

**Pharmacy Prior Authorization
Growth Hormone - Clinical Guidelines**

Preferred Agent: Norditropin

Non-Preferred Agents: Genotropin, Humatrope, Omnitrope, Nutropin, Saizen, Zorbitive, Zomacton, Serostim, Skytrofa

Coverage criteria for a Non-preferred growth hormone product:

- Member meets one of following criteria:
 - There was inadequate response, intolerable side effect, or contraindication to preferred agent
 - Member has inability to use vial formulation due to disability
 - For example: visual/physical impairment
 - There is no preferred product appropriate for the condition being treated
- In addition, for Skytrofa, member is at least one year of age and weighs at least 11.5kg

I. Growth Hormone Deficiency in Children and Adolescents:

- Provider must submit documentation of medical records that include the following:
 - Weight, height, growth velocity
 - 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 deficiency:**
 - Member meets one of the following:
 - Height:
 - Height is greater than 2 standard deviation below mid parental height (projected height) -
 - OR**
 - Growth Velocity:
 - Growth Velocity is greater than 2 standard deviation below population mean for age and gender
 - OR**
 - Delayed skeletal maturation (delayed bone age confirmed by X-ray):
 - Bone age compared to chronological age is equal to or greater than 2 standard

**Pharmacy Prior Authorization
Growth Hormone - Clinical Guidelines**

deviation below mean for age and gender

- For example, delayed more than or equal to 2 years compared with chronological age

AND

- Member meets one of following laboratory results:
 - Two provocative growth hormone (GH) stimulation test
 - For example: Arginine, Clonidine, Glucagon, Insulin, Levodopa, 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

- Age is less than 1 year 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 physician's lab

AND

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

Prader-Willi Syndrome:

- Member meets the following for initial approval:
 - Prescribed by or in consultation with a pediatric endocrinologist, pediatric nephrologist, or endocrinologist
 - 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 is greater than 2 standard deviation below population mean for age and gender
 - Epiphyses are open (confirmation of open growth plates in members over 12 years of age)

Turner Syndrome (Gonadal Dysgenesis):

- Member meets the following for initial approval:
 - 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, at least 2 years of age, with Bone Age less than 14 years
 - Growth velocity is greater than 2 standard deviation below population mean for age and gender
 - Epiphyses are open (confirmation of open growth plates in members over 12 years of age)

Noonan Syndrome (Norditropin):

- Member meets the following for initial approval:
 - Prescribed by or in consultation with a pediatric endocrinologist, pediatric nephrologist, or endocrinologist
 - Diagnosis of Noonan Syndrome

**Pharmacy Prior Authorization
Growth Hormone - Clinical Guidelines**

- Epiphyses are open (confirmation of open growth plates in members over 12 years of age)
- Bone age compared to chronological age is equal to or greater than 2 standard deviation below mean for age and gender (for example: delayed more than or equal to 2 years compared with chronological age); **OR**
- Growth velocity 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)

- Member meets the following for initial approval:
 - 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 compared to chronological age is equal to or greater than 2 standard deviation below mean for age and gender (for example: delayed more than or equal to 2 years compared with chronological age); **OR**
 - Growth velocity is greater than 2 standard deviation below population mean for age and gender

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

- Member meets the following for initial approval:
 - Prescribed by or in consultation with a pediatric endocrinologist, pediatric nephrologist, or endocrinologist
 - Diagnosis of pediatric growth failure due to chronic renal insufficiency
 - For example, serum creatinine is less than 30 mg/dl, up to the time of renal transplant
 - Bone age compared to chronological age is equal to, or greater than 2 standard deviation below mean for age and gender
 - For example, delayed more than or equal to 2 years compared with chronological age**OR**
 - Growth velocity is greater than 2 standard deviation below population mean for age and gender

Note: Prior to initiation of growth hormone treatment, existing metabolic derangements such as malnutrition, zinc deficiency, and secondary hyperparathyroidism should be corrected.

Growth Failure in Children Small for Gestational Age:

- Provider must submit documentation of medical records that include the following:
 - Gestational Age, birth weight, height, and growth chart
- Member is greater than 2 years of age
- Diagnosis of small for gestational age (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 the following:
 - Gestational age is below the 3rd percentile for birth weight and length
 - More than 2 standard deviation below population mean**AND**

**Pharmacy Prior Authorization
Growth Hormone - Clinical Guidelines**

- Height remains below the 3rd percentile for age and gender
 - More than 2 standard deviation below population mean

Initial Approval duration: 12 months

Renewal criteria for growth hormone therapy in Children:

- Provider must submit documentation of medical records that include the following:
 - Previous height, current height and expected adult height goal
- Positive response to therapy showing:
 - 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
 - Bone age is less than 16 years for males and less than 14 years for females
 - Growth (epiphyseal) plates are still open

Renewal Criteria for children with Prader Willi Syndrome:

- Documentation of medical records supporting positive response to therapy such as increase in total lean body mass, decrease in fat mass

Renewal Approval duration: 12 months

Discontinuation criteria for growth hormone 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 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

- Provider must submit documentation of medical records that include the following:
 - Member has attained expected adult height
 - Closed epiphyses on bone radiograph
 - Member is at high risk of growth hormone deficiency due to childhood-onset growth hormone deficiency (COGHD) from one of following:
 - Hypothalamic-pituitary structural defect or tumor
 - At least 3 deficiency of anterior pituitary hormones
 - For example, follicle-stimulating hormone (FSH)/luteinizing hormone (LH), thyroid-stimulating hormone (TSH), adrenocorticotrophic hormone (ACTH), Prolactin), pan hypopituitarism
 - Genetic cause of growth hormone
 - Insulin-like growth factor (IGF-1) is below the age and gender adjusted normal range as provided by physician's lab
- OR**
- Member has stopped growth hormone therapy for at least one month and has undergone one provocative growth hormone stimulation test (for example: insulin tolerance test (ITT), glucagon) confirming transition phase growth hormone deficiency **AND** one of following peak values:
 - Insulin tolerance test (ITT): Less than or equal to 5ng/mL

**Pharmacy Prior Authorization
Growth Hormone - Clinical Guidelines**

- Glucagon: Less than or equal to 3ng/mL

Note:

- Transition Phase is 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 defined as a person between the age of 10 and 19 per the World Health Organization (WHO)
- There is no proven benefit to continuing growth hormone treatment in adulthood for childhood growth hormone 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:**

- Provider must submit documentation of medical records that include the following for renewal requests:
 - Positive response to therapy
 - For example, increase in total lean body mass, exercise capacity or insulin-like growth factor-1 (IGF-1) level

Renewal Approval duration: 12 months**III. Adult Growth Hormone Deficiency:**

- Provider must submit documentation of medical records supporting diagnosis, stimulation test results, and insulin-like growth factor-1 (IGF-1) levels
- Diagnosis is for one of the following:
 - childhood-onset growth hormone deficiency (COGHD)
 - adult-onset growth hormone deficiency (AOGHD)
- 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
- Member has undergone one provocative growth hormone stimulation test (for example: insulin tolerance test (ITT), glucagon, macimorelin) confirming adult growth hormone deficiency **AND** one of following peak values:
 - Insulin tolerance test (ITT): Less than or equal to 5ng/mL
 - Glucagon: Less than or equal to 3ng/mL
 - Macrilen (macimorelin): Less than 2.8ng/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 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.

- 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

**Pharmacy Prior Authorization
Growth Hormone - Clinical Guidelines**

- For example: follicle-stimulating hormone (FSH)/luteinizing hormone (LH), thyroid-stimulating hormone (TSH), adrenocorticotrophic hormone (ACTH), Prolactin), pan-hypopituitarism;

AND

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

Initial Approval duration: 12 months**Renewal criteria for Adult Growth Hormone deficiency:**

- Provider must submit documentation of medical records that include the following for renewal requests:
 - Chart notes, insulin-like growth factor-1 (IGF-1) levels
- Positive response to therapy
 - For example, increase in total lean body mass, exercise capacity, or insulin-like growth factor-1 (IGF-1) levels

Renewal Approval duration: 12 months**IV. HIV-associated Cachexia or Wasting (Serostim):**

- Provider must submit documentation of medical records that include the following, prior to initiation of therapy, and after initiation of therapy, with Serostim for renewal requests:
 - Body mass index (BMI), weight, and ideal body weight (IBW)
 - Prescribed by or in consultation with an infectious Disease or Human Immunodeficiency Virus (HIV) Specialist
 - Member is currently on antiretroviral therapy
 - There was inadequate response, intolerable side effects, or contraindication to megestrol acetate or dronabinol
 - 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
 - Body mass index (BMI) less than 20 kg/m² 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 for HIV-associated Cachexia or Wasting (Serostim):**

- Documentation of medical records supporting positive response to therapy:
 - Body mass index (BMI) has improved or stabilized
- Member is currently on antiretroviral therapy

Renewal Approval duration: 9 months (Maximum total: 48 weeks)**V. Short Bowel Syndrome (Zorbtive):**

- Diagnosis is for Short Bowel syndrome
- Member is 18 years of age or older
- Member is currently receiving specialized nutrition support

**Pharmacy Prior Authorization
Growth Hormone - Clinical Guidelines**

- For example, intravenous parenteral nutrition, fluid, and micronutrient supplements
- Member has not previously received 4 weeks of treatment with Zorbtive

Initial Approval duration: 4 weeks.

Treatment with Zorbtive will not be approved beyond 4 weeks as administration for more than 4 weeks has not been adequately studied.

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*

**Pharmacy Prior Authorization
Growth Hormone - Clinical Guidelines**

- 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. Central Nervous System (CNS) infraction (for example, Sheehan's syndrome)
8. Inflammatory lesions (for example, autoimmune hypophysitis)
9. Infiltrative lesions (for example, sarcoidosis, histiocytosis)
10. Head trauma/traumatic brain injury
11. Aneurysmal subarachnoid hemorrhage

Pituitary Hormones (other than growth hormones)

1. ACTH (adrenocorticotrophic hormone)
2. ADH (Antidiuretic hormone)
3. FSH (follicle stimulating hormone)

**Pharmacy Prior Authorization
Growth Hormone - Clinical Guidelines**

- 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 |

**Pharmacy Prior Authorization
Growth Hormone - Clinical Guidelines**

| | | | |
|------|-----|-----|-----|
| 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 |

**Pharmacy Prior Authorization
Growth Hormone - Clinical Guidelines**

| | | | |
|------|-----|-----|-----|
| 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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Pharmacy Prior Authorization Growth Hormone - Clinical Guidelines

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**Pharmacy Prior Authorization
Growth Hormone - Clinical Guidelines**

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