



**BlueCross BlueShield  
of Alabama**

## **Growth Hormone Prior Authorization Program Summary**

The preferred product is Omnitrope.

This program applies to Commercial, NetResults A series, SourceRx, and Health Insurance Marketplace.

### **OBJECTIVE**

The intent of the Growth Hormone Prior Authorization (PA) Criteria is to appropriately select patients for therapy according to Food and Drug Administration (FDA) approved product labeling and/or clinical guidelines and/or clinical studies. When criteria for use are met, the preferred agent, Omnitrope, may be approved for use; use of the nonpreferred growth hormone products may be approved if the prescriber indicates failure of, documented intolerance of, FDA labeled contraindication to, or hypersensitivity to Omnitrope.

#### **TARGET AGENTS**

*Preferred Growth Hormone products*  
Omnitrope® (somatropin)

*Nonpreferred Growth Hormone products*

Genotropin® (somatropin)  
Humatrope® (somatropin)  
Norditropin® NordiFlex, Norditropin Flexpro (somatropin)  
Nutropin AQ® (somatropin)  
Nutropin AQ Nuspin® (somatropin)  
Saizen®, Saizen Click.Easy (somatropin)  
Serostim® (somatropin)  
Zomacton® (somatropin)  
Zorbtive® (somatropin)

### **PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

**Growth Hormone (GH) products** will be approved as below.

For **Children - Initial Evaluation** when the following is met:

1. The patient has ONE of the following diagnoses:
  - a. The patient is a neonate ( $\leq 4$  months of age) with hypoglycemia in the absence of metabolic disorder  
**AND**
  - i. The GH level is  $< 20$  ng/mL
  - OR**
  - b. The patient has a diagnosis of Turner's Syndrome  
**OR**
  - c. The patient has a diagnosis of Noonan Syndrome  
**OR**
  - d. The patient has a diagnosis of Prader-Willi Syndrome  
**OR**
  - e. The patient has a diagnosis of SHOX gene deficiency  
**OR**
  - f. The patient has a diagnosis of short bowel syndrome (SBS) AND is receiving enteral or parenteral nutritional support or other specialized nutritional support  
**OR**
  - g. The patient has a diagnosis of panhypopituitarism or has deficiencies in at least 3 or more pituitary axes AND serum IGF-1 levels below the age- and sex-appropriate reference range when off GH therapy

**OR**

- h. The patient has a diagnosis of chronic renal insufficiency and BOTH of the following:
- i. The patient's height is more than 2 standard deviations (SD) below the mean (less than the third percentile) compared to normal children of the same age

**AND**

- ii. Other etiologies for growth retardation have been ruled out

**OR**

- i. The patient has a diagnosis of growth hormone deficiency (GHD), short stature, or other AND BOTH of the following:

- i. The patient has ONE of the following:

1. Height more than 2 SD below the mean for age and sex

**OR**

2. Height more than 1.5 SD below the midparental height

**OR**

3. A decrease in height SD of more than 0.5 over one year in children >2 years of age

**OR**

4. Height velocity more than 2 SD below the mean over one year or more than 1.5 SD sustained over two years.

**AND**

- ii. The patient has failed at least 2 GH stimulation tests (peak GH value of <10 mcg/L after stimulation)

**OR**

- j. The patient has a diagnosis of small for gestational age (SGA) and ALL of the following:

- i. The patient is at least 2 years of age

**AND**

- ii. The patient has a documented birth weight and/or length that is 2 or more standard deviations (SD) below the mean for gestational age

**AND**

- iii. At 24 months of age, the patient failed to manifest catch-up growth evidenced by a height 2 or more standard deviations (SD) below the mean for age and sex

**AND**

2. The patient does not have any FDA labeled contraindication(s) to therapy with the requested agent

**AND**

3. For all agents except Omnitrope, ONE of the following:
  - a. The patient has failed the preferred growth hormone product Omnitrope

**OR**

  - b. The patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred growth hormone product Omnitrope

**OR**

  - c. The prescriber has submitted documentation in support of the use of the non-preferred growth hormone product, for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

**Length of Approval:** 4 weeks for SBS  
12 months for other indications

For **Children – Renewal Evaluation** when BOTH of the following are met:

1. The patient has been approved for the requested GH product previously through the Prime Therapeutics PA process

- AND**
2. ONE of the following:
    - a. The patient has a diagnosis of short bowel syndrome (SBS) AND has shown clinical benefit from treatment with growth hormone

**OR**

    - b. The patient has any other diagnosis AND ALL of the following:
      - i. The patient does not have closed epiphyses

**AND**

      - ii. The patient's height is increased or height velocity has improved since initiation or last GH approval

- AND**
3. The patient is being monitored for side effects of GH

- AND**
4. The patient does not have any FDA labeled contraindication(s) to therapy with the requested agent

**Length of Approval:** 4 weeks for SBS  
12 months for other indications

For **Adults - Initial Evaluation** when ANY ONE of the following is met:

1. The patient has ONE of the following diagnoses:
    - a. The patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following:
      - i. The patient is receiving antiretroviral therapy and GH concurrently

**AND**

      - ii. ONE of the following:
        1. The patient has had an unintentional weight loss of 10% or more of body weight over 12 months

**OR**

        2. The patient has had an unintentional weight loss of >7.5% over 6 months

**OR**

        3. The patient has a mid-upper arm circumference <10<sup>th</sup> percentile

**OR**

        4. The patient has a body cell mass (BCM) loss ≥5% over 6 months as documented by bioelectrical impedance analysis

**OR**

        5. The patient has a BCM <35% for males or <23% for females AND a BMI of <27 kg/m<sup>2</sup>
- AND**
- iii. ONE of the following:
    1. The patient's medication history indicates use of an appetite stimulant (dronabinol or megestrol)

**OR**

    2. The patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to an appetite stimulant (dronabinol or megestrol)
- OR**
- b. The patient has a diagnosis of short bowel syndrome (SBS) AND is receiving enteral or parenteral nutritional support or other specialized nutritional support
- OR**
- c. The patient has a diagnosis of childhood growth hormone deficiency (GHD) with genetic or organic origin AND ONE of the following:
    - i. The patient has a low IGF-1 (insulin-like growth factor-1) level without GH replacement

**OR**

- ii. The patient has failed at least one growth hormone (GH) stimulation test as an adult (peak GH value of  $\leq 5$  mcg/L after stimulation)

**OR**

- d. The patient has a diagnosis of acquired adult GHD secondary to structural lesions or trauma **AND ONE** of the following:

- i. The patient has a diagnosis of panhypopituitarism or is deficient in at least 3 or more pituitary hormones and the patient's IGF-1 level is low

**OR**

- ii. The patient has failed at least one growth hormone (GH) stimulation test as an adult

**OR**

- e. The patient has a diagnosis of idiopathic GHD (adult or childhood onset)

**AND** the following:

- i. The patient has failed at least two growth hormone (GH) stimulation tests as an adult

**AND**

- 2. The patient does not have any FDA labeled contraindication(s) to therapy with the requested agent

**AND**

- 3. For all agents except Omnitrope, then **ONE** of the following:

- a. The patient has failed the preferred growth hormone product Omnitrope

**OR**

- b. The patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred growth hormone product Omnitrope

**OR**

- c. The prescriber has submitted documentation in support of the use of the non-preferred growth hormone product, for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

**Length of Approval:** 4 weeks for SBS;  
12 weeks for AIDs wasting/cachexia;  
12 months for other indications

For **Adults - Renewal Evaluation** when **ANY ONE** of the following is met:

- 1. The patient has been approved for the requested GH product previously through the Prime Therapeutics PA process

**AND**

- 2. **ONE** of the following:

- a. The patient has a diagnosis of short bowel syndrome (SBS) **AND** has shown clinical benefit from treatment with growth hormone

**OR**

- b. The patient has a diagnosis of AIDS wasting/cachexia **AND BOTH** of the following:

- i. The patient continues to receive concurrent antiretroviral and GH therapy

**AND**

- ii. The patient shows evidence of benefit of GH treatment (weight increase or weight stabilization)

**OR**

- c. The patient has any other diagnosis **AND ALL** of the following:

- i. The patient's IGF-1 level has been evaluated to confirm the appropriateness of the current dose

**AND**

- ii. The patient has had benefits from GH therapy in any of the following response parameters; body composition, hip-to-waist ratio, cardiovascular health, bone mineral density, serum cholesterol, physical strength, or quality of life

**AND**

3. The patient does not have any FDA labeled contraindication(s) to therapy with the requested agent
- AND**
4. The patient is being monitored for adverse effects of GH

**Length of Approval:** 4 weeks for SBS;  
12 weeks for AIDs wasting/cachexia;  
12 months for other indications

*This pharmacy policy is not an authorization, certification, explanation of benefits or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All pharmacy policies are based on (i) information in FDA approved package inserts (and black box warning, alerts, or other information disseminated by the FDA as applicable); (ii) research of current medical and pharmacy literature; and/or (iii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*The purpose of Blue Cross and Blue Shield of Alabama's pharmacy policies are to provide a guide to coverage. Pharmacy policies are not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.*

*Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.*

**FDA APPROVED INDICATIONS AND DOSAGE \*\* 1-8,26,29**

Available Products	GHD* IN CHILDREN	GHD IN ADULTS <sup>±</sup>	CKD	PWS	TS	SGA	ISS	SHOX	HIV	NS	SBS
<b>Genotropin<sup>®</sup></b> (mg/kg/week)	✓ 0.16-0.24	✓ 0.04-0.08		✓ 0.24	✓ 0.33	✓ Up to 0.48	✓ Up to 0.47				
<b>Humatrope<sup>®</sup></b> (mg/kg/week <sup>^</sup> )	✓ 0.18-0.3	✓ 0.006-0.0125 <sup>^</sup> mg/kg/day			✓ Up to 0.375	✓ Up to 0.47	✓ Up to 0.37	✓ 0.35			
<b>Norditropin<sup>®</sup></b> (mg/kg/day)	✓ 0.024-0.034	✓ 0.004-0.016		✓ 0.24	✓ Up to 0.067	✓ Up to 0.067	✓ Up to 0.47			✓ Up to 0.066	
<b>Nutropin<sup>®</sup> AQ</b> (mg/kg/week)	✓ 0.3-0.7	✓ 0.006-0.025 (≤35 y.o.) or up to 0.0125 (>35 y.o.) mg/kg/day	✓ Up to 0.35		✓ Up to 0.375		✓ Up to 0.3				
<b>Omnitrope</b> (mg/kg/week)	✓ 0.16-0.24	✓ 0.04-0.08		✓ 0.24	✓ 0.33	✓ Up to 0.48	✓ Up to 0.47				
<b>Saizen<sup>®</sup></b> (mg/kg/week)	✓ 0.18	✓ 0.005 initial mg/kg/day May be increased to no more than 0.01 mg/kg/day after 4 weeks									
<b>Serostim<sup>®</sup></b> (mg/kg/day)									✓ 0.1 (up to 6 mg daily)		
<b>Zomacton<sup>®</sup></b> (mg/kg 3 times/week)	✓ 0.1 (up to 0.3 mg/kg/week)	✓ Non-weight based: initial 0.15-0.3 mg/day and may increase every 1-2 months by 0.1-0.2 mg/day  Weight based (not recommended for obese): Initial 0.006									



therapy allows the body to use fat for energy, thereby preserving lean body mass.<sup>2</sup> Diagnosis of wasting may utilize any of the following elements: subjective global assessment; mid-upper arm circumference and skin-fold; guidelines proposed in 2001 delineate parameters of time, body cell mass (BCM) loss, and loss of total body mass (BMI).<sup>23</sup>

Short bowel syndrome (SBS) is a malabsorption disorder caused by either the surgical removal of the small intestine or the loss of its absorptive function due to various diseases. In clinical studies, the administration of GH enhanced the transmucosal transport of water, electrolytes, and nutrients. Zorbitive is indicated for the treatment of SBS in patients receiving specialized nutritional support.<sup>4</sup>

The principal features of Noonan Syndrome, a congenital disorder, include heart malformation, short stature, indentation of the chest, learning disabilities, impaired blood clotting, and a certain configuration of facial features. Short stature is present in as many as 80% of patients.<sup>13</sup>

Short stature may be the only apparent feature present in children with GHD.<sup>20</sup> The following features indicate a need for further investigation; severe short stature (height more than three SD below the mean), height more than 1.5 SD below the midparental height, height more than two SD below the mean and a height velocity over one year more than one SD below the mean for chronological age, or a decrease in height SD of more than 0.5 over one year in children over two years of age.<sup>20</sup> Patients who have GHD presenting at infancy or have acquired GHD, short stature may not yet be apparent. These patients may present with height velocities more than 2 SD below the mean over one year or more than 1.5 SD sustained over two years.<sup>20</sup>

The International Societies of Pediatric Endocrinology and the Growth Hormone Research Society state that the definition of short gestation age (SGA) is not straightforward; however, they recommend that SGA should be defined as a weight and/or length less than -2 SD because this will identify the majority of those in whom ongoing growth assessment is required (this definition is also mirrored in other publications).<sup>27,29</sup> It is believed that identification of SGA is important since these infants are at an increased risk for perinatal morbidity, associated health problems (e.g. neurodevelopmental disorders), persistent short stature, and metabolic alterations in later life. Regarding GH therapy, they state that there should be a positive response to GH treatment (height velocity SD score more than +0.5 in the first year of treatment). If there is an inadequate response, reevaluation is indicated, including consideration of compliance, GH dose, diagnosis, and the decision to discontinue treatment. In those with a positive response to GH, withdrawal of GH therapy after 2–3 yr leads to catch-down growth and is not recommended. Discontinuation of GH treatment in adolescence is recommended when the growth rate falls to less than 2 cm/yr.<sup>27</sup>

The Royal College of Obstetricians and Gynecologists (2013) define SGA as an infant born with a birth weight less than the 10th percentile. Historically SGA birth has been defined using population percentiles. But, the use of percentiles customized for maternal characteristics (maternal height, weight, parity and ethnic group) as well as gestational age at delivery and infant sex, identifies small babies at higher risk of morbidity and mortality than those identified by population percentiles. With respect to the fetus, definitions of SGA birth and severe SGA vary. They defined SGA birth as an estimated fetal weight (EFW) or abdominal circumference (AC) less than the 10th percentile and severe SGA as an EFW or AC less than the 3rd percentile.<sup>28</sup>

### **Laboratory Tests for Diagnosis of GHD**

Evaluation for GHD should be considered if the following conditions exist:<sup>10-12,19</sup>

- A child with a standing height of more than 3 standard deviation below the mean for chronological age, sex, and ethnic background
- A child with a height velocity below the fifth to tenth percentile for age, with no clear etiology



- A child with a standing height that is 2 SD to 3 SD below the mean for chronologic age, and with growth deceleration (growth velocity less than the twenty-fifth percentile) that cannot otherwise be explained
- Hypothalamic-pituitary dysfunction (e.g., microphallus, septo-optic dysplasia, intracranial tumor, history of cranial irradiation) with decelerating growth
- Deficits in other hypothalamic-pituitary hormones, either congenital or acquired
- Adults with manifestations suggestive of GHD

In newborns, a serum growth hormone level of < 20 ng/mL is highly suggestive of GHD.

Guidelines recommend that the presence of deficiencies in three or more pituitary axes (panhypopituitarism) and serum IGF-1 levels below the age- and sex-appropriate reference range when off GH therapy are deemed GHD, and do not require further stimulation testing.<sup>17,22,24</sup>

GH stimulation (provocative) tests play a critical role in the diagnosis of GHD. The most frequently used tests include the insulin tolerance test (ITT); arginine; growth hormone releasing hormone (GHRH), with or without arginine; levodopa (L-dopa); glucagon, with or without a beta blocker, such as propranolol; and clonidine.<sup>10,11,19</sup>

Most endocrinologists use a cutoff serum growth hormone concentration of more than 10 mcg/L in children and of more than 3 mcg/L (some authorities use 5 mcg/L) in adults to define normal response on provocative tests. The following are the most recent guidelines regarding stimulation testing; however, they are both outdated (2009 and 2011) and not up-to-date with current clinical practice.<sup>10,11,17,19</sup>

- The Growth Hormone Research Society has recommended the ITT as the standard test for the diagnosis of GHD in adults.<sup>11</sup>
- In an ITT, insulin is administered intravenously to produce a nadir in the plasma glucose level of less than 40 mg/dL (2.2 mmol/L); serum (or blood) glucose and serum growth hormone levels are measured at times 0, 15, 30, 60, 90, and 120 minutes after administering insulin. An experienced staff under the direct supervision of a physician should perform the test. GHD is diagnosed when the growth hormone level is less than 5 mcg/L.
- An ITT is contraindicated in patients with cardiovascular disease, cerebrovascular disease, or seizure disorders, or in patients older than 65 years.
- The GHRH-arginine test was used by many centers as an alternative to the ITT. When the GHRH-arginine test was employed, a GHD was diagnosed when the growth hormone level was < 4.1 mcg/L. However, manufacture of Geref (GHRH) was indefinitely discontinued in 2008 and unavailability of recombinant GHRH in the United States has created a need for a reliable alternative to this test. To establish the diagnosis of adult GHD in patients with child-onset GHD, the ITT is the preferred test. The glucagon test, and rarely the ARG test, are acceptable alternatives.
- In patients with a GHD of hypothalamic origin (as a result, for example, of irradiation), GHRH can give falsely normal testing. In such patients, ITT or glucagon should be used.<sup>17</sup>
- In patients where the ITT is not desirable and when recombinant GHRH is not available, the glucagon test is a reliable alternative, but not the levodopa and clonidine tests.<sup>17</sup>

Some clinicians require that these criteria occur on 2 provocative tests because of the high frequency of false-negative results for each single test.<sup>10,19</sup>

### **Treatment of Growth Hormone Deficiency**

All somatotropin (GH) therapy is indicated in children with growth hormone deficiency (GHD) with an abnormal growth velocity curve, and an untreated growth velocity less than the tenth percentile for bone age and gender.<sup>13</sup> The American Association of Clinical Endocrinologists (AACE) and the National Institute for Health and Clinical Excellence (NICE) recommend somatotropins in children with GHD, Turner's syndrome, chronic renal insufficiency, and Prader-Willi Syndrome.<sup>17-18</sup> The NICE 2010 updated guidelines also include the recommendation for the

use of somatotropins in children born small for gestational age with subsequent failure at 4 years of age or later and short stature homeobox-containing gene (SHOX) deficiency.<sup>18</sup> There is no differentiation between different somatotropin products made in either guideline, and no specific product is recommended over another.

The American Association of Clinical Endocrinologists Medical Guidelines for GH use in GH Deficient Adults and Transition Patients-2009 Update recommendations include<sup>17</sup>:

- GH should only be prescribed to patients with clinical features suggestive of adult GHD and biochemically proven evidence of adult GHD.
- No data are available to suggest that GH has beneficial effects in treating aging and age-related conditions and the enhancement of sporting performance; therefore, we do not recommend the prescription of GH to patients for any reason other than the well-defined approved uses of the drug.
- For childhood GH treatment of conditions other than GHD, such as Turner's syndrome and idiopathic short stature, there is no proven benefit to continuing GH treatment in adulthood; hence, there is no indication to retest these patients when final height is achieved.
- On restarting GH therapy, the starting dose of GH in transition patients should be approximately 50% of the dose between the pediatric doses required for growth and the adult dose.
- "There is no evidence that one GH product is more advantageous over the other, apart from differences in pen devices, dose increments and decrements, and whether or not the product requires refrigeration; therefore, we do not recommend the use of one commercial GH preparation over another."

The Endocrine Society Clinical Practice guideline (2011) for evaluation and treatment of adult growth hormone deficiency recommends that 2 stimulation tests be performed for patients with idiopathic GHD due to the difficulty in accurately diagnosing this condition. These guidelines also advise that deficiencies in 3 or more pituitary axes is strongly suggestive of GHD and stimulation testing is optional in this situation.<sup>22</sup>

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