# Somatropin (Growth Hormone)

**Genotropin®, Humatrope®, Norditropin®, Nutropin®, Nutropin AQ®, Nutropin AQ NuSpin®, Omnitrope®, Saizen®, Zomacton®, Zorbtive®**

## FDA-Labeled Indications:

<table>
<thead>
<tr>
<th>Medication</th>
<th>GHD*: Children</th>
<th>GHD*: Adult</th>
<th>Growth Failure due to Chronic Renal Insufficiency</th>
<th>Growth Failure in Children Born SGA*</th>
<th>Prader-Willi Syndrome in Children</th>
<th>Turner’s Syndrome</th>
<th>Noonan Syndrome</th>
<th>ISS^</th>
<th>SHOX Deficiency</th>
<th>Short Bowel Syndrome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotropin¹</td>
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<td>Nutropin AQ³</td>
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<td>Nutropin AQ NuSpin⁴</td>
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<td>Saizen⁵</td>
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<td>Zorbtive⁸</td>
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</tbody>
</table>

*GHD (growth hormone deficiency). ▪SGA (small for gestational age). ^ISS (Idiopathic short stature). ¨ Short Stature Homeobox-Containing gene

**Dosage Form/Strength:** ¹, ², ³, ⁴, ⁵, ⁶, ⁷, ⁸

- Genotropin: 12mg and 5.8mg powder for Injection
- Genotropin Miniquick: 0.2mg, 0.4mg, 0.6mg, 0.8mg, 1mg, 1.2mg, 1.4mg, 1.6mg, 1.8mg, 2mg powder for injection
- Humatrope: 5mg powder for injection
- Humatrope Cartridge Kit: 6mg, 12mg, 24mg powder for injection
- Norditropin FlexPro Prefilled Pen: 5mg/1.5mL, 10mg/1.5mL, 15mg/1.5mL, 30mg/3mL solution for injection
- Nutropin AQ NuSpin: 10mg, 20mg solution for injection
- Nutropin AQ NuSpin Cartridge: 5mg/2mL solution for injection
- Nutropin AQ Pen Cartridge: 10mg/2mL, 20mg/2mL
- Omnitrope: 5.8mg powder for injection
- Omnitrope: 5mg/1.5mL, 10mg/1.5mL solution for injection
- Saizen: 5mg, 8.8mg powder for injection
- Saizen Click.Easy Cartridge: 8.8mg powder for injection
- Zomacton: 5mg, 10mg powder for injection
- Zorbtive: 8.8mg powder for injection

**Growth Chart References:**
Refer to the following location for links to the WHO and CDC growth charts.⁹

[http://www.cdc.gov/growthcharts/index.htm](http://www.cdc.gov/growthcharts/index.htm)
**Step Therapy Criteria:**

<table>
<thead>
<tr>
<th>First-Line Medication(s)</th>
<th>GHD Children</th>
<th>GHD Transition Adolescent</th>
<th>GHD Adult</th>
<th>Growth Failure due to Chronic Renal Insufficiency</th>
<th>Growth failure in Children Born SGA</th>
<th>Prader-Willi Syndrome</th>
<th>Turner’s Syndrome</th>
<th>Noonan Syndrome</th>
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<tbody>
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<td>Genotropin, Norditropin, Nutropin</td>
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<td></td>
</tr>
</tbody>
</table>

*If the requested medication is listed in the “Second-Line Medication(s)” row for the patient’s diagnosis, the patient must have tried and failed at least one of the “First-Line Medications” for the diagnosis, before a Second-Line medication may be approved. If the requested medication is one of the “First-Line Medications” for the patient’s diagnosis, clinical criteria will apply, but no step therapy will be required.*
## Clinical Criteria Specific for Diagnosis:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Approval Criteria</th>
<th>Denial Criteria</th>
<th>Reauthorization Approval Criteria</th>
<th>Reauthorization Denial Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short stature associated with SHOX deficiency 10, 11, 12, 13</td>
<td>Diagnosis confirmed by molecular or genetic testing</td>
<td>Diagnosis has not been confirmed by molecular or genetic testing</td>
<td>Pediatric patient who has not reached final adult height or completed linear growth</td>
<td>Patient has reached final adult height or has completed linear growth.</td>
</tr>
<tr>
<td>Short stature associated with Noonan Syndrome 13, 14, 15, 16</td>
<td>Diagnosis confirmed by molecular or genetic testing</td>
<td>o Diagnosis has not been confirmed by molecular or genetic testing</td>
<td>Pediatric patient who has not reached final adult height or completed linear growth</td>
<td>Patient who has reached final adult height or completed linear growth</td>
</tr>
<tr>
<td>Short stature associated with Turner's Syndrome 10, 13, 17, 18</td>
<td>Diagnosis confirmed by genetic testing</td>
<td>o Diagnosis has not been confirmed by genetic testing</td>
<td>Pediatric patient who has not reached final adult height or completed linear growth</td>
<td>Patient has reached final adult height or has completed linear growth.</td>
</tr>
<tr>
<td>Short stature associated with Prader-Willi Syndrome 13, 19, 20</td>
<td>o Diagnosis confirmed by genetic testing</td>
<td>o Diagnosis has not been confirmed by genetic testing</td>
<td>o Patient has a BMI &lt;35 kg/m^2.</td>
<td>Patient has reached final adult height or has completed linear growth.</td>
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<tr>
<td></td>
<td>o Patient has a BMI less than 35 kg/m^2.</td>
<td>o The patient has a BMI ≥35 kg/m^2.</td>
<td>o Patient does not have severe respiratory impairment or untreated severe obstructive sleep apnea</td>
<td>o Patient has a BMI ≥35 kg/m^2.</td>
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<td>o Patient does not have severe respiratory impairment or untreated severe obstructive sleep apnea</td>
<td>o The patient has severe respiratory impairment or untreated severe obstructive sleep apnea</td>
<td>o Patient has not yet reached final adult height or completed linear growth</td>
<td>o Patient has severe respiratory impairment or untreated severe obstructive sleep apnea</td>
</tr>
</tbody>
</table>
**Indication** | **Approval Criteria** | **Denial Criteria** | **Reauthorization Approval Criteria** | **Reauthorization Denial Criteria**
--- | --- | --- | --- | ---
**Pediatric growth failure due to chronic kidney disease** 13, 20, 21, 22, 23 | o Patient has a diagnosis of kidney failure with a GFR ≤ 25 mL/min/1.73 m² who is awaiting a kidney transplant.  
o Patient has optimal dietary nutrition (caloric intake).  
o Patient has growth failure as determined by height ≥ 2 standard deviations below the mean for age and gender  
o Patient has growth velocity < 10th percentile of normal for age and gender over the past year | o Patient does not have a diagnosis of kidney failure with a GFR ≤ 25 mL/min/1.73 m² who is awaiting a kidney transplant.  
o Patient does not have optimal dietary nutrition (caloric intake).  
o Patient does not have growth failure as determined by height ≥ 2 standard deviations below the mean for age and gender  
o Patient does not have a growth velocity < 10th percentile of normal for age and gender over the past year.  
o Patient has attained mid-parental target height.  
   OR  
   ▪ The patient’s height is within the 3rd percentile of normal adult height (65 inches for boys and 60 inches for girls).  
o Patient’s epiphyses are closed.  
o Step Therapy Criteria in Table 1 is not met | o Patient has not received a kidney transplant.  
o Patient has previously received ≤ 3 years of growth hormone treatment.  
o Patient has not attained mid-parental target height.  
   OR  
   ▪ The patient’s height is not within the 3rd percentile of normal adult height (65 inches for boys and 60 inches for girls).  
o Patient’s epiphyses are closed.  
o Patient has reached final adult height or has completed linear growth | o Patient has received a kidney transplant.  
o Patient has previously received > 3 years of growth hormone treatment.  
o Patient has attained mid-parental target height.  
   OR  
   ▪ The patient’s height is within the 3rd percentile of normal adult height (65 inches for boys and 60 inches for girls).  
o Patient’s epiphyses are closed.  
o Patient has reached final adult height or has completed linear growth
### Prior Authorization Criteria

#### Indication

<table>
<thead>
<tr>
<th>Growth failure in children born small for gestational age (includes Intrauterine growth restriction or Russell-Silver syndrome)</th>
</tr>
</thead>
</table>

#### Approval Criteria

- Patient was born small for gestational age, defined as birth weight or length $\geq 2$ standard deviations (SD) below the mean for gestational age
- Patient’s growth has not caught up before 4 years of age, defined as height $< 2$ SD below the mean for age and gender
- Other causes for short stature have been ruled out

#### Denial Criteria

- Patient was not born small for gestational age, defined as birth weight or length $\geq 2$ standard deviations (SD) below the mean for gestational age
- Patient’s growth has caught up before 4 years of age, defined as height $< 2$ SD below the mean for age and gender
- Other causes for short stature have not been ruled out
- Step Therapy Criteria in Table 1 is not met

#### Reauthorization Approval Criteria

- Patient was born small for gestational age, defined as birth weight or length $\geq 2$ standard deviations (SD) below the mean for gestational age
- Patient’s height has not caught up to being $< 2$ SD below the mean for age and gender
- Pediatric patient who has not reached final adult height or completed linear growth

#### Reauthorization Denial Criteria

- Patient was not born small for gestational age, defined as birth weight or length $\geq 2$ standard deviations (SD) below the mean for gestational age
- Patient’s height has caught up to being $< 2$ SD below the mean for age and gender
- Patient has reached final adult height or has completed linear growth
<table>
<thead>
<tr>
<th>Indication</th>
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<th>Reauthorization Approval Criteria</th>
<th>Reauthorization Denial Criteria</th>
</tr>
</thead>
</table>
| Diagnosis of growth hormone deficiency in children 13, 20, 25, 26, 27 | o Patient’s epiphyses are open.  
   o Patient has been evaluated, and ruled out, for other causes of growth failure (i.e. hypothyroidism, chronic illness, malignancy, celiac disease, malnutrition)  
   o Patient has growth failure AND has additional pituitary hormone deficiencies.  
      - Patient has growth failure, AND has had surgery or irradiation in the region of the hypothalamus or pituitary.  
      - Patient has a growth velocity of ≥2 standard deviations (SD) below the mean for age and gender for the past year  
         - Patient’s height is ≥2 SD below the mean for age and gender, AND a growth velocity >1 SD below the mean for age for the past year  
         - Step Therapy Criteria in Table 1 is not met | o Patient’s epiphyses are closed.  
   o Other causes of growth failure have not been ruled out.  
   o Patient has a growth velocity of <2 standard deviations (SD) below the mean for age and gender for the past year  
      - Patient’s height is either <2 SD below the mean for age and gender, OR the growth velocity is ≤1 SD below the mean for age for the past year  
   o Patient has not had a documented subnormal response to 2 standard GH stimulation tests.  
      - The patient has either not had a subnormal response to one GH stimulation test AND has not had a documented low IGF-1 based on age and gender normal values  
      - Patient does not have growth failure AND additional pituitary hormone deficiencies.  
       - Patient does not have growth failure, AND had surgery or irradiation in the region of the hypothalamus or pituitary.  
       - Step Therapy Criteria in Table 1 is not met | o The patient’s epiphyses have not closed  
   o Patient’s pre-treatment growth rate has doubled, OR  
      - Patient has had an increase in pre-treatment growth rate of ≥3 cm/year for the first year of therapy, OR  
      - Patient’s growth rate is ≥2.5 cm/year for treatment beyond the first year of therapy  
   o The patient has not yet achieved Mid-Parental Height. [Please Note: Mid-Parental Height = (father’s height + mother’s height) ÷ 2, plus 2.5 inches for males, or minus 2.5 inches for females], OR  
   o The patient’s height is within the 3rd percentile of normal adult height (65 inches for boys and 60 inches for girls). | o Bone age = 16 years for males or = 14 years for females  
   o The patient’s epiphyses have closed  
   o Patient’s growth rate is <2.5 cm/year for the past year.  
   o Whichever occurs sooner:  
      - Either the patient has reached Mid-Parental Height. [Please Note: Mid-Parental Height = (father’s height + mother’s height) ÷ 2, plus 2.5 inches for males, or minus 2.5 inches for females], OR  
      - The patient’s height is within the 3rd percentile of normal adult height (65 inches for boys and 60 inches for girls). |
<table>
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</thead>
<tbody>
<tr>
<td>Diagnosis of growth hormone deficiency in a transition patient (an adolescent or young adult patient with childhood-onset GH deficiency, who has completed linear growth, and his/her growth rate is &lt; 2cm/ year):</td>
<td>o GH treatment has been stopped for at least one month after final height is achieved AND o The diagnosis of GHD has been reconfirmed by one of the following, ▪ Patient has ≥3 pituitary hormone deficiencies AND an IGF-1 level &lt;2.5 percentile off GH therapy, OR ▪ Patient has ≤2 pituitary hormone deficiencies AND an IGF-1 level &lt;50th percentile for age and gender, AND a suboptimal response to a growth hormone stimulation test. OR ▪ The patient had childhood-onset growth hormone deficiency AND multiple pituitary hormone deficiencies AND a low IGF-1 level AND has a suboptimal response following at least one growth hormone stimulation test.</td>
<td>o GH treatment has not been stopped for at least one month after final height is achieved o The diagnosis of GHD has not been reconfirmed by one of the following, ▪ Patient has ≥3 pituitary hormone deficiencies AND an IGF-1 level &lt;2.5 percentile off GH therapy. ▪ Patient has ≤2 pituitary hormone deficiencies AND an IGF-1 level &lt;50th percentile for age and gender, AND a suboptimal response to a growth hormone stimulation test. ▪ The patient had childhood-onset growth hormone deficiency AND multiple pituitary hormone deficiencies AND a low IGF-1 level AND had a suboptimal response following at least one growth hormone stimulation test. ▪ Step Therapy Criteria in Table 1 is not met</td>
<td>o Patient has had a yearly clinical assessment and an evaluation for adverse effects, IGF-1 levels, and other parameters of GH response o The patient’s clinical assessment indicates that the patient is responding to GH treatment o The patient’s clinical assessment indicates that the patient continues to need GH treatment</td>
<td>o Patient has not had a yearly clinical assessment and an evaluation for adverse effects, IGF-1 levels, and other parameters of GH response o The patient’s clinical assessment indicates that the patient is not responding to GH treatment. o The patient’s clinical assessment indicates that the patient no longer needs GH treatment.</td>
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</table>

Growth Hormone criteria
Version 2
Last updated: 4/21/2016
Approved: 4/29/2016
Effective for Dates of Service: 10/3/2016 and thereafter
<table>
<thead>
<tr>
<th>Indication</th>
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<th>Denial Criteria</th>
<th>Reauthorization Approval Criteria</th>
<th>Reauthorization Denial Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis of Adult Growth Hormone Deficiency&lt;sup&gt;13, 28&lt;/sup&gt;</td>
<td>- GH treatment has been stopped for at least a month</td>
<td>- GH treatment has not been stopped for at least one month</td>
<td>- Patient has had a yearly clinical assessment and an evaluation for adverse effects, IGF-1 levels, and other parameters of GH response.</td>
<td>- Patient has not had a yearly clinical assessment and an evaluation for adverse effects, IGF-1 levels, and other parameters of GH response.</td>
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<td>- Patient has ≥3 pituitary hormone deficiencies AND - Has an IGF-1 level &lt;2.5&lt;sup&gt;th&lt;/sup&gt; percentile off GH therapy. OR - Patient has ≤2 pituitary hormone deficiencies AND - Has an IGF-1 level &lt;50&lt;sup&gt;th&lt;/sup&gt; percentile for age and gender when off GH therapy, AND - Had a suboptimal response to a GH stimulation test. OR - Patient history of hypothalamic disease, cranial irradiation, surgery near pituitary gland/ hypothalamus, head trauma or aneurysmal subarachnoid hemorrhage. AND - Patient has multiple pituitary hormone deficiencies, AND - Patient has a serum IGF-1 level below the age and gender appropriate reference range when off GH therapy, AND - Patient had a subnormal response for age to at least one standard GH stimulation test. OR - Documented GHD in childhood AND - Patient had a subnormal response to 2 standard GH stimulation tests after being off GH therapy.</td>
<td>- Patient does not have ≥3 pituitary hormone deficiencies AND - An IGF-1 level &lt;2.5 percentile off GH therapy. OR - Patient does not have ≤2 pituitary hormone deficiencies AND - IGF-1 level &lt;50&lt;sup&gt;th&lt;/sup&gt; percentile, AND - Suboptimal response to a GH stimulation test. OR - Patient without a history of cranial irradiation, hypothalamic disease, surgery near hypothalamus/ pituitary gland, aneurysmal subarachnoid hemorrhage, or head trauma. WITH - Multiple pituitary hormone deficiencies, AND - A serum IGF-1 level below the age and gender appropriate reference range when off GH therapy, AND - A subnormal response to at least one standard GH stimulation test when off GH therapy. OR - Patient has not had a diagnosis of GHD in childhood, AND - A subnormal response to 2 standard GH stimulation tests.</td>
<td>- Patient’s clinical assessment indicates that the patient is not responding to GH treatment.</td>
<td>- The patient’s clinical assessment indicates that the patient is responding to GH treatment.</td>
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Growth Hormone criteria
Version 2
Last updated: 4/21/2016
Approved: 4/29/2016
Effective for Dates of Service: 10/3/2016 and thereafter
Denial Criteria for All Requests: 13, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39

- The patient has one or more of the following contraindications or exclusions to the use of GH therapy:
  - An active malignancy or history of malignancy in the past 12 months
  - Active proliferative or severe non-proliferative diabetic retinopathy
  - An acute critical illness; OR,
- Growth hormone is being used for a diagnosis of idiopathic short stature or short bowel syndrome; OR,
- Treatment of any diagnosis other than: GH deficiency, Prader-Willi syndrome, Noonan syndrome, SHOX deficiency, Turner’s syndrome, growth failure in children born SGA (Including intrauterine growth restriction or Russell-Silver syndrome), or growth failure due to CKD.
  - Some examples of non-approvable diagnoses include: Cystic Fibrosis, Constitutional delay of growth and development, or central precocious puberty; OR,
- Being used to increase body mass or strength for professional, recreational, or social reasons (for example: athletes, bodybuilders) ; OR,
- Being used to reverse the effects of aging (anti-aging) ; OR,
- Being used to counteract an acute or chronic catabolic illness (excluding HIV/AIDS) which is causing protein wasting changes.
  - For example: burns, sepsis, surgery, trauma, cancer, chronic hemodialysis; OR,
- Concurrent use with Increlex® (mecasermin).

Length of Authorization:

- Initial coverage may be approved for up to 6 months.
- Subsequent re-authorizations may be approved for 12 months.

Quantity Limit: None

References / Footnotes:


ALASKA MEDICAID
Prior Authorization Criteria

Growth Hormone criteria
Version 2
Last updated: 4/21/2016
Approved: 4/29/2016
Effective for Dates of Service: 10/3/2016 and thereafter


