Growth Hormone Agents

WA.PHAR.50 Growth Hormone Agents

Background:

Human growth hormone, also known as somatotropin, is produced in the anterior lobe of the pituitary gland. This hormone plays an important role in growth, metabolism, and maintenance of body fat, muscle and bone.

Medical necessity

Drug	Medical Necessity
Genotropin® Humatrope® Norditropin® Nutropin®/Nutropin AQ® Omnitrope® Saizen® Serostim® Zomacton® Zorbtive®	Somatotropin may be considered medically necessary when used for: Children/adolescents with the following: • Neonatal Hypoglycemia • Growth Hormone Deficiency • Genetic disease with Primary Effects on Growth • Small for Gestational Age • Growth Failure associated with Chronic Renal Insufficiency Adults with the following: • Growth Hormone Deficiency • Prader-Willi Syndrome • Human Immunodeficiency Virus (HIV)-Related Wasting or Cachexia • Short Bowel Syndrome *Preferred growth hormone agents: Genotropin and Norditropin

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Genotropin® Humatrope® Norditropin® Nutropin®/Nutropin Aq® Omnitrope® Saizen® Serostim® Zomacton® Zorbtive®	**Neonatal Hypoglycemia** 1. Diagnosis of ONE of the following: a. Less than (<) 4 months of age with growth deficiency b. History of neonatal hypoglycemia associated with pituitary disease c. Panhypopituitarism 2. Prescribed by or in consultation with an endocrinologist or neonatalogist
	Growth Hormone Deficiency (Peds) 1. **All** of the following: a. Diagnosis of pediatric GH deficiency as confirmed by **one** of the following: i. Projected height is > 2.0 standard deviations [SD] below mid-parental height ii. Height is > 2.25 SD below population mean iii. Growth velocity is > 2 SD below mean

iv. Delayed skeletal maturation of > 2 SD below mean

b. **One** of the following:

i. **Both** of the following:

1. Patient is male
2. Bone age < 16 years

ii. **Both** of the following:

1. Patient is female
2. Bone age < 14 years

2. Submission of medical records (e.g., chart notes, laboratory values) documenting **one** of the following:

a. **ONE** of the following:

i. Patient has undergone **two** of the following provocative GH stimulation tests:

1. Arginine
2. Clonidine
3. Glucagon
4. Insulin
5. Levodopa
6. Growth hormone releasing hormone

ii. **Both** of the following:

1. Patient is < 1 year of age
2. **One** of the following is below adjusted normal range:

a. Insulin-like Growth Factor 1 (IGF-1/ Somatomedin-C)

b. Insulin Growth Factor Binding Protein-3 (IGFBP-3)

3. Prescribed by or in consultation with an endocrinologist

Growth Hormone Deficiency (Adults)

1. Diagnosis of adult GH deficiency as a result of **one** of the following:

a. Clinical records supporting a diagnosis of childhood-onset GHD

b. **Both** of the following:

i. Adult-onset GHD

ii. Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

2. Submission of medical records (e.g., chart notes, laboratory values) documenting **one** of the following:

a. **Both** of the following:

i. Patient has undergone **one** of the following GH stimulation tests to confirm adult GH deficiency:

1. Insulin tolerance test (ITT)
2. Arginine & GHRH (GHRH+ARG)
3. Glucagon
4. Arginine (ARG)

ii. **One** of the following peak GH values:
1. ITT ≤ 5 µg/L
2. GHRH+ARG (≤ 11 µg/L if body mass index [BMI] <25 kg/m^2; ≤8 µg/L if BMI ≥ 25 and <30 kg/m^2; ≤4µg/L if BMI ≥ 30 kg/m^2)
3. Glucagon ≤ 3 µg/L
4. ARG ≤ 0.4 µg/L

b. **Both** of the following:
i. Deficiency of **three** of the following anterior pituitary hormones:
1. Prolactin
2. ACTH
3. TSH
4. FSH/LH
ii. IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

3. **One** of the following:
a. Diagnosis of panhypopituitarism
b. Other diagnosis **and** not used in combination with the following:
i. Aromatase inhibitors [e.g., Arimidex (anastrozole), Femara (letrozole)]
ii. Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]
4. Prescribed by or in consultation with an endocrinologist

Genetic disease with Primary Effects on Growth (Peds)

1. Prader-Willi Syndrome
a. Diagnosis of Prader-Willi Syndrome
b. BMI <35
c. Prescribed by or in consultation with an endocrinologist

2. Turner Syndrome
a. Diagnosis of Turner Syndrome
b. **Both** of the following:
i. Patient is female
ii. Bone age < 14 years
c. **ONE** of the following:
i. Standing height > 3 SD below mean
ii. Standing height 2-3 SD below mean with deceleration of 2 heights measured by endocrinologist at least 6 months apart (≥1 year) or 4 heights measured by primary physician at least 6 months apart (≥2 years)
iii. Growth velocity of 2 SD below the mean over 1 year
d. Prescribed by or in consultation with an endocrinologist

3. Noonan Syndrome
a. Diagnosis of Noonan Syndrome
b. **One** of the following:

i. **Both** of the following:
1. Patient is male
2. Bone age < 16 years

ii. **Both** of the following:
1. Patient is female
2. Bone age < 14 years

c. **ONE** of the following:
i. Standing height > 3 SD below mean
ii. Standing height 2-3 SD below mean with deceleration of 2 heights measured by endocrinologist at least 6 months apart (≥1 year) or 4 heights measured by primary physician at least 6 months apart (≥2 years)
iii. Growth velocity of 2 SD below the mean over 1 year

d. Prescribed by or in consultation with an endocrinologist

4. Short-Stature Homeobox (SHOX) Gene Deficiency
a. Diagnosis of pediatric growth failure with short-stature homeobox (SHOX) gene deficiency as confirmed by genetic testing
b. **One** of the following:
i. **Both** of the following:
1. Patient is male
2. Bone age < 16 years

ii. **Both** of the following:
1. Patient is female
2. Bone age < 14 years

c. **ONE** of the following:
i. Standing height > 3 SD below mean
ii. Standing height 2-3 SD below mean with deceleration of 2 heights measured by endocrinologist at least 6 months apart (≥1 year) or 4 heights measured by primary physician at least 6 months apart (≥ 2 years)
iii. Growth velocity of 2 SD below the mean over 1 year

d. Prescribed by or in consultation with an endocrinologist

Prader-Willi Syndrome in Adults
1. Diagnosis of Prader-Willi Syndrome
2. Prescribed by or in consultation with an endocrinologist

Small for Gestational Age (Peds)
1. Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life
2. Documentation that **one** of the following is ≥ 2 SD below mean for gestational age:
a. Birth weight
b. Birth length
3. **One** of the following:
a. **Both** of the following:
i. Patient is male
ii. Bone age < 16 years

b. **Both** of the following:

	i. Patient is female ii. Bone age < 14 years 4. Prescribed by or in consultation with an endocrinologist
	Growth Failure associated with Chronic Renal Insufficiency (Peds) 1. Diagnosis of pediatric growth failure associated with chronic renal insufficiency 2. **ONE** of the following: a. Structural or functional abnormalities of the kidney for ≥3 months b. GFR <60 mL/min per 1.73 m² for ≥3 months c. Occurrence of **ONE** each of above together for any duration of time 3. **One** of the following: a. **Both** of the following: i. Patient is male ii. Bone age less than (<) 16 years b. **Both** of the following: i. Patient is female ii. Bone age less than (<) 14 years 4. Prescribed by or in consultation with an endocrinologist or nephrologist or gastroenterologist
	Human Immunodeficiency Virus (HIV)-Related Wasting or Cachexia 1. Diagnosis of HIV-associated wasting syndrome or cachexia 2. **ALL** of the following: a. Unintentional weight loss of > 10% from baseline b. Weighs less than or equal to (≤) 90% ideal body weight (IBW) c. Greater than or equal to (≥) 18 years of age 3. Patient's anti-retroviral therapy has been optimized to decrease the viral load 4. Patient has not had weight loss as a result of other underlying treatable conditions 5. Treatment therapies other than growth hormone have been suboptimal 6. Prescribed by or in consultation with physician specializing in HIV diagnosis and management
	Short Bowel Syndrome 1. Diagnosis of short bowel syndrome 2. Greater than or equal to (≥) 18 years of age 3. Specialized nutritional support 4. Prescribed by or in consultation with a gastroenterologist
	Criteria (Reauthorization)
	1. Documentation of open epiphyseal plates 2. Documentation of positive clinical benefit Approve for 12 months

Coding:

HCPCS Code	Description
J2941	Injection, somatropin, 1mg

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