HUMAN GROWTH HORMONES CRITERIA

**Pharmacology:**
Somatropin (rDNA Origin), is a polypeptide hormone of recombinant DNA origin. The amino acid sequence of these products is identical to that of human growth hormone of pituitary origin. Human growth hormone (hGH) is a 191-amino acid polypeptide hormone secreted by the anterior pituitary gland. It has important metabolic effects including stimulation of protein synthesis and cellular uptake of amino acids.

**Indications:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>GHD (ped)</th>
<th>PWS</th>
<th>Turner Syndrome</th>
<th>CKD</th>
<th>SGA</th>
<th>GHD (adult)</th>
<th>ISS</th>
<th>SHOX</th>
<th>SBS</th>
<th>HIV wasting or cachexia</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotropin®</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td></td>
<td></td>
<td>Hypopitutarism (Adults)</td>
</tr>
<tr>
<td>Humatrope®</td>
<td>X</td>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td></td>
<td></td>
<td>Noonan Syndrome</td>
</tr>
<tr>
<td>Norditropin®</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td></td>
<td></td>
<td></td>
<td>CKD up to the time of renal transplantation. (Pediatric)</td>
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<tr>
<td>Nutropin AQ®</td>
<td>X</td>
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<td>X</td>
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</tr>
<tr>
<td>Omnitrope®</td>
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<td></td>
<td>X</td>
<td>X</td>
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<tr>
<td>Saizen®</td>
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<td>Serostim®</td>
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<tr>
<td>Zomacton™ (name change from Tev-Tropin)</td>
<td>X</td>
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<td>Zorbtive®</td>
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<td>X</td>
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</tr>
</tbody>
</table>

GHD=growth hormone deficiency; PWS=Prader-Willi Syndrome; CKD=Chronic kidney disease; SGA=small gestational age; ISS=idiopathic short stature, SHOX=short stature homeobox gene, SBS=short bowel syndrome.

**Medications:**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Dosage Strengths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotropin®</td>
<td>somatropin</td>
<td>5, 12 mg cartridge, 0.2, 0.4, 0.6, 0.8, 1, 1.2, 1.4, 1.6, 1.8, 2 mg syringe device</td>
</tr>
<tr>
<td>Humatrope®</td>
<td>somatropin</td>
<td>5 mg vial, 6, 12, 24 mg cartridge kits</td>
</tr>
<tr>
<td>Norditropin®</td>
<td>somatropin</td>
<td>5, 10, 15, 30 mg prefilled pen</td>
</tr>
<tr>
<td>Nutropin AQ®</td>
<td>somatropin</td>
<td>5, 10, 20 mg NuSpin prefilled cartridge 10mg/2ml, 20mg/2ml pen cartridge</td>
</tr>
<tr>
<td>Omnitrope®</td>
<td>somatropin</td>
<td>5.8 mg vial, 5mg/1.5ml, 10mg/1.5ml cartridge</td>
</tr>
<tr>
<td>Saizen®</td>
<td>somatropin</td>
<td>5 mg, 8.8 mg vial, 8.8 mg cartridge</td>
</tr>
<tr>
<td>Serostim®</td>
<td>somatropin</td>
<td>5, 6mg single dose vial, 4mg multi dose vial</td>
</tr>
<tr>
<td>Zorbtive® (name change from Tev-Tropin)</td>
<td>somatropin</td>
<td>5, 10 mg vial</td>
</tr>
<tr>
<td>Zorbtive®</td>
<td>somatropin</td>
<td>8.8 mg vial</td>
</tr>
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</table>
Criteria for Approval:

**PEDIATRICS (18 AND UNDER):**
A. Prescriber is an endocrinologist or nephrologist or one has been consulted on this case, AND
B. MRI of the brain has been performed (to document absence of a brain tumor) AND
C. One of the following diagnoses:
   1. Patient has a diagnosis of growth hormone deficiency, AND
      a) Patient’s height is more than 2 SD below average for the population mean height for age and sex, and a height velocity measured over one year to be 1 SD below the mean for chronological age, or for children over two years of age, a decrease in height SD of more than 0.5 over one year, AND
      b) Other causes of poor growth have been ruled out, including hypothyroidism, chronic illness, malnutrition, malabsorption and genetic syndrome AND
      c) Growth hormone response of less than 10ng/ml to at least two provocative stimuli of growth hormone release: insulin, levodopa, L-Arginine, clonidine, or glucagons, OR

   2. Patient has a diagnosis of Noonan Syndrome, Short stature homeobox gene, Turner Syndrome, Prader-Willi Syndrome, or chronic kidney disease (Nutropin AQ only) AND meets auxological criteria for short stature – height more than 2 standard deviations below normal for age, OR

   3. Patient has a diagnosis of small for gestational age (including Russell-Silver variant) AND height is more than 2.25 standard deviations below normal for age and sex AND failure to catch up in growth by 2 years of age, OR

   4. Patient is newborn with hypoglycemia and a diagnosis of hypopituitarism or panhypopituitarism.

**ADULTS (OVER 18)**
A. Prescriber is an endocrinologist, AND
B. ALL of the following diagnoses and conditions have been met:
   1. Patient has a diagnosis of growth hormone deficiency, AND
   2. The etiology for patient’s diagnosis of growth hormone deficiency is Adult Onset Growth Hormone Deficiency (AO-GHD), alone or with multiple hormone deficiencies, such as hypopituitarism, as a result of hypothalamic or pituitary disease, radiation therapy, surgery or trauma, AND
   3. GHD has been confirmed by growth hormone stimulation tests and rule-out of other hormonal deficiency, as follows: growth hormone response of fewer than five nanograms per mL to at least two provocative stimuli of growth hormone release: insulin, levodopa, L-Arginine, clonidine or glucagon when measured by polyclonal antibody (RIA) or fewer than 2.5 nanograms per mL when measured by monoclonal antibody (IRMA), AND
   4. Rule-out other hormonal deficiencies (thyroid, cortisol or sex steroids),
      a) Stimulation testing would not produce a clinical response such as in a diagnosis of panhypopituitarism as defined by the absence of all anterior pituitary hormones [Lutenizing Hormone (LH), Follicle Stimulating Hormone (FSH), Thyroid Stimulating Hormone (TSH), Adrenocorticotropic Hormone (ACTH) and Growth Hormone (GH).
OR
5. Patient has a diagnosis of AIDS Wasting or cachexia (for Serostim only), AND
   a) Patient has a documented failure, intolerance, or contraindication to appetite stimulants and/or other anabolic agents (both Megace and Marinol)

OR
6. Patient has a diagnosis of short bowel syndrome (Zorbtive® only)

Criteria for Denial:
A. Failure to meet criteria for authorization, OR
B. Constitutional delay of growth and development, OR
C. Skeletal dysplasias, OR
D. Osteogenesis imperfecta, OR
E. Down’s syndrome and other syndromes associated with short stature and sanguinant diathesis (Fanconi’s syndrome and Bloom’s syndrome), OR
F. Continuation of growth hormone treatment once epiphyses are closed
   OR

The following diagnosis for which GH cannot be the primary treatment:
G. Obesity, OR
H. Osteoporosis, OR
I. Muscular Dystrophy, OR
J. Infertility, OR
K. Increased athletic performance, OR
L. Somatopause.

Length of Authorization:
Pediatrics: 1 year.
A. Reauthorization is contingent upon response as shown by growth curve chart. Patient must demonstrate improved/normalized growth velocity. [Growth velocity has increased by at least 2 cm in the first year and is greater than 2.5 cm per year] and that epiphyses are not fused

Adults: 1 year.
A. Reauthorization is contingent upon prescriber affirmation of positive response to therapy (improved body composition, reduced body fat, and increased lean body mass).

Adults/Serostim: 3 months initial; then 1 year.
A. Reauthorization is contingent upon improvement in lean body mass or weight measurements.

References:
3. Humatrope [package insert]; Indianapolis, IN; Eli Lilly and Company; April 2015.
7. Saizen [package insert]; Rockland MA; Serono, Inc; June 2014.
8. Serostim [package insert]; Rockland MA; Serono, Inc; October 2015.
9. Zomacton [package insert]; Sellersville, PA; Gate Pharmaceuticals/TEVA; February 2016.
10. Zorbtive [package insert]; Rockland MA; Serono, Inc; January 2012.


23. Molitch ME. Diagnosis of GH deficiency in adults--how good do the criteria need to be? J Clin Endocrinol Metab. Feb 2002;87(2):473-476.

<table>
<thead>
<tr>
<th>Review:</th>
<th>Reason for Review:</th>
<th>Date Approved:</th>
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<tbody>
<tr>
<td>Pharmacy &amp; Therapeutic Committee</td>
<td>New</td>
<td>11/2/06</td>
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<td>Commissioner</td>
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<td>11/16/06</td>
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<td>Update</td>
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