Pharmacy Policy Bulletin: J-0150 Human Growth Hormone - Commercial and Healthcare Reform - Delaware	
Number: J-0150	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial (1.)**: **1.** Growth Hormone = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☐ All ☒ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0150-028	**Original Date:** 03/08/2012
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Genotropin (somatropin) • Humatrope (somatropin) • Ngenla (somatrogon-ghla) • Norditropin (somatropin) • Nutropin (somatropin) • Omnitrope (somatropin) • Saizen (somatropin) • Serostim (somatropin) • Skytrofa (lonapegsomatropin-tcgd) • Sogroya (somapacitan-beco) • Zomacton (somatropin) • Zorbtive (somatropin)
FDA-Approved Indication(s):	• Genotropin (somatropin) ○ Pediatric Patients ▪ growth failure due to an inadequate secretion of endogenous growth hormone (GH) ▪ growth failure due to Prader-Willi syndrome (PWS). The diagnosis of PWS should be confirmed by appropriate genetic testing. ▪ growth failure in children born small for gestational age (SGA) who fail to manifest catch-up growth by age 2 years. ▪ growth failure associated with Turner syndrome. ▪ 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, 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. ○ Adult Patients ▪ replacement of endogenous GH in adults with growth hormone deficiency (GHD) who meet either of the following two criteria:

- Adult Onset (AO): Patients who have GHD, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; or
- Childhood Onset (CO): Patients who were GH deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes.

- Humatrope (somatropin)
  - Pediatric Patients
    - growth failure due to inadequate secretion of endogenous growth hormone (GH)
    - short stature associated with Turner syndrome
    - Idiopathic Short Stature (ISS), height standard deviation score (SDS) < -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range
    - short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency
    - short stature born small for gestational age (SGA) with no catch-up growth by 2 years to 4 years of age
  - Adult Patients
    - replacement of endogenous GH in adults with GH deficiency
- Ngenla (somatrogon-ghla)
  - Pediatric Patients
    - growth failure due to inadequate secretion of endogenous growth hormone (GH) in pediatric patients aged 3 years and older
- Norditropin (somatropin)
  - Pediatric Patients
    - growth failure due to inadequate secretion of endogenous growth hormone (GH)
    - short stature associated with Noonan syndrome
    - short stature associated with Turner syndrome
    - short stature born small for gestational age (SGA) with no catch-up growth by age 2 years to 4 years of age
    - idiopathic Short Stature (ISS), height standard deviation score (SDS) < -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range
    - growth failure due to Prader-Willi syndrome (PWS)
  - Adult Patients
    - replacement of endogenous GH in adults with growth hormone deficiency (GHD)
- Nutropin (somatropin)
  - Pediatric Patients
    - growth failure due to inadequate secretion of endogenous growth hormone (GH)
    - growth failure associated with Chronic Kidney Disease (CKD) up to the time of renal transplantation. Nutropin AQ therapy should be used in conjunction with optimal management of CKD.
    - Idiopathic short stature (ISS), also called non-growth hormone deficient short stature, defined by height 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. ▪ short stature associated with Turner Syndrome (TS) ○ Adult Patients ▪ replacement of endogenous GH in adults with growth hormone deficiency (GHD) who meet either of the following two criteria: • Adult Onset: Patients who have GHD, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; or • Childhood Onset: Patients who were GH deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes. • Omnitrope (somatropin) ○ Pediatric Patients ▪ growth failure due to inadequate secretion of endogenous growth hormone (GH). ▪ growth failure due to Prader-Willi Syndrome (PWS). The diagnosis of PWS should be confirmed by appropriate genetic testing. ▪ growth failure in children born small for gestational age (SGA) who fail to manifest catch-up growth by age 2 years ▪ growth failure associated with Turner syndrome ▪ 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, 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. ○ Adult Patients ▪ replacement of endogenous GH in adults with growth hormone deficiency (GHD) who meet either of the following two criteria: • Adult Onset (AO): Patients who have GHD, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; or • Childhood Onset (CO): Patients who were GH deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes. • Saizen (somatropin) ○ Pediatric Patients ▪ growth failure due to inadequate secretion of endogenous growth hormone (GH) ○ Adult Patients ▪ replacement of endogenous GH in adults with growth hormone deficiency (GHD) who meet either of the following two criteria: • Adult Onset: Patients who have GHD, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; or

	• Childhood Onset: Patients who were GH deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes.
	• Serostim (somatropin)
	  ○ HIV patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance. Concomitant antiretroviral therapy is necessary.
	• Skytrofa (lonapegsomatropin-tcgd)
	  ○ Pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone.
	  ○ Replacement of endogenous growth hormone in adults with growth hormone deficiency.
	• Sogroya (somapacitan-beco)
	  ○ Pediatric Patients
	  ▪ treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH)
	  ○ Adult Patients
	  ▪ replacement of endogenous GH in adults with growth hormone deficiency (GHD)
	• Zomacton (somatropin)
	  ○ Pediatric Patients
	  ▪ growth failure due to inadequate secretion of endogenous growth hormone (GH)
	  ▪ short stature associated with Turner syndrome
	  ▪ idiopathic short stature (ISS), height standard deviation score (HSDS) ≤ -2.25 and associated with growth rates unlikely to permit attainment of adult height in the normal range
	  ▪ short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency
	  ▪ short stature born small for gestational age (SGA) with no catch-up growth by 2 years to 4 years of age
	  ○ Adult Patients
	  ▪ replacement of endogenous GH in adults with growth hormone deficiency (GHD)
	• Zorbtive (somatropin)
	  ○ short bowel syndrome in adult patients receiving specialized nutritional support

Background:	• Somatropin is a polypeptide hormone of recombinant DNA origin. The amino acid sequence of these products is identical to that of human growth hormone.
	• **Growth Failure due to Growth Hormone Deficiency**
	  ○ In growth hormone deficiency (GHD), growth failure is due to an inadequate secretion of normal endogenous growth hormone (GH). GHD in pediatrics can occur due to a genetic cause, acquired, or idiopathic. Genetic GHD is due to abnormalities in hypothalamic/pituitary development and function. Acquired GHD includes pituitary tumors, craniopharyngioma, trauma, infection, inflammation, or irradiation. Idiopathic GHD has no etiology identified.
	  ○ Neonatal GHD could be present due to hypoglycemia, prolonged jaundice, microphallus, or traumatic delivery.
	  ○ The administration of GH to children with GHD has resulted in increased linear growth and subsequent normal adult stature. Patients should be

	closely monitored for GH antibodies and continued response to the therapy. ○ The World Health Organization and consensus guidelines from the Growth Hormone Research Society state that a height more than 2 standard deviations below the mean can be used to define short stature. Interpretation of growth data requires the most recent relevant population standards available. Growth data should be expressed as standard deviation scores rather than as percentiles. ○ In children, GH therapy is typically discontinued when growth velocity is less than 2 cm per year, when epiphyseal fusion has occurred, or when the height reaches the 5th percentile of adult height. In patients with chronic renal failure undergoing transplantation, GH therapy is discontinued at the time of transplant. ○ Adult GHD is rare and can be caused by damage or because of continued deficiency first diagnosed in childhood. According to the American Association of Clinical Endocrinology, to continue treatment with GH therapy in adulthood, retesting for GHD with GH-stimulation test/s is recommended in most transition patients (for example, when longitudinal growth is complete, at least 1 month after discontinuation of pediatric GH therapy). Closure of the epiphyseal plate indicates that longitudinal growth is complete. Epiphyseal fusion generally occurs around 14-15 years in females and 16-17 years in males. • **Growth Failure due to Chronic Renal Disease (CKD)**: ○ Growth failure is a complication of CKD in which children do not grow as expected. • **Non-GHD Impaired Growth**: ○ Idiopathic short stature (ISS): Condition characterized by a height more than 2 standard deviations below the corresponding average height for a given age, sex, and population, without findings of disease (specifically, no evidence in systemic, endocrine, nutritional, or chromosomal abnormalities). Patients are of normal birth weight and are GH sufficient. ○ Small for gestational age (SGA): Infants smaller or less developed than normal for the infant's sex and gestational age. Defined as birth weight and/or birth length less than 2 standard deviation below the mean. About 90% of infants born with SGA will show catch-up growth within the first 2 years of life. • **Short Stature due to Genetic or Chromosomal Disorders**: ○ Growth hormone deficiency: Genetic abnormalities in hypothalamic/pituitary development and function. ○ Noonan Syndrome: Autosomal dominant genetic disorder. ○ Prader-Willi Syndrome: Genetic disorder caused by chromosome 15 with hypothalamic-pituitary dysfunction that affects multiple systems of the body. ○ Turner Syndrome: Congenital disorder caused by the loss of all, or a critical part, of one X chromosome, only occurs in females. ○ Short Stature Homeobox-containing gene (SHOX): The SHOX gene is located on the distal ends of the X and Y chromosomes and encodes a homeodomain transcription factor responsible for a significant proportion of long-bone growth. • **AIDS-Wasting**: Involuntary loss of more than 10% of body weight (especially muscle mass), plus at least 30 days of either diarrhea or weakness and fever. HIV-associated wasting syndrome is an AIDS-defining condition. • **Short Bowel Syndrome (SBS)**: Related to poor absorption of nutrients due to any type of surgery to take out part of the small intestine. • ICD-10 Code Information:

	○ ICD-10: E23 “Hypofunction and other disorders of the pituitary gland” may apply as a cause of GHD; however, the prescriber must confirm that the member has a specific diagnosis of GHD. ○ ICD-10: E23.0 “Hypopituitarism” may apply to multiple pituitary growth hormone deficiencies; however, the prescriber must specify the multiple deficiencies. ○ ICD-10: Z92.3 “Personal history of irradiation” may apply to central nervous system (CNS) irradiation; however, the prescriber must specify irradiation was at the CNS level. ○ ICD-10: Q87.1 “Congenital malformation syndromes predominantly associated with short stature” may apply to Noonan Syndrome; however, the prescriber must specify the diagnosis. ○ ICD-10: E34.3 “Short stature due to endocrine disorder” may apply to short stature homeobox-containing gene (SHOX); however, the prescriber must specify the diagnosis. ○ ICD-10: R64 “Cachexia” may apply to HIV/AIDS-wasting; however, the however, the prescriber must specify the diagnosis. ○ ICD-10: K90.9 “Intestinal malabsorption, unspecified” may apply to short bowel syndrome (SBS); however, the prescriber must specify the diagnosis. • Prescribing Considerations: ○ Recombinant DNA growth hormone drugs should be prescribed under the supervision of an endocrinologist. ○ **Growth Hormone Deficiency (GHD)**: ▪ Twenty-four (24) hour continuous measurements of GH, serum levels of insulin-like growth factors (IGF) or insulin-like growth factor binding protein (IGFBP) are considered inadequate to document GHD. ▪ Patients who were treated with somatropin for GHD in childhood and whose epiphyses are closed should be reevaluated before continuation of somatropin therapy at the reduced dose level recommended for growth hormone deficient adults. Confirmation of the diagnosis of adult GHD in both groups involves an appropriate GH provocative test with two exceptions: (1) patients with multiple other pituitary hormone deficiencies due to organic disease; and (2) patients with congenital/genetic GHD. ▪ Research has shown that patients who were treated with recombinant GH as children and adolescents and followed for up to 25 years, the risk of developing a cardiovascular event (for example, heart attack or stroke) was two-thirds higher for men and twice as high for women than among the untreated but otherwise similar people. Due to the risk of GH treatment leading to serious adverse health effects years later, carefully consider GH treatment among children who are short for their age but do not have a GHD or other medical condition that limits growth. ○ **Short Bowel Syndrome**: ▪ Administration of Zorbtive for more than 4 weeks has not been studied.

Approval Criteria

Table 1: Summary of Preferred Growth Hormone Products by Formulary

	Commercial & HCR Comprehensive, HCR Essential	Commercial National Select Formulary	Commercial Core

Preferred Products	Genotropin Humatrope Norditropin	Genotropin Omnitrope	Genotropin Humatrope Norditropin
Non-preferred Products	Ngenla Nutropin Omnitrope Saizen Skytrofa Sogroya Zomacton[2]	Humatrope[1] Ngenla Norditropin Nutropin Saizen Skytrofa Sogroya Zomacton[1]	Ngenla Nutropin Omnitrope Saizen Skytrofa Sogroya Zomacton[2]

[1]Humatrope and Zomacton are exempt from preferred product requirements when used for children with short stature homeobox-containing gene (SHOX) deficiency for the Commercial National Select Formulary.
[2]Zomacton requires a trial of Humatrope when used for children with SHOX deficiency for the Commercial & HCR Comprehensive, HCR Essential, and Commercial Core formularies; a trial of Genotropin and Norditropin is not required for this diagnosis.

I. Growth Hormone Deficiency

A. Children

1. Initial Authorization

When a benefit, coverage of Genotropin, Humatrope, Ngenla Norditropin, Nutropin, Omnitrope, Saizen, Skytrofa, Sogroya, or Zomacton may be covered when all of the following criteria are met **(a. and b.):**

a. The member meets one (1) of the following criteria **(i. or ii.)**:

i. The member is not a neonate and is using the product to treat documented growth failure due to inadequate secretion of endogenous growth hormone (no ICD-10 code) and meets all of the following criteria **(A) through F)):**

A) If the request is for Skytrofa, the member meets all of the following criteria **(1) and 2))**:

1) The member is 1 year of age or older.

2) The member weighs at least 11.5 kg.

B) If the request is for Sogroya, the member is 2.5 years of age or older.

C) If the request is for Ngenla, the member is 3 years of age or older.

D) The member meets one (1) of the following criteria, **(1) or 2))**:

1) Clinical documentation (specifically, growth charts) indicating a height at least 2 standard deviations below the age-appropriate mean.

2) Clinical documentation (specifically, growth charts) indicating a growth velocity at least 2 standard deviations below the age-appropriate mean.

E) The member has a subnormal response (< 10 ng/mL) to two (2) of the following standard growth hormone stimulation tests (1) through 6)):

1) arginine

2) clonidine

3) glucagon

4) insulin

5) L-dopa

6) propranolol

F) The member meets one (1) of the following criteria (1) or 2)):

1) If female, bone age ≤ 14 years

2) If male, bone age ≤ 16 years

ii. The member is a neonate and is using the product to treat growth failure due to inadequate secretion of endogenous growth hormone (no ICD-10 code) and meets all of the following criteria **(A) and B))**:

A) The request is for Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, or Zomacton.

B) The member has a growth hormone level < 10 ng/mL.

b. If the request is for a non-preferred growth hormone product, the member has experienced therapeutic failure or intolerance to all of the preferred products (see Table 1).

2. Reauthorization

When a benefit, reauthorization of Genotropin, Humatrope, Ngenla, Norditropin, Nutropin, Omnitrope, Saizen, Skytrofa, Sogroya, or Zomacton may be approved when all of the following criteria are met **(a. and b.)**:

a. The member meets one (1) of the following criteria **(i. or ii.)**:

i. Clinical documentation (for example, growth charts) indicating a growth velocity of at least 2 cm/year.

ii. Clinical documentation (for example, growth charts) indicating a growth velocity < 2 cm/year may be evaluated using the adult criteria, **B. (Adults, Approval Criteria)**, below.

b. The member meets one (1) of the following criteria **(i., ii., or iii.)**:

i. The member is a female with a chronological age > 14 and a bone age ≤ 14 years.

ii. The member is a male with a chronological age > 16 years and a bone age ≤ 16 years.

iii. The member meets one (1) of the following criteria **(A) or B))**:

A) The member is female with a chronological age ≤ 14 years

B) The member is a male with a chronological age ≤ 16 years

B. Adults

1. Initial Authorization

When a benefit, coverage of Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Skytrofa, Sogroya, or Zomacton may be approved when all of the following criteria are met **(a., b., and c.):**

a. The product is used to treat replacement of endogenous growth hormone in adults with growth hormone deficiency and one (1) of the following criteria are met **(i., ii., or iii.)**:

i. Documentation of multiple pituitary growth hormone deficiencies (no ICD-10 code).

ii. Documentation of central nervous system (CNS) irradiation (no ICD-10 code).

iii. The member has reconfirmation of growth hormone deficiency (no ICD-10 code) in adulthood defined as all of the following **(A), B), and C)):**

A) Epiphyseal fusion has occurred.

B) The member has not used growth hormone for at least 1 month.

C) The member has a response to all of the following standard growth hormone stimulation tests **(1) and 2))**:

1) One (1) of the following growth hormone stimulation tests **(a) or b))**:

a) arginine (serum growth hormone concentration ≤ 4.1 ng/mL)

b) macimorelin (serum growth hormone concentration < 2.8 ng/mL)

2) One (1) of the following growth hormone stimulation tests **(a) or b))**:

a) Insulin (serum growth hormone concentration ≤ 5 ng/mL)

b) Glucagon stimulation test (serum growth hormone concentration ≤ 3 ng/mL for patients with body mass index (BMI) ≤ 25 kg/m^2 or growth hormone ≤ 1 ng/mL for BMI > 25 kg/m^2)

b. If the request is for a non-preferred growth hormone product, the member has experienced therapeutic failure or intolerance to all of the preferred products (see Table 1).

c. If the request is for Sogroya, the requested dose does not exceed 8 mg once weekly.

2. Reauthorization

When a benefit, reauthorization of Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Skytrofa, Sogroya, or Zomacton may be approved when all of the

following criteria are met **(a. and b.)**:

- **a.** The prescriber attests that the member has experienced positive clinical response to therapy.
- **b.** If the request is for Sogroya, the requested dose does not exceed 8 mg once weekly.

II. Children with Chronic Kidney Disease (CKD)

A. Initial Authorization

When a benefit, coverage of Nutropin may be approved when all of the following criteria are met **(1., 2., and 3.)**:

1. The member has a diagnosis of CKD (ICD-10: N18) defined as an estimated glomerular filtration rate (GFR) < 89 ml/min per 1.73 m^2.
2. The member meets one (1) of the following criteria, **(a. or b.)**:
   - **a.** The member meets all of the following criteria **(i. and ii.)**:
     - **i.** Clinical documentation (for example, growth charts) indicating a growth velocity less than the 10^{th} percentile over 12 months.
     - **ii.** Clinical documentation (for example, growth charts) indicating a height between 2.25 and 2.5 standard deviations below the age-appropriate mean.
   - **b.** Clinical documentation (for example, growth charts) indicating a height at least 2.5 standard deviations below the age-appropriate mean.
3. The member meets one (1) of the following criteria **(a. or b.)**:
   - **a.** If female, bone age ≤ 14 years
   - **b.** If male, bone age ≤ 16 years

B. Reauthorization

When a benefit, reauthorization of Nutropin may be approved when all of the following criteria are met **(1. and 2.)**:

1. Clinical documentation (for example, growth charts) indicating a growth velocity of at least 2 cm/year.
2. The member meets one (1) of the following criteria is met **(a., b., or c.)**:
   - **a.** The member is a female with a chronological age > 14 years and a bone age ≤ 14 years.
   - **b.** The member is a male with a chronological age > 16 years and a bone age ≤ 16 years.
   - **c.** The member meets one (1) of the following criteria **(i. or ii.)**:
     - **i.** The member is female with a chronological age ≤ 14 years
     - **ii.** The member is a male with a chronological age ≤ 16 years

III. Children with Idiopathic Short Stature (ISS)

A. Initial Authorization

When a benefit, coverage of Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, or Zomacton may be approved when all the following criteria are met **(1. through 5.)**:

1. The member has a diagnosis of ISS (ICD-10: R62.52).
2. Indication (for example, growth charts) of a height less than 2.25 standard deviations below the age-appropriate mean.
3. Indication (for example, growth charts) of a growth velocity less than the 10^{th} percentile over 12 months.
4. The member meets one (1) of the following criteria **(a. or b.)**:
   - **a.** If female, bone age ≤ 14 years
   - **b.** If male, bone age ≤ 16 years
5. If the request is for a non-preferred growth hormone product, the member has experienced therapeutic failure or intolerance to all of the preferred products (see Table 1).

B. Reauthorization

When a benefit, reauthorization of Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, or Zomacton may be approved when all the following criteria are met **(1. and 2.)**:

1. Clinical documentation (for example, growth charts) indicating a growth velocity of at least 2 cm/year.
2. The member meets one (1) of the following criteria is met **(a., b., or c.)**:
   - **a.** The member is a female with a chronological age > 14 years and a bone age ≤ 14 years.
   - **b.** The member is a male with a chronological age > 16 years and a bone age ≤ 16 years.
   - **c.** The member meets one (1) of the following criteria **(i. or ii.)**:
     - **i.** The member is female with a chronological age ≤ 14 years
     - **ii.** The member is a male with a chronological age ≤ 16 years

IV. Children with Noonan Syndrome

A. Initial Authorization

When a benefit, coverage of Norditropin may be approved when all of the following criteria are met **(1. and 2.)**:

1. The member has a diagnosis of Noonan Syndrome (no ICD-10 code).
2. The member meets one (1) of the following criteria **(a. or b.):**
   - **a.** If female, bone age ≤ 14 years
   - **b.** If male, bone age ≤ 16 years

B. Reauthorization

When a benefit, reauthorization of Norditropin may be approved when all of the following criteria are met **(1. and 2.)**:

1. Clinical documentation (for example, growth charts) indicating a growth velocity of at least 2 cm/year.
2. The member meets one (1) of the following criteria is met **(a., b., or c.)**:
   - **a.** The member is a female with a chronological age > 14 years and a bone age ≤ 14 years.
   - **b.** The member is a male with a chronological age > 16 years and a bone age ≤ 16 years.
   - **c.** The member meets one (1) of the following criteria **(i. or ii.)**:
     - **i.** The member is female with a chronological age ≤ 14 years
     - **ii.** The member is a male with a chronological age ≤ 16 years

V. Children with Prader-Willi Syndrome

A. Initial Authorization

When a benefit, coverage of Genotropin, Norditropin, or Omnitrope may be approved when all of the following criteria are met **(1., 2., and 3.)**:

1. The member has a diagnosis of Prader-Willi Syndrome (ICD-10: Q87.11).
2. The member meets one (1) of the following criteria **(a. or b.)**:
   - **a.** If female, bone age ≤ 14 years
   - **b.** If male, bone age ≤ 16 years
3. If the request is for a non-preferred growth hormone product, the member has experienced therapeutic failure or intolerance to all of the preferred products (see Table 1).

B. Reauthorization

When a benefit, reauthorization of Genotropin, Norditropin, or Omnitrope may be approved when all of the following criteria are met **(1. and 2.)**:

1. Clinical documentation (for example, growth charts) indicating a growth velocity of at least 2 cm/year.
2. The member meets one (1) of the following criteria is met **(a., b., or c.)**:
   - **a.** The member is a female with a chronological age > 14 years and a bone age ≤ 14 years.
   - **b.** The member is a male with a chronological age > 16 years and a bone age ≤ 16 years.
   - **c.** The member meets one (1) of the following criteria **(i. or ii.)**:

i. The member is female with a chronological age ≤ 14 years
ii. The member is a male with a chronological age ≤ 16 years

VI. Children with Short Stature Homeobox-containing gene (SHOX) Deficiency

A. Initial Authorization

When a benefit, coverage of Humatrope or Zomacton may be approved when all of the following criteria are met **(1., 2., and 3.)**:

1. The member has a diagnosis of SHOX deficiency (no ICD-10 code).
2. The member meets one (1) of the following criteria **(a. or b.)**:
   a. If female, bone age ≤ 14 years
   b. If male, bone age ≤ 16 years
3. If the request is for a non-preferred growth hormone product, the member has experienced therapeutic failure or intolerance to all of the preferred products (see Table 1).

B. Reauthorization

When a benefit, reauthorization of Humatrope or Zomacton may be approved when all of the following criteria are met **(1. and 2.)**:

1. Clinical documentation (for example, growth charts) indicating a growth velocity of at least 2 cm/year.
2. The member meets one (1) of the following criteria is met **(a., b., or c.)**:
   a. The member is a female with a chronological age > 14 years and a bone age ≤ 14 years.
   b. The member is a male with a chronological age > 16 years and a bone age ≤ 16 years.
   c. The member meets one (1) of the following criteria **(i. or ii.)**:
      i. The member is female with a chronological age ≤ 14 years
      ii. The member is a male with a chronological age ≤ 16 years

VII. Children Small for Gestational Age (SGA)

A. Initial Authorization

When a benefit, coverage of Genotropin, Humatrope, Norditropin, Omnitrope, or Zomacton may be approved when all the following criteria are met **(1. through4.)**:

1. The member has a diagnosis of SGA (ICD-10: P05.1X).
2. The member has failed to have catch-up growth by 2 years of age.
3. The member meets one (1) of the following criteria **(a. or b.)**:
   a. The member has a birth weight at least 2 standard deviations below the gestational age-appropriate mean.
   b. The member has a birth crown heel length at least 2 standard deviations below the gestational age-appropriate mean.
4. If the request is for a non-preferred growth hormone product, the member has experienced therapeutic failure or intolerance to all of the preferred products (see Table 1).

B. Reauthorization

When a benefit, reauthorization of Genotropin, Humatrope, Norditropin, Omnitrope, or Zomacton may be approved when all the following criteria are met **(1. and 2.)**:

1. Clinical documentation (for example, growth charts) indicating a growth velocity of at least 2 cm/year.
2. The member meets one (1) of the following criteria **(a., b., or c.)**:
   a. The member is a female with a chronological age > 14 years and a bone age ≤ 14 years.
   b. The member is a male with a chronological age > 16 years and a bone age ≤ 16 years.
   c. The member meets one (1) of the following criteria **(i. or ii.)**:
      i. The member is female with a chronological age ≤ 14 years

ii. The member is a male with a chronological age ≤ 16 years

VIII. Turner's Syndrome

A. Initial Authorization

When a benefit, coverage of Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, or Zomacton may be approved when all of the following criteria are met **(1., 2., and 3.)**:

1. The member has a diagnosis of Turner's Syndrome, defined as 45, XO genotype (ICD-10: Q96).
2. For members above the age of 14 years, the member's bone age is ≤ 14 years.
3. If the request is for a non-preferred growth hormone product, the member has experienced therapeutic failure or intolerance to all of the preferred products (see Table 1).

B. Reauthorization

When a benefit, reauthorization of Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, or Zomacton may be approved when all the following criteria are met **(1. and 2.)**:

1. Clinical documentation (for example, growth charts) indicating a growth velocity of at least 2 cm/year.
2. The member meets one (1) of the following criteria is met **(a. or b.)**:
   - **a.** The member has a chronological age > 14 years and a bone age ≤ 14 years.
   - **b.** The member has a chronological age ≤ 14 years.

IX. Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS)-Wasting (no ICD-10 code)

A. Initial Authorization

When a benefit, coverage of Serostim may be approved when all of the following criteria are met **(1., 2., and 3.)**:

1. The member has a diagnosis of HIV or AIDS.
2. The member is currently taking antiretroviral therapy.
3. The member has a weight loss of at least 10% from baseline.

B. Reauthorization after 12 weeks of Initial Therapy

When a benefit, reauthorization of Serostim may be approved when the following criterion is met **(1.)**:

1. The member has experienced and maintained an increase in weight from the start of therapy.

X. Short Bowel Syndrome (SBS)

A. Initial Authorization

When a benefit, coverage of Zorbtive may be approved when all the following criteria are met **(1. and 2.)**:

1. The member has a diagnosis of short bowel syndrome (no ICD-10 code).
2. The member is receiving optimal management for short bowel syndrome, including specialized nutritional support.

B. Reauthorization

When a benefit, reauthorization of Zorbtive may be approved when all of the following criteria are met **(1. and 2.)**:

1. The member meets one (1) of the following criteria **(a. or b.)**:
   - **a.** The member has experienced an increase in weight from baseline.
   - **b.** The member has experienced a decrease in parenteral/intravenous nutrition requirement from baseline.
2. The member continues to be dependent on parenteral/intravenous nutrition support.

XI. Burn Patients

A. Initial Authorization
When a benefit, coverage of a growth hormone product may be approved when all of the following criteria are met **(1. and 2.)**:
1. The member is being hospitalized for third degree burns (ICD-10: T20.3X).
2. If the request is for a non-preferred growth hormone product, the member has experienced therapeutic failure or intolerance to all of the plan-preferred products (see Table 1).

B. Reauthorization
When a benefit, coverage of a growth hormone product may be approved when the following criterion is met **(1.)**:
1. The member has experienced a positive clinical response to therapy.

XII. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Short bowel syndrome (SBS) is defined as < 200 cm of functional small bowel.
II. Use of growth hormone is not indicated or recommended in patients with achondroplasia as it can potentially worsen the disproportion seen in these patients.
III. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
IV. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Commercial and HCR Plans:

- **Growth Hormone (GH) Deficiency, Chronic Kidney Disease (CKD), Idiopathic Short Stature (ISS), Prader-Willi Syndrome, Noonan Syndrome, Short Stature Homeobox-containing gene (SHOX), Small for Gestational Age (SGA), Turner's Syndrome, and Burn Patients**: If approved, up to a 12 month authorization may be granted.
- **HIV/AIDs-Wasting**:
  - Initial Authorization: If approved, up to a 12 week authorization may be granted.
  - Reauthorization: If approved, up to a 12 month authorization may be granted.
- **Short Bowel Syndrome (SBS)**:
  - Initial Authorization: If approved, up to a 4 week authorization may be granted.
  - Reauthorization: If approved, up to a 3 month authorization may be granted.

Automatic Approval Criteria

None

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