



Inland Empire Health Plan

Drug Class Prior Authorization Criteria
Growth Hormones

Line of Business: Medicaid

P & T Approval Date: May 7, 2021

Effective Date: May 7, 2021

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 vial, Saizen, Serostim, Zorbtive (Somatropin)

CRITERIA:

OMNITROPE vial (SOMATROPIN)

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 deviation 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 midparental 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 deviation 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 the following requirement:

- a. Height greater than 2 standard deviation 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 the following requirement:
a. Height greater than 2 standard deviation 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 deviation 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

GENOTROPIN, HUMATROPE, NORDITROPIN, SAIZEN, ZORBTIVE (SOMATROPIN)

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 deviation below the mean or less than 3% for age and gender.
- c. Failure or clinically significant adverse effects to the formulary alternative: Omnitrope vial.

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 midparental 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 deviation 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).

c. Failure or clinically significant adverse effects to the formulary alternative: Omnitrope vial.

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 the following requirement:
a. Height greater than 2 standard deviation below the mean or less than 3% for age and gender.
b. Failure or clinically significant adverse effects to the formulary alternative: Omnitrope vial.

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 the following requirement:
a. Height greater than 2 standard deviation below the mean or less than 3% for age and gender.
b. Failure or clinically significant adverse effects to the formulary alternative: Omnitrope vial.

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 deviation below the mean or less than 3% for age and gender by age 2.
- c. Failure or clinically significant adverse effects to the formulary alternative: Omnitrope vial.

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.
- c. Failure or clinically significant adverse effects to the formulary alternative: Omnitrope vial.

Age Restrictions: Must age of 18 years or older

Prescriber Restrictions: Endocrinologist

Other Criteria: N/A

NUTROPIN (SOMATROPIN)

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 deviation below the mean or less than 3% for age and gender.
- c. Failure or clinically significant adverse effects to the formulary alternative: Omnitrope vial.

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 midparental 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 deviation 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).
- c. Failure or clinically significant adverse effects to the formulary alternative: Omnitrope vial.

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 the following requirement:
a. Height greater than 2 standard deviation below the mean or less than 3% for age and gender.
b. Failure or clinically significant adverse effects to the formulary alternative: Omnitrope vial.

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.
c. Failure or clinically significant adverse effects to the formulary alternative: Omnitrope vial.

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 deviation 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

SEROSTIM (SOMATROPIN)

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. Involuntary weight loss greater than 10% of normal baseline body weight or body mass index (BMI) less than 20 kg/m² without a concurrent condition other than HIV infection that may have contributed to the condition.
- b. Currently receiving antiviral agents.
- 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 level 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. 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.
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Change Control		
Date	Change	RPH
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 PAUpdated 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