Pharmacy Prior Authorization
Growth Hormone - Clinical Guidelines

Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Serostim, somatropin, Zorbtive, Zomacton

Preferred Product:

Genotropin and Norditropin are the preferred Growth Hormone agents. Non-preferred product will be considered with documentation to support trial and failure or contraindication to both preferred agents.

I. Growth Hormone Deficiency in Children and Adolescents:

Note: Provider must submit chart notes that include the following documentation: weight, height, growth velocity, and lab values (Growth Hormone (GH) levels, insulin-like growth factor-1 (IGF-1) / insulin-like growth factor-binding 3 (IGFBP-3)), stimulation test results, bone age

Growth Hormone will be approved for members who meet all of the following criteria at initiation of treatment:

- Must be prescribed by or in consultation with a Pediatric Endocrinologist, Pediatric Nephrologist or Endocrinologist
- Infant is less than 4 months of age and has growth hormone deficiency; OR
- History of neonatal hypoglycemia associated with pituitary disease; OR
- Diagnosis of pan hypopituitarism; OR
- History of irradiation, surgery or trauma to hypothalamic-pituitary area; OR
- A defined central nervous system (CNS) pathology confirmed by magnetic resonance imaging (MRI) or computed tomography (CT); OR
    - Note: magnetic resonance imaging (MRI)/computed tomography (CT) should be done to exclude a brain tumor (for example, craniopharyngioma). Members with growth hormone deficiency (GHD) have an abnormality of the pituitary gland (for example: ectopic bright spot, empty or small sella)
- Diagnosis of Pediatric growth hormone (GH) deficiency confirmed by following:
    - Member must meet one of the following:
        - Height:
            - Height is greater than 2 standard deviation (SD) below mid parental height (projected height); OR
            - Height is greater than 2.25 standard deviation (SD) below population mean for age and gender

        OR
        - Growth Velocity:
            - Growth Velocity (GV) is greater than 2 standard deviation (SD) below population mean for age and gender

        OR
        - Delayed skeletal maturation (delayed bone age confirmed by X-ray):
            - Bone age (BA) compared to chronological age (CA) is equal to or greater than 2 standard deviation (SD) below mean for age and gender (for example: delayed more than or equal to 2 years compared with chronological age)

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AND

- Member must meet ONE of following laboratory results:
    - Member has undergone two provocative growth hormone (GH) stimulation test (for example: Arginine, Clonidine, Glucagon, Insulin, Levodopa, growth hormone-releasing hormone (GhRh)) **AND** growth hormone (GH) response values are less than 10 mcg/L;
      OR
    - One abnormal growth hormone (GH) test is sufficient for children with defined central nervous system (CNS) pathology, multiple pituitary hormone deficiency (MPHD), history of irradiation, or a genetic defect affecting the growth hormone (GH) axis;
      OR
    - Member is less than 1 year of age AND IGF-1 (insulin-like growth factor) or insulin-like growth factor-binding 3 (IGFBP-3) is below the age and gender adjusted normal range as provided by the physician's lab

AND

- Epiphyses are open (confirmation of open growth plates in members over 12 years of age)
- Other pituitary hormone deficiencies (for example: hypothyroidism, chronic ischemic disease) have been ruled out

Prader-Willi Syndrome (PWS):

- Member must meet the following for initial approval:
    - Must be prescribed by or in consultation with a Pediatric Endocrinologist, Pediatric Nephrologist or Endocrinologist; AND
    - Diagnosis of Prader-Willi Syndrome (deletion in chromosomal 15q11.2-q13 region, maternal uniparental disomy in chromosome 15, imprinting defects or translocations involving chromosome 15)
    - Growth velocity (GV) is greater than 2 standard deviation (SD) below population mean for age and gender
    - Epiphyses are open (confirmation of open growth plates in members over 12 years of age)

Turner Syndrome (TS, gonadal Dysgenesis):

- Member must meet the following for initial approval:
    - Must be prescribed by or in consultation with a Pediatric Endocrinologist, Pediatric Nephrologist or Endocrinologist
    - Diagnosis of Turner Syndrome (characterized by the loss of part or all of an X chromosome)
    - Member is Female (greater than 2 years of age) and Bone age is less than 14 years
    - Growth velocity (GV) is greater than 2 standard deviation (SD) below population mean for age and gender
    - Epiphyses are open (confirmation of open growth plates in members over 12 years of age)

Noonan Syndrome (NS): (Norditropin only)

- Member must meet the following for initial approval:
    - Must be prescribed by or in consultation with a Pediatric Endocrinologist, Pediatric Nephrologist or Endocrinologist
    - Diagnosis of Noonan Syndrome
    - Epiphyses are open (confirmation of open growth plates in members over 12 years of age)

- Bone age (BA) compared to chronological age (CA) is equal to or greater than 2 standard deviation (SD) below mean for age and gender (for example: delayed more than or equal to 2 years compared with chronological age); OR
- Growth velocity (GV) is greater than 2 standard deviation (SD) below population mean for age and gender

Short stature with SHOX (short stature homeobox-containing gene) deficiency (SHOXD): (Humatrope only)

- Member must meet the following for initial approval:
  - Must be prescribed by or in consultation with a Pediatric Endocrinologist, Pediatric Nephrologist or Endocrinologist
  - Diagnosis of pediatric growth failure with short-stature homeobox (SHOX) gene deficiency as confirmed by genetic testing
  - Epiphyses are open (confirmation of open growth plates in members over 12 years of age)
  - Bone age (BA) compared to chronological age (CA) is equal to or greater than 2 standard deviation (SD) below mean for age and gender (for example: delayed more than or equal to 2 years compared with chronological age); OR
  - Growth velocity (GV) is greater than 2 standard deviation (SD) below population mean for age and gender

Growth failure associated with Chronic Renal Insufficiency (CRI) or Chronic Kidney disease (CKD) (up to the time of renal transplantation): (Nutropin only)

- Member must meet the following for initial approval:
  - Must be prescribed by or in consultation with a Pediatric Endocrinologist, Pediatric Nephrologist or Endocrinologist
  - Diagnosis of pediatric growth failure due to chronic renal insufficiency (e.g., serum creatinine is less than 30 mg/dl, up to the time of renal transplant)
  - Bone age (BA) compared to chronological age (CA) is equal to or greater than 2 standard deviation (SD) below mean for age and gender (for example: delayed more than or equal to 2 years compared with chronological age); OR
  - Growth velocity (GV) is greater than 2 standard deviation (SD) below population mean for age and gender
- Note: Prior to initiation of growth hormone (GH) treatment, existing metabolic derangements such as malnutrition, zinc deficiency, and secondary hyperparathyroidism should be corrected.

Growth failure in Children Small for Gestational Age (SGA):

Note: Provider must submit chart notes with that include the following documentation: Gestational Age (GA), birth weight, height, and growth chart

- Member must meet the following for initial approval:
  - Member is greater than 2 years of age
  - Diagnosis of small for gestational age (SGA) (fetal growth retardation) in a child who failed to achieve catch-up growth in first 24 months of life (by 2 years of age) using a 0-36 month growth chart and showing:
    - Member is below the 3rd percentile for gestational age (more than 2 standard deviation (SD) below population mean) for birth weight and length; AND
    - Member's height remains below the 3rd percentile (more than 2 standard deviation (SD) below population age and gender)

Initial Approval duration: 12 months

Renewal criteria for growth hormone (GH) therapy in Children:

Note: Provider must submit documentation for renewal: previous height, current height and expected adult height goal.

Member must meet the following for renewal approval:

- Documentation supporting positive response to therapy:
  - Height increase of at least 2.5cm/year (post-pubertal growth rate) or 4.5cm/year (pre-pubertal growth rate)
  - Expected final height is not achieved

  AND
- Bone age is less than16 years for males; less than 14 years for females; AND
- Growth (epiphyseal) plates are still open

For children with Prader Willi Syndrome (PWS):

- Documentation supporting positive response to therapy (for example: increase in total lean body mass, decrease in fat mass); OR above renewal requirements.

Renewal Approval duration: 12 months

Discontinuation criteria for growth hormone (GH) therapy in Children:

- Expected final adult height has been reached; OR
- Member had poor response to treatment, generally defined as an increase in growth velocity (GV) of less than 50% from baseline in the 1st year of therapy; OR
- Increase in height velocity is less than 2 cm total growth in 1 year of therapy; OR
- Epiphyseal fusion has occurred; or
- There are persistent and uncorrectable problems with adherence to treatment

II. Transition Phase Adolescent members

Member must meet the following for initial approval:

- Member has attained expected adult height
- Closed epiphyses on bone radiograph
- Member is at high risk of growth hormone (GH) deficiency due to childhood-onset growth hormone deficiency (COGHD) from one of following:
  - Hypothalamic-pituitary structural defect or tumor; OR
  - At least 3 deficiency of anterior pituitary hormones (for example: follicle-stimulating hormone (FSH)/luteinizing hormone (LH), thyroid-stimulating hormone (TSH), adrenocorticotropic hormone (ACTH), Prolactin), pan hypopituitarism; OR
  - Genetic cause of growth hormone (GH)

AND

- Insulin-like growth factor (IGF-1) is below the age and gender adjusted normal range as provided by the physician's lab

OR

- Member has stopped growth hormone (GH) therapy for at least one month and has undergone ONE provocative growth hormone (GH) stimulation test (for example: insulin tolerance test (ITT), Arginine+ growth

hormone-releasing hormone (GHRH), glucagon, Arginine) confirming transition phase growth hormone (GH) deficiency **AND** one of following peak values:

- Insulin tolerance test (ITT) is less than or equal to 5 ng/ml
- Arginine+ growth hormone-releasing hormone (GHRH): less than or equal to 11 ng/ml if body mass index (BMI) less than 25 kg/m^2;less than or equal to 8 ng/ml if body mass index (BMI) greater than or equal to 25 and less than 30 kg/m^2; less than or equal to 4 ng/ml if body mass index (BMI) greater than or equal to 30 kg/m^2
- Glucagon: less than or equal to 3 ng/ml
- Arginine: less than or equal to 0.4 ng/ml

Note:

- Transition Phase: Defined as period of life starting in late puberty and ending with full adult maturation (from mid to late teenage years until 6-7 years after achievement of final height)
- Adolescent: is a person between ages of 10 and 19 as defined by the World Health Organization (WHO)
- There is no proven benefit to continuing growth hormone (GH) treatment in adulthood for childhood growth hormone (GH) treatment of conditions other than growth hormone deficiency (for example: Turner's syndrome)

Initial Approval duration: 12 months

Renewal criteria for Transition Phase Adolescent members:

Note: Provider must submit documentation for renewal: chart notes, insulin-like growth factor-1 (IGF-1) levels
Member must meet the following for renewal approval:

- Documentation supporting positive response to therapy (for example: increased in total lean body mass, increased exercise capacity or increased insulin-like growth factor-1 (IGF-1) levels)

Renewal Approval duration: 12 months

III. Adult Growth Hormone Deficiency:

Note: Provider must submit documentation supporting diagnosis, stimulation test results, insulin-like growth factor-1 (IGF-1) levels.

Member must meet the following for initial approval:

- Diagnosis of childhood-onset growth hormone deficiency (COGHD); OR
- Diagnosis of adult-onset growth hormone deficiency (AOGHD);
  AND
- Documentation supporting hormone deficiency is due to hypothalamic-pituitary disease from organic or known causes (for example: damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage);
  AND
- Member has undergone ONE provocative growth hormone (GH) stimulation test (for example: insulin tolerance test (ITT), Arginine+ growth hormone-releasing hormone (GHRH), glucagon, Arginine, macimorelin)

confirming adult growth hormone (GH) deficiency **AND** one of following peak values:

- Insulin tolerance test (ITT) is less than or equal to 5 ng/ml
- Arginine+ growth hormone-releasing hormone (GHRH): less than or equal to 11 ng/ml if body mass index (BMI) less than 25 kg/m^2;less than or equal to 8 ng/ml if body mass index (BMI) greater than or equal to 25 and less than 30 kg/m^2; less than or equal to 4 ng/ml if body mass index (BMI) greater than or equal to 30 kg/m^2
- Glucagon: less than or equal to 3 ng/ml
- Arginine: less than or equal to 0.4 ng/ml
- Macimorelin: less than 2.8 ng/mL

Note: Insulin tolerance test (ITT) is gold standard stimulation test agent. Insulin tolerance test (ITT) is contraindicated with coronary artery disease, seizures, abnormal electrocardiogram (EKG) with history of Ischemic heart disease or cardiovascular disease, and not appropriate for those greater than age 60 years. Others should be used when Insulin tolerance test (ITT) is contraindicated. Glucagon has more diagnostic accuracy. Arginine alone is rarely used.

- If arginine is used alone, a second stimulation test may be required depending on insulin-like growth factor-1 (IGF-1) levels.
- If the insulin-like growth factor-1 (IGF-1) is subnormal with presentation of a hypothalamic disorder then one stimulation test is required.
- If the insulin-like growth factor-1 (IGF-1) is normal with hypothalamic disorder then two stimulation tests are required.

OR;

- Member has at least 3 deficiency of anterior pituitary hormones (for example: follicle-stimulating hormone (FSH)/luteinizing hormone (LH), thyroid-stimulating hormone (TSH), adrenocorticotropic hormone (ACTH), Prolactin), pan hypopituitarism;
  AND
- IGF-1 (insulin-like Growth factor) is below the age and gender adjusted normal range as provided by the physician's lab

Initial Approval duration: 12 months

<u>Renewal criteria for Adult Growth Hormone deficiency:</u>

Note: Provider must submit documentation for renewal: chart notes, insulin-like growth factor-1 (IGF-1) levels
Member must meet the following criteria for renewal approval:

- Documentation supporting positive response to therapy (for example: increased in total lean body mass, increased exercise capacity or increased insulin-like growth factor-1 (IGF-1) levels)

Renewal Approval duration: 12 months

<u>HIV-associated Cachexia or Wasting:</u> *(Serostim only)*

Note: Provider must submit documentation of body mass index (BMI), weight, and ideal body weight (IBW) (prior to initiation and after initiation of Serostim for renewals)

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- Member must meet the following for initial approval:
  - Prescribed by or in consultation with an infectious Disease or Human Immunodeficiency Virus (HIV) Specialist; AND
  - Currently on antiretroviral therapy; AND
  - Inadequate response, intolerable side effects or contraindication to megestrol acetate or dronabinol; AND
  - Member has not had weight loss due to other causes (for example: depression, mycobacterium avium complex (MAC), chronic infectious diarrhea, or malignancy with exception of Kaposi's sarcoma limited to skin or mucous membranes); AND
  - Body mass index (BMI) less than 20 kg/m^2 prior to initiating therapy with Serostim; OR
  - Unintentional weight loss of more than 10% over last 12 months or more than 5% over the last 6 months; OR
  - Member weights less than 90% of the lower limit of ideal body weight (IBW)

Initial approval duration: 3 months

Renewal criteria

Member must meet the following for renewal approval:

- Documentation supporting positive response to therapy (body mass index (BMI) has improved or stabilized)
- Currently on antiretroviral therapy

Renewal Approval duration: 9 months (Maximum total: 48 weeks)

Short Bowel Syndrome: *(Zorbtive only)*

Member must meet the following for approval:

- Diagnosis of Short Bowel syndrome; AND
- Member is 18 years or older
- Member is currently receiving specialized nutrition support (e.g., intravenous (IV) parenteral nutrition, fluid, and micronutrient supplements); AND
- Member has not previously received 4 weeks of treatment with Zorbtive

Initial Approval: 4 weeks. Note that treatment with Zorbtive will not be approved beyond 4 weeks as administration for more than 4 weeks has not been adequately studied.

Coverage criteria for a Non-preferred growth hormone (GH) product:

Member must meet ONE of following criteria:

- Inadequate response, an intolerable side effect or has contraindication to preferred agent; OR
- Inability to use vial formulation due to disability (for example: visual/physical impairment); OR
- There is no preferred product appropriate for the condition being treated

Non Coverage Criteria:

- Idiopathic Short Stature (ISS)*

*Aetna does not consider Idiopathic short stature (ISS) an illness, disease or injury therefore it is not a covered plan

benefit.

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Use not approved by the Food and Drugs Administration (FDA) and the use is unapproved and not supported by the literature or evidence as an accepted off-label use

- Amyotrophic lateral sclerosis
- Anabolic therapy to enhance body mass or strength for professional, recreational or social reasons
- Anti-aging
- Burn injuries
- Chronic catabolic states, including inflammatory bowel disease, pharmacologic glucocorticoid administration, and respiratory failure
- Constitutional delay of growth and development
- Insulin-like growth factor-I (insulin-like growth factor-1 (IGF-1)) deficiency (also known as neurosecretory defect) Russell-Silver syndrome (that does not result in small for gestational age)
- Stem Cell mobilization
- Traumatic brain injury
- Wound healing

Additional Information:

Examples of Hypothalamic/Pituitary/CNS disorders:

Congenital structural abnormalities:

1. Optic nerve hypoplasia/septic-optic dysplasia
2. Agenesis of corpus callosum
3. Empty sella syndrome
4. Ectopic posterior pituitary
5. Pituitary aplasia/hypoplasia
6. Pituitary stalk defect
7. Vascular malformations

Congenital genetic abnormalities: Mutations in growth hormone-releasing hormone (GHRH) receptor, growth hormone (GH) gene, growth hormone (GH) receptor or pituitary transcription factors

Acquired structural abnormalities (or causes of hypothalamic/pituitary damage):

1. Central Nervous System (CNS) tumors/neoplasms (for example: craniopharyngioma, glioma, pituitary adenoma)
2. Cysts (Rathke cleft cyst or arachnoid cleft cyst)
3. Surgery
4. Radiation
5. Chemotherapy
6. Central Nervous System (CNS) infections
7. Centra Nervous System (CNS) infraction (e.g., Sheehan's syndrome)
8. Inflammatory lesions (e.g., autoimmune hypophysitis)
9. Infiltrative lesions (e.g., sarcoidosis, histiocytosis)
10. Head trauma/traumatic brain injury
11. Aneurysmal subarachnoid hemorrhage

Pituitary Hormones (other than growth hormones)

1. ACTH (adrenocorticotropic hormone)

2. ADH (Antidiuretic hormone)
3. FSH (follicle stimulating hormone)
4. LH (luteinizing hormone)
5. Oxytocin
6. Prolactin
7. TSH (thyroid stimulating hormone)

Appendix

Growth Charts:

Growth charts for infants, children and adolescents are posted at the following internet sites:
Centers for Disease Control and Prevention:
https://www.cdc.gov/growthcharts/cdc_charts.htm
(This link includes growth charts with curves down to 2 standard deviations (approximately 3rd percentile)).
https://www.cdc.gov/nccdphp/dnpa/growthcharts/resources/growthchart.pdf
https://www.aafp.org/afp/2015/0701/p43.pdf

Height Velocity Tables:

Figure 1: Height Velocity (cm/year) -- Girls

Age	3rd Percentile	10th Percentile	25th Percentile
2.0	6.4	7.1	8.4
2.5	5.8	6.7	7.7
3.0	5.5	6.3	7.2
3.5	5.2	6.0	6.7
4.0	5.0	5.8	6.4
4.5	4.8	5.4	6.2
5.0	4.6	5.2	5.9
5.5	4.5	5.0	5.7
6.0	4.4	5.0	5.6
6.5	4.3	4.9	5.5
7.0	4.3	4.8	5.4
7.5	4.3	4.8	5.3
8.0	4.2	4.7	5.2
8.5	4.1	4.7	5.2
9.0	4.1	4.8	5.2
9.5	4.2	4.9	5.3
10.0	4.4	5.0	5.6

10.5	4.8	4.6	6.1
11.0	5.8	6.4	7.0
11.5	6.1	6.9	7.5
12.0	5.2	6.3	6.8
12.5	3.5	4.6	5.5
13.0	2.4	3.0	3.7
13.5	1.3	1.7	2.4
14.0	0.3	0.8	1.4
14.5	0	0.2	0.5

Figure 2: Height Velocity (cm/year) -- Boys

Age	3rd Percentile	10th Percentile	25th Percentile
2.0	6.3	6.7	8.0
2.5	5.7	6.4	7.4
3.0	5.4	6.1	7.0
3.5	5.1	5.8	6.6
4.0	4.9	5.7	6.3
4.5	4.8	5.5	6.1
5.0	4.6	5.3	5.9
5.5	4.4	5.1	5.7
6.0	4.3	5.0	5.7
6.5	4.2	4.9	5.4
7.0	4.1	4.7	5.3
7.5	4.0	4.6	5.2
8.0	3.8	4.5	5.0
8.5	3.8	4.4	4.9
9.0	3.8	4.4	4.8
9.5	3.8	4.3	4.7
10.0	3.7	4.2	4.7

10.5	3.7	4.2	4.6
11.0	3.7	4.2	4.6
11.5	3.8	4.2	4.8
12.0	4.0	4.7	5.1
12.5	4.9	5.5	6.2
13.0	6.1	7.3	8.0
13.5	7.1	8.0	8.7
14.0	6.0	7.2	7.5
14.5	4.3	5.1	5.6
15.0	2.3	3.5	4.0
15.5	1.1	2.2	2.6
16.0	0.3	1.2	1.6
16.5	0.0	0.5	1.0
17.0	0.0	0.1	0.5

Source: Interpolated from data from Tanner and Davies (1995).
Conversion Factor: 1 centimeter (cm) = 0.394 inches (in). 1 in = 2.54 cm.
Note: Assuming a normal distribution, 1 standard deviation below the mean is approximately equal to the 16th percentile, 2 standard deviations below the mean is equal to the 2nd percentile, and 3 standard deviations below the mean is equal to the 1/10th (0.1) percentile.

Weight for Gestational Age Table:

Small for gestational age is generally defined as weight for gestational age below the 10th percentile at birth. A chart indicating the 10th and 90th percentiles of weight for gestational age at birth is presented in Pediatrics 2014;133;844 (Talge et al 2014) Table-1 and Table-2 and is available at the following website:

http://pediatrics.aappublications.org/content/pediatrics/133/5/844.full.pdf
Normal Results of a growth hormone (GH) Stimulation Test (using arginine, glucagon or insulin):Available at:
https://emedicine.medscape.com/article/2089136-overview

- Normal peak value -- at least 10 ng/ml
- Indeterminate -- 5 to 10 ng/ml
- Subnormal -- 5 ng/ml

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