2019-0405
2. Genotropin. Prescribing Information. Pfizer; 2019. Accessed November 19, 2024. <http://labeling.pfizer.com/ShowLabeling.aspx?id=577>
3. Humatrope. Prescribing Information. Eli Lilly; 2023. Accessed November 19, 2024. <http://uspl.lilly.com/humatrope/humatrope.html#pi>
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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.