



Drug Class Prior Authorization Criteria
Growth Hormone

Line of Business: Medicaid

P & T Approval Date: May 5, 2023

Effective Date: June 2, 2023

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Drugs Requiring Prior Authorization Review: Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Serostim, Zomacton (Somatropin)

| FDA indication | Genotropin | Humatrope | Norditropin | Nutropin | Omnitrope | Saizen | Serostim | Zomacton |
|--|------------|-----------|-------------|----------|-----------|--------|----------|----------|
| Child Growth Hormone Deficiency | x | x | x | x | x | x | | x |
| Child Idiopathic Short Stature | x | x | x | x | x | | | x |
| Turner Syndrome | x | x | x | x | x | | | x |
| Prader-Willi Syndrome | x | | x | | x | | | |
| Small for Gestational Age (SGA) Children | x | x | x | | x | | | x |
| Adult Growth Hormone Deficiency (GHD) | x | x | x | x | x | x | | x |
| Growth failure secondary to Chronic Kidney Disease | | | | x | | | | |
| AIDS-associated wasting | | | | | | | x | |

Note: "x" indicates the criteria for each FDA indication applicable for each agent within this policy

Covered Uses: *Child Growth Hormone Deficiency (GHD)
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: CCS Eligible

Required Medical Information: Must meet all of the following requirements:

- a. Two provocative stimulation tests of growth hormone release with peak growth hormone level of less than 10 ng/mL.
- b. Height greater than 2 standard deviations below the mean or less than 3% for age and gender.

Age Restrictions: Must be less than 18 years old

Prescriber Restrictions: Endocrinologist, Pediatrician

Other Criteria: N/A

Covered Uses: *Child Idiopathic Short Stature who pass GH stimulation tests
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: N/A

Required Medical Information:

Must meet all of the following requirements:

- a. Less than 2.25 SD below the mean in height or greater than 2 SD below the mid-parental height percentile.
- b. Must meet "1" of the following requirements:
 - i. Growth velocity less than the 25th percentile for bone age.
 - ii. Bone age greater than 2 standard deviations below the mean for age.
 - iii. Low serum insulin-like growth factor 1 (IGF-1) and/or insulin-like growth factor binding protein 3 (IGFBP3).

Age Restrictions: N/A

Prescriber Restrictions: Endocrinologist, Pediatrician

Other Criteria: N/A

Covered Uses: *Turner Syndrome
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: N/A

Required Medical Information:

Must meet all of the following requirement:

- a. Height greater than 2 standard deviations below the mean or less than 3% for age and gender.

Age Restrictions: Must be less than 18 years old

Prescriber Restrictions: Endocrinologist, Pediatrician

Other Criteria: N/A

Covered Uses: *Prader-Willi Syndrome
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: N/A

Required Medical Information: Must meet all of the following requirement:
a. Height greater than 2 standard deviations below the mean or less than 3% for age and gender.

Age Restrictions: Must be less than 18 years old

Prescriber Restrictions: Endocrinologist, Pediatrician

Other Criteria: N/A

Covered Uses: *Small for Gestational Age (SGA) Children
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: N/A

Required Medical Information: Must meet all of the following requirements:
a. Birth weight below the 10th percentile for gestational age.
b. Height greater than 2 standard deviations below the mean or less than 3% for age and gender by age 2.

Age Restrictions: Must be less than 18 years old

Prescriber Restrictions: Endocrinologist, Pediatrician

Other Criteria: N/A

Covered Uses: *Adult Growth Hormone Deficiency (GHD)
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: N/A

Required Medical Information: Must meet all of the following requirements:
a. Two provocative stimulation tests of growth hormone release with peak growth hormone level of less than 5 ng/mL.
b. Documented GHD associated with pituitary disease, irradiation, surgery, or trauma.

Age Restrictions: Must age of 18 years or older

Prescriber Restrictions: Endocrinologist

Other Criteria: N/A

Covered Uses: *Chronic Kidney Disease (CKD)
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: CCS Eligible

Required Medical Information: Must meet all of the following requirements:

- a. Height greater than 2 standard deviations below the mean or less than 3% for age and gender.
- b. Prior to renal transplantation.

Age Restrictions: Must be less than 18 years old

Prescriber Restrictions: Endocrinologist, Nephrologist or Pediatrician

Other Criteria: N/A

Covered Uses: *AIDS-associated wasting
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: N/A

Required Medical Information: Must meet all of the following requirements:

- a. One of the following criteria for HIV-associated wasting:
 - i. Body mass index (BMI) less than 20 kg/m²
 - ii. BMI between 20 kg/m² and 25 kg/m² and
 - i. Involuntary weight loss greater than 10% within past 12 months, or,
 - ii. Involuntary weight loss greater than 7.5 % within past 6 months.
- b. Currently receiving antiviral agents and has a viral load assay and a CD4 count.
- c. Failure or intolerance to appetite stimulants.
- d. Failure or contraindication to anabolic steroid treatment.

Age Restrictions: N/A

Prescriber Restrictions: Endocrinologist, HIV Specialist

Other Criteria: N/A

Section I: Monitoring

- a. Should be performed by a pediatric endocrinologist in partnership with the pediatrician or primary care physician and should be conducted on a 3 to 6 months basis (90 to 180 days).
- b. Increase in height and change in height velocity should be assessed.
- c. Monitoring of serum IGF-I (preferred for GHD) and IGFBP-3 levels (for short stature in children younger than 3 years).
- d. Monitoring T₄ and TSH to detect hypothyroidism (can appear during GH therapy).

Section II: Therapy End Point

- a. Pediatric:
 - i. Treatment to continue until final height or epiphyseal closure has been documented.
 - ii. Bone age greater than 15 years for girls and greater than 16 years for boys.
 - iii. Growth rate less than 2.5cm / year.
 - iv. Achievement of mid-parental adult height.
 - v. Further treatment is generally futile if no increase in growth rate or serum IGF over baseline within the first 6 months to 1 year (180 days to 365 days) in a compliant patient receiving an appropriate dose of GH.
- b. Adult:
 - i. IGF-I levels above normal.
 - ii. Decrease in LDL, increase in HDL, and a change in body composition.
 - iii. Decrease in body fat and an increase in bone density.
 - iv. If a patient shows no improvement when maximum dose is achieved, treatment should be discontinued.

References:

- 1. California Department of Health Care Services. Medi-Cal Provider Manual: Injections, Drugs S-Z Policy (inject drug s-z). Accessed April 13, 2023.
- 2. 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.

| Change Control | | |
|----------------|---|--------|
| Date | Change | RPH |
| 05/05/2023 | <ul style="list-style-type: none">• Updated policy to: include criteria for Omnitrope, Zomacton, and exclude criteria for Zorbtive• Created a table for FDA indications covered in this criteria | TL, SV |

| | | |
|------------|--|---------------|
| | <ul style="list-style-type: none"> Removed criteria "Failure or clinically significant adverse effects to the formulary alternative: Omnitrope vial." Updated Serostim BMI criteria Updated reference | |
| 04/15/2022 | <ul style="list-style-type: none"> Removed Omnitrope vial as it not a formulary alternative | VM |
| 04/16/2021 | <ul style="list-style-type: none"> Renew with no changes | JM |
| 02/19/2020 | <ul style="list-style-type: none"> Renew with no changes | ND |
| 02/20/2019 | <ul style="list-style-type: none"> Added Omnitrope vial to Formulary with PA Updated criteria for Genotropin, Humatrope, Norditropin, Nutropin, Saizen, Zorbtive to require trial and failure of formulary alternative: Omnitrope vial | ND |
| 06/29/2018 | <ul style="list-style-type: none"> Changed Format | IK |
| 02/21/2018 | <ul style="list-style-type: none"> Renewed with no new updates/changes. | Clinical Team |