



## Pharmacy Prior Authorization Growth Hormone- Clinical Guidelines

Genotropin<sup>®</sup>  
Humatrope<sup>®</sup>  
Norditropin<sup>®</sup>

Nutropin<sup>®</sup>  
Omnitrope<sup>®</sup>  
Saizen<sup>®</sup>

Serostim<sup>®</sup>  
Zorbtive<sup>®</sup>

Zomacton<sup>®</sup>  
somatropin

### **General Criteria for Approval:**

Omnitrope vial formulation is the preferred Growth Hormone product; consideration for an alternative product will be provided upon one of the following:

1. Documentation to support trial and failure or contraindication to preferred product
2. An inability or disability to use vial formation (i.e., visual impairment) Or
3. Treatment is for an indication not supported by the preferred GH product

### **Additional Criteria Based on Indication:**

#### **Growth Hormone Deficiency:**

**For patients who meet all of the following** (with submitted charts notes and lab results):

- Documentation to support diagnosis of GHD of children with growth failure due to inadequate secretion of endogenous growth hormone.
- Prescribed by a Pediatric Endocrinologist
- Failure of 2 standard growth hormone stimulation tests (serum peak GH level of < 10 ng/mL, after stimulation with insulin, levodopa, arginine, propranolol, clonidine or glucagon). Note: one abnormal GH test is sufficient for children with brain tumors and irradiation with documented multiple pituitary hormone deficiency (MPHD).
- Appropriate imaging (MRI or CT) of the brain to exclude tumor on hypothalamic-pituitary region.

#### **AND one of the following:**

- Child has severe growth retardation with height standard deviation score (SDS) more than 3 SDS below the mean for chronological age and sex; **OR**
- Child has moderate growth retardation with height SDS between -2 and -3 SDS below the mean chronological age and sex and decreased growth rate (growth velocity measured over one year below 25th percentile for age and sex); **OR**
- Child exhibits severe deceleration in growth rate (growth velocity measured over 1 year –2 SDS below the mean for age and sex); **OR**
- Child has decreasing growth rate combined with a predisposing condition such as previous cranial irradiation or tumor; **OR**
- Child exhibits evidence of other pituitary hormone deficiencies or signs of congenital GHD (hypoglycemia, micropallus)

#### **Turner Syndrome, Prader Willi Syndrome, SHOX, or Noonan's Syndrome:**

*(Noonan Syndrome: Norditropin)*

*(Prader-Willi Syndrome: Genotropin, Omnitrope)*

*(Turner Syndrome: Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope)*

*(SHOX: Humatrope)*

**For patients who meet all of the following** (with submitted charts notes and lab results):

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- Prescribed by an Pediatric Endocrinologist
- Documentation and lab results to support diagnosis (e.g., Turner Syndrome confirmed by karyotype studies, Prader-Willi Syndrome confirmed by genetic testing).

**AND one of the following:**

- Child has severe growth retardation with height standard deviation score (SDS) more than 3 SDS below the mean for chronological age and sex; **OR**
- Child has moderate growth retardation with height SDS between -2 and -3 SDS below the mean chronological age and sex and decreased growth rate (growth velocity measured over one year below 25th percentile for age and sex); **OR**
- Child exhibits severe deceleration in growth rate (growth velocity measured over 1 year –2 SDS below the mean for age and sex)

**Chronic Renal Insufficiency:** (*Nutropin*)

**For patients who meet all of the following** (with submitted charts notes and lab results):

- Prescribed by a Pediatric Endocrinologist or Pediatric Nephrologist
- Documentation to support diagnosis of CRI
- Patient has not received a renal transplant
- Existing metabolic abnormalities (e.g., malnutrition, acidosis, secondary hyperparathyroidism and hyperphosphatemia - correct phosphorus to < 1.5 times the upper limit for age) have been corrected.

**AND one of the following:**

- Child has severe growth retardation with height standard deviation score (SDS) more than 3 SDS below the mean for chronological age and sex; **OR**
- Child has moderate growth retardation with height SDS between -2 and -3 SDS below the mean chronological age and sex and decreased growth rate (growth velocity measured over one year below 25th percentile for age and sex); **OR**
- Child exhibits severe deceleration in growth rate (growth velocity measured over 1 year –2 SDS below the mean for age and sex)

**Small for Gestational Age (SGA):** (*Genotropin, Humatrope, Norditropin, Omnitrope*)

**For patients who meet all of the following** (with submitted charts notes and lab results):

- Prescribed by a Pediatric Endocrinologist
- Documentation to support diagnosis defined as birth weight or length 2 or more standard deviations below the mean for gestational age.
- Child fails to manifest catch up growth by age 2-4 years of age, defined as height 2 or more standard deviations below the mean for age and sex.

Note: Review must include evaluation of growth curves from birth

**Adult Growth Hormone Deficiency (Adult-onset or childhood- onset):**

(*Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen*)

**For patients who meet all of the following** (with submitted charts notes and lab results):

- Prescribed by an Endocrinologist
- Lab results to support Baseline IGF-1

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- Documentation to support diagnosis of Growth Hormone Deficiency of childhood onset (i.e., Idiopathic/Isolated GHD or MPHD) **OR** Growth Hormone Deficiency of adult-onset (i.e., hypothalamic or pituitary disease, panhypopituitarism, cranial irradiation, pituitary adenoma, or aneurysmal subarachnoid hemorrhage).
- Member is currently receiving treatment for the pituitary deficient hormone(s).
- Member has failed to respond to at least two GH stimulation tests\* [GH peak < 5 ng/ml during an insulin tolerance test or a cross-validated GH threshold in an equivalent test (growth hormone releasing hormone, arginine, or glucagon)]. Note: only one standard GH stimulation test is required if member has low IGF-1 (i.e., -2 SDS below the mean).

**\*Childhood-Onset Transition patients:** Retesting is recommended after 1-3 month of GH treatment discontinuation. Retesting is not required for patients with known mutations, embryopathic congenital defects, irreversible hypothalamic-pituitary structural lesions, panhypopituitarism (at least 3 pituitary deficiencies), and IGF-1 levels below the mean for age and sex. For conditions such as Turner's Syndrome or ISS there is no proven benefit of continuing treatment into adulthood.

**\*\*Adult-onset:** Stimulation test is not required for members with irreversible hypothalamic-pituitary structural lesions, panhypopituitarism (at least 3 pituitary deficiencies) , and IGF-1 levels below the mean for age and sex. If GH deficiency is due to traumatic brain injury or aneurysmal subarachnoid hemorrhage, GH deficiency may be transient; therefore, GH stimulation testing should be performed at least 12 months after the event.

### Adult HIV Wasting/cachexia: (Serostim)

**For patients who meet all of the following** (with submitted charts notes and lab results):

- Prescribed by or in consultation with an infectious Disease Specialist
- Documentation to support member's height, weight, or ideal body weight (IBW)
- Involuntary weight loss of > 10% of pre-illness baseline body weight or body mass index (BMI) < 20 kg/m<sup>2</sup>, in the absence of a concurrent illness or medical condition other than HIV infection that may cause the weight loss.
- Member is receiving anti-retroviral therapy
- Member has tried and failed or is intolerant to megestrol

### Adults Short Bowel Syndrome: (Zorbtive)

**For patients who meet all of the following** (with submitted charts notes and lab results):

- Age > 18 years of age
- Patient is receiving specialized nutrition support which may include dietary adjustments, enteral feedings, parental nutrition, fluid and macronutrients (e.g. TPN or PPN)

### Initial Approval Duration:

- Adults and pediatrics indications- 6 months
- Short Bowel Syndrome (Zorbtive)- 4 weeks only
- HIV wasting- 3 months

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### Reauthorization - Pediatric Indications

- 6 months
- Documentation required:
  - Final height has not been achieved
  - No evidence of epiphyseal closure
  - Growth velocity is > 5cm/year on current dose or < 5 cm/year with intended dose increase. (Note: Growth velocity will typically decrease as final height is approached (growth velocity <2 cm/year).
  - For PWS: evidence of improvement in body composition
  - Note: for Chronic Renal Insufficiency (CRI) there is insufficient data regarding the benefit of treatment beyond three years
- **Criteria for Discontinuation in Children or Adolescent:**
  - Adult height has been reached
  - Epiphyseal plate closure
  - Uncorrectable problem with adherence
  - Decline of height velocity of < 2.0 cm in the past year. **Note:** At completion of linear growth (i.e., growth rate less than 2 cm/year), available guidelines indicate that GH treatment should be stopped for at least 3 months, and GH status should be re-assessed to determine whether continued GH treatment into adulthood is necessary.

### Reauthorization - Adult Indications

#### **Adults with GHD:**

- 6 months if IGF-1 is low but dose is being increased **OR**
- 1 year if IGF-1 is at a stable range
- Requires documentation to support improved response to treatment (i.e, BMI, lipid panel, bone density, or QOL)

#### **Adults with wasting due to HIV: (*Serostim*)**

- 12 weeks (maximum 48 weeks)
- Requires documentation to support response to therapy

#### **Adults with SBS:** No renewals authorized

### Non Coverage Criteria:

- Untreated Hypothyroidism
- Diagnosis of Idiopathic Short Stature (ISS)
- Off-label treatment for anti-aging or performance enhancement
- Children with closed epiphyses
- Acute critical illness
- Active proliferative or severe non-proliferative Diabetic Retinopathy
- Any hypersensitivity or contraindications to somatotropin
- Children with PWS who are severely obese or have severe respiratory impairment

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### Additional Information:

- SI Units = Conventional Units X 1 (mcg/L = ng/mL X 1)
- Stimulation Test: Insulin Tolerance Test (ITT) is the gold standard, however it is contraindicated in patients with seizures, CVD, or cerebrovascular disease
- Other peak values for adults include Glucagon  $\leq$  3.0 mcg/L and ARG  $<$  0.4 mcg/L

### References:

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