Growth Hormone Pediatric

**Description**

**Humatrope**, **Norditropin**, Genotropin, Nutropin, Nutropin AQ, Omnitrope, Saizen, Zomacton (aka. Tev-Tropin)  
*participating medication*

**Background**

Somatropin is a synthetically manufactured genetic copy of natural human growth hormone produced in the pituitary gland. It has the same effect as natural human growth hormone made in the body. Growth hormone (GH) contributes to overall bone, muscle, and organ growth and development in humans. Children with inadequate production of growth hormone, which can be due to various diseases and reasons, require growth hormone replacement in order to complete their development from childhood to adulthood (1-2).

Somatropin, commonly referred to growth hormone, is currently marketed for use in children under the following brands: Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, Omnitrope, Saizen, and Zomacton (formerly known as Tev-Tropin).

Use of any growth hormone in children can cause a number of potentially serious adverse effects; therefore regular and routine monitoring is required. Sometimes treatment may need to be permanently stopped. These adverse effects include the development of impaired glucose tolerance and diabetes mellitus, upper airway obstruction and sleep apnea in patients with Prader-Willi syndrome, progression or recurrence of tumors in patients with preexisting tumors, intracranial hypertension, the worsening of hypothyroidism, bone defects, kidney problems and the worsening of pre-existing scoliosis, and pancreatitis (1-2).
Regulatory Status
FDA-approved indication: Pediatric growth hormone is indicated for: growth hormone deficiency (GHD)/insufficiency; growth failure secondary to chronic renal insufficiency pre-transplantation, Noonan Syndrome, Prader-Willi Syndrome, Turner Syndrome or SHOX (short stature homeobox-containing gene) deficiency; small for gestational age (SGA) for children who have not reached a normal height range by age 2 to 4 years or idiopathic short stature (ISS) (3-9).

Although the FDA-labeled indications vary for the growth hormone products, guidelines address all somatropin products collectively (1-2).

Related policies
Grow Hormone – Adult Therapy, Serostim, Zorbtive

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Growth hormones may be considered medically necessary for pediatric patients aged 17 years or under, with open epiphyses and without evidence of active neoplasm, not being used in combination with another somatropin agent (such as Serostim, Zorbtive or any other GH) for the treatment of growth failure due to inadequate secretion of endogenous growth hormone as defined by having ALL of the following: height below 3rd percentile for age or acquired growth hormone deficiency due to CNS lesions, and growth hormone level less than 10 on stimulation test or subnormal IGF-1 level for age or subnormal IGFBP-3 level for age; growth failure due to being small for gestational age who fail to manifest catch-up growth by age 2 to 4 years; growth failure due to Noonan Syndrome, Prader-Willi Syndrome, SHOX (short stature homeobox-containing gene) deficiency, Turner Syndrome or idiopathic short stature (ISS), also called non-growth hormone-deficient short stature, defined by height standard deviation score (SDS) ≤ -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, and in whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means.

Growth hormone is considered investigational for patients less than 17 years old and for all other indications.

Prior-Approval Requirements
Age 17 years of age or under

Diagnoses:

For INITIATION of therapy, the patient must have ALL of the following:

1. Open epiphyses (as determined within the last year by radiographic evidence)
2. NO evidence of tumor activity or active neoplasm
3. NOT being used in combination with another somatropin agent (such as Serostim, Zorbtive or any other GH)

AND ONE of the following:

1. Growth failure due to inadequate secretion of endogenous growth hormone as defined by having ALL of the following:
   a. Height below 3rd percentile for age or acquired growth hormone deficiency due to CNS lesions
   b. Growth hormone level less than 10 on stimulation test or subnormal IGF-1 level for age or subnormal IGFBP-3 level for age
2. Growth failure in children born small for gestational age who fail to manifest catch-up growth by age 2 to 4 years
3. Growth failure due to chronic renal insufficiency up to the time of renal transplantation
4. Growth failure due to Noonan Syndrome
5. Growth failure due to Prader-Willi Syndrome
6. Growth failure due to SHOX (short stature homeobox-containing gene) deficiency
7. Growth failure due to Turner Syndrome
8. Idiopathic short stature (ISS), also called non-growth hormone-deficient short stature, defined by height standard deviation score (SDS) ≤-2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, and in whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means
### Policy Guidelines

#### Pre - PA Allowance

None

#### Prior - Approval Limits

| Duration | 12 months |

#### Prior – Approval Renewal Limits

| Duration | 12 months |

### Rationale

#### Summary

Pituitary growth hormone is a peptide that exerts anabolic effects on target tissues. GH secretion is regulated by a balance between growth hormone–releasing hormone (GHRH) and growth hormone-inhibiting (somatostatin) factors. Other growth hormone–releasing peptides (GHRPs) are known to stimulate GH. Receptors for the GHRPs have been identified, and the natural ligand for these receptors has been determined to be ghrelin (1-2).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of pediatric growth hormones while maintaining optimal therapeutic outcomes.
References

Policy History

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>November 2011</td>
<td>All pediatric growth hormones separated into their own respective individual criteria documents. All diagnoses required to get initial prior authorization to start growth hormone replacement were removed from the renewal sections as these are verified before treatment is started. Criteria rewritten to contain all current FDA labeled indications. All non-FDA labeled indications were removed from the criteria. Humatrope is currently FDA indicated for pediatric patients for treatment of the following: growth failure due to an inadequate secretion of endogenous growth hormone, growth failure in children born small for gestational age who fail to manifest catch-up growth by age 2 to 4 years, growth failure associated with Turner syndrome, idiopathic short stature (ISS), and growth failure associated with SHOX (short stature homeobox-containing gene deficiency). Idiopathic short stature, also called non-growth hormone-deficient short Stature, is defined by a height standard deviation score (SDS) ≤-2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, in pediatric patients whose epiphyses are not closed and for whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means.</td>
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<tr>
<td>December 2012</td>
<td>Annual review-no change in the policy statement and editorial updates</td>
</tr>
<tr>
<td>July 2013</td>
<td>Individual child growth hormone criteria merged into one criteria.</td>
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<tr>
<td>December 2014</td>
<td>Annual editorial and reference update</td>
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<td>Date</td>
<td>Event</td>
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<tr>
<td>March 2015</td>
<td>Annual editorial and reference update</td>
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<tr>
<td>June 2015</td>
<td>Tev-Tropin has changed its name to Zomacton</td>
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<tr>
<td>September 2016</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>December 2017</td>
<td>Annual review and reference update</td>
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### Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2017 and is effective on January 1, 2018.