Approval Criteria Department of Pharmacy Services

**Generic Name:** Human growth hormone, somatropin

**Brand Name:** Tev-tropin, Humatrope, Nutropin, Nutropin AQ, Genotropin, Norditropin, Saizen, Omnitrope, Serostim, Zorbtive

**Medication Class:** Growth hormone

<table>
<thead>
<tr>
<th>FDA Approved Uses</th>
<th>Genotropin</th>
<th>Humatrope</th>
<th>Norditropin</th>
<th>Nutropin / Nutropin AQ</th>
<th>Omnitrope</th>
<th>Saizen</th>
<th>Serostim</th>
<th>Tev-Tropin</th>
<th>Zorbtive</th>
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<tbody>
<tr>
<td>Growth failure in children</td>
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<td>Growth failure associated with CKD</td>
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<td>Growth failure associated with Noonan Syndrome</td>
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<td>Growth failure associated with Prader-Willi Syndrome</td>
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<td>Growth failure associated with SHOX deficiency</td>
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<td>Growth failure associated with Turner Syndrome</td>
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<td>GHD in adults</td>
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<td>Idiopathic short stature</td>
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<td>Short bowel syndrome</td>
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<td>Wasting or cachexia associated with HIV</td>
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**Criteria for use**

- The indicated diagnosis (including any applicable labs and tests) and medication usage must be supported by documentation from the patient's medical record
- If patient meets the criteria for Growth hormone therapy, MWHP may identify a preferred formulary product for approval
- Must be prescribed by an endocrinologist
- Patient must exhibit clinical features of the syndrome of GHD in adults as associated with abnormal body composition, reduced physical performance, altered lipid metabolism, decreased bone mass, increased insulin resistance, **AND** reduced quality of life (QOL). Baseline levels must be provided:
- Cardiovascular
  - Systolic and diastolic blood pressure
  - Heart rate
  - Electrocardiogram results

- Metabolic
  - Fasting glucose
  - HbA1c
  - Fasting lipid profile
  - Body composition
    - BMI, waist circumference, waist-to-hip ratio, lean and fat mass quantification using DEXA scans

- Osteopenia / Osteoporosis
  - Measurement of bone mineral content and BMD

- Quality of Life
  - Must be documented on a self-rating questionnaire such as Hopkins Symptom Checklist, Nottingham Health Profile, Psychological General Well-being index, QOL Assessment of GHD in Adults (QOL-AGHDA), Questions on Life Satisfaction – Hypopituitarism (QLS-H)

<table>
<thead>
<tr>
<th>Indication</th>
<th>Criteria for use</th>
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<tbody>
<tr>
<td>Growth failure in children</td>
<td>N/A in adults</td>
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<tr>
<td>Growth failure associated with</td>
<td>N/A in adults</td>
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<tr>
<td>Noonan Syndrome</td>
<td>Not a covered benefit in adults</td>
</tr>
<tr>
<td>Growth failure associated with Prader-Willi Syndrome</td>
<td>N/A in adults</td>
</tr>
<tr>
<td>Growth failure associated with SHOX deficiency</td>
<td>N/A in adults</td>
</tr>
<tr>
<td>Growth failure associated with Turner Syndrome</td>
<td>N/A in Adults</td>
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<tr>
<td>GHD in adults - Transition Patients with childhood-onset GHD (COGHD) continuing into adulthood</td>
<td>✓ Patient must have clinically documented COGHD</td>
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<td>✓ Patient must have stopped growing under the influence of GH therapy</td>
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<td>• GH therapy must be discontinued for at least 1 month</td>
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<td>• GH status must be re-evaluated:</td>
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<td>Patient had clinically documented severe GHD in childhood due to:</td>
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<td>➔ Irreversible hypothalamic-pituitary structural disease in childhood or central nervous system tumors or Multiple Pituitary Hormone Deficiency (MPHD, panhypopituitarism) with documented deficiency of at least 3 pituitary hormones, or receipt of high-dose cranial radiation</td>
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<td>➔ Patient has IGF-1 levels more than 2 SD (&lt;3 percentile) below the mean</td>
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OR
### Not Approved If

- Patient had childhood GH treatment for conditions other than GHD, such as Turner Syndrome or ISS
- Patients with acute catabolism, critically ill patients and burn patients
- Pregnancy: GH therapy should be discontinued if pregnancy is confirmed
- Short stature / growth failure without growth hormone deficiency
- Patients with Down Syndrome, Fanconi’s Syndrome, or Bloom Syndrome
- Patient’s with idiopathic short stature (ISS) or SHOX Deficiency
- Patients with Familial Short Stature
- Patients with constitutional delays
- Patients with Noonan Syndrome
- Patients with Laron Syndrome (GH Insensitivity)
- Diagnosis of growth hormone deficiency not confirmed by biochemical test
- Growth hormone use for patients with non-specific symptomology such as lipidemia, depression, or weight gain
- Used for antiaging
- Performance enhancement in athletes
- Patient has any contraindications to the use of growth hormone

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<table>
<thead>
<tr>
<th>GHD in adults</th>
<th>GH status must be evaluated:</th>
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<tbody>
<tr>
<td>Patients with adult-onset GHD (AOGHD)</td>
<td>- Patient has clinically documented MPhD (panhypopituitarism)</td>
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<td>o Documented deficiency of at least 3 pituitary hormones</td>
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<td>o Patient has IGF-1 levels more than 2 SD (&lt;3 percentile) below the mean</td>
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<td>OR</td>
<td>- Patient has low IGF-1 (&lt; 50 percentile or &lt; 0 SD) and laboratory evidence of GHD as evidenced by subnormal response to at least 2 provocative stimulation tests:</td>
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<td>o Response less than 5 ng/ml to the insulin tolerance test (ITT)</td>
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<td>o Less than 3 ng/ml to the glucagon test</td>
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<td>o Less than 4 ng/ml to the arginine test</td>
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<thead>
<tr>
<th>Idiopathic short stature</th>
<th>N/A in adults</th>
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<tbody>
<tr>
<td>Short bowel syndrome</td>
<td>Not a covered</td>
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<tr>
<td>Wasting or cachexia associated with HIV</td>
<td>Clinical diagnosis of AIDS with all of the following criteria met:</td>
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<td>- Involuntary weight loss of &gt; 10% of pre-illness baseline body weight or body mass index (BMI) &lt; 20 kg/m². In the absence of a concurrent illness or medical condition other than HIV infection that may cause weight loss;</td>
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<td>- Failed to adequately respond to, or are intolerant to, alternative therapies (i.e. Dronabinol, Megace);</td>
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<td>- Been on anti-retroviral therapy for &gt; 30 days prior</td>
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Required Medical Information
- Clinical documentation of diagnosis
- Results of clinical laboratory, imaging, and cardiology tests identified in criteria above
  - Fasting glucose
  - Hemoglobin A1c
  - Fasting lipid profile
  - Bone mineral content and density
  - Blood Pressure
  - Heart rate
  - Electrocardiogram
- Clinical documentation of height, weight, and BMI
- Documentation of self-rating questionnaire such as the Hopkins Symptom Checklist, Nottingham Health Profile, Psychological General Well-being Index, QOL Assessment of GHD in Adults (QOL-AGHDA), Questions on Life Satisfaction – Hypopituitarism (QLS-H)

Contraindications
- Hypersensitivity to somatropin, growth hormone, or any of the excipients or diluents in these products (ie. Benzoyl peroxide, metacresol); pediatric patients with closed epiphyses; active proliferative, preproliferative, or severe nonproliferative diabetic retinopathy; active malignancy; evidence of progression or recurrence of an underlying intracranial tumor; acute critical illness caused by complications following open-heart or abdominal surgery of multiple accidental trauma, or to treat patients having acute respiratory failure; patients with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea; or have severe respiratory impairment

Dosing
- Adults – Growth Hormone Deficiency
  - Genotropin / Omnitrope
    - Initial: 0.04 mg/kg/wk, given in 6 or 7 divided daily subcutaneous injections increased at 4 – 8 week intervals
    - Maximum: 0.08 mg/kg/wk
  - Humatrope
    - Initial: 0.006 mg/kg/day subcutaneous injection increased to a maximum dose of 0.0125 mg/kg/day
  - Norditropin
    - Initial: 0.004 mg/kg/day subcutaneous injection increased after approximately 6 weeks to a maximum of 0.016 mg/kg/day
  - Nutropin / Nutropin AQ
    - 0.006 mg/kg/day subcutaneously increased to a maximum of 0.025 mg/kg/day in patients 35 years of age and younger; 0.0125 mg/kg/day in patients older than 35 years of age
  - Saizen
    - 0.005 mg/kg/day subcutaneously increased to a maximum of 0.01mg/kg/day
- Adults – Short bowel syndrome (Zorptive only)
  - mg/kg/day subcutaneously for 4 weeks
- Adults – Wasting or cachexia associated with HIV (Serostim only)
  - 0.1 mg/kg/day subcutaneously at bedtime increased to a maximum of 6 mg/day

Authorization
- COGHD - 6 months
- AOGHD – 6 months
- AIDS related wasting – 12 weeks
- Continuation of therapy for COGHD, AOGHD requires clinical documentation of IGF-1, fasting glucose, HbA1c, BMI, waste circumference, waste-to-hip ratio, thyroid function, assessment of HPA axis, testosterone, fasting lipid panel, blood pressure, heart rate, electrocardiogram, BMD (at
baseline and every 2 years thereafter), glucocorticoid requirements
- IGF-1 is in the middle (50 percentile or 0 SD) of the reference range for age and gender based on specific lab reference values (dose reduction required if above normal)
- Must not be experiencing any side effects of GH treatment
  - Arthralgia, back pain, chest pain, new-onset diabetes mellitus (Type II), edema, hypertension, headaches, hypothyroidism, infection, insulin resistance, myalgias
- Evidence of improvement or benefits from treatment in at least two (2) of the following groups:
  - Cardiovascular
    - Systolic and diastolic blood pressure
    - Heart rate
    - Electrocardiogram results
  - Metabolic
    - Fasting glucose
    - HbA1c
    - Fasting lipid profile
    - Body composition
      - BMI, waist circumference, waist-to-hip ratio, lean and fat mass quantification using DEXA scans
  - Osteopenia / osteoporosis
    - Measurement of BMD every 2 years
  - Quality of life / physical activity tolerance
    - Must be documented on a self-rating questionnaire such as Hopkins Symptom Checklist, Nottingham Health Profile, Psychological General Well-being index, QOL Assessment of GHD in Adults (QOL-AGHDA), Questions on Life Satisfaction – Hypopituitarism (QLS-H)
- Continuation for AIDS related wasting requires that the BMI has stabilized or increased during the previous 12 weeks of therapy.

Approved by P&T: 07/16/2013

References
3. Humatrope [package insert]. Indianapolis, IN: Lilly USA LLC; August 2011.