Growth Hormone - Children

Generic Name: Somatropin, somapacitan-beco, somatropin-ghla, lonapegsomatropin-tcgd (children)

Therapeutic Class or Brand Name: Growth Hormone (children)

Applicable Drugs (if Therapeutic Class): Genotropin, Humatrope, Ngenla, Norditropin, Nutropin AQ, Omnitrope, Saizen, Skytrofa, Sogroya, Zomacton.

Preferred: Genotropin, Norditropin

Non-preferred: Humatrope, Ngenla, Nutropin AQ, Omnitrope, Saizen, Sogroya, Skytrofa, Zomacton.

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 5/20/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

I. Documented diagnosis of one of the following conditions A through H AND must meet criteria listed under applicable diagnosis:

A. Growth hormone deficiency (GHD) and criteria 1 through 3 are met:

1. Documented biochemical growth hormone deficiency by meeting ONE of criteria a through e:

a) Two growth hormone (GH) stimulation tests below 10 ng/ml (microgram/L).

b) At least one GH stimulation test level less than 15 ng/ml, AND IGF-I and IGF-BP3 levels below normal for the patient's bone age and gender.

c) One GH stimulation test below 10 ng/ml (microgram/L) is sufficient for children with defined CNS pathology, history of irradiation, or genetic conditions associated with GHD.

d) GH stimulation tests, IGF-1 or IGF-BP3 levels are not needed for GHD if multiple pituitary hormone deficiencies exist (at least two other in addition to GHD).

e) GH stimulation tests, IGF-1 or IGF-BP3 levels are not needed for congenital GHD (low GH levels detected during acute episode of hypoglycemia).

2. Must provide an initial bone age and demonstration of open growth plates.

3. Documented short stature/growth failure (subnormal growth rate) by meeting ONE of criteria a, b, OR c:

a) Height is below the 3rd percentile for the patient's age and gender.

b) Height is below the 5th percentile for the patient's age and gender, and untreated growth velocity with a minimum of 1 year of growth data is below the 25th percentile for the patient's age and gender.

c) If GHD criteria under 1e are met, short stature/growth failure is not needed.

B. GHD in adolescents during transition period and criteria 1 through 5 are met:
    1. Documentation that the patient has persistent GHD by meeting ONE of criteria a or b:
        a) At least one pituitary hormone deficiency (other than growth hormone) requiring hormone replacement AND at least one known cause for pituitary disease or a condition affecting pituitary function, including pituitary tumor, surgical damage, hypothalamic disease, irradiation, trauma, panhypopituitarism, or infiltrative diseases (histoplasmosis, Sheehan syndrome, autoimmune hypophysitis, or sarcoidosis).
        b) At least three pituitary hormone deficiencies (other than growth hormone) requiring hormone replacement.
    2. Documented biochemical growth hormone deficiency by meeting ONE of criteria a through c:
        a) One IGF-1 level below the age and gender adjusted normal range.
        b) One GH provocative stimulation test (with insulin, levodopa, arginine, propranolol, clonidine, or glucagon) with a measured peak level of less than 5 ng/ml.
        c) IGF-1 or GH stimulation tests are not needed if multiple pituitary hormone deficiencies exist (at least two other in addition to GHD).
    3. The patient does not have disorders other than GHD for which GH treatment is indicated, including Prader-Willi syndrome, children born small for gestational age, Turner syndrome, Noonan syndrome, chronic kidney disease, and idiopathic short stature.
    4. Documentation that patient has attained expected adult height.
    5. Demonstration of closed epiphyses on bone radiograph.

C. Growth failure due to Prader-Willi Syndrome (PWS) and criteria 1 and 2 are met:
    1. Documentation that the diagnosis of PWS has been confirmed by appropriate genetic testing.
    2. Must provide an initial bone age and demonstration of open growth plates.

D. Growth failure in children born small for gestational age (SGA) who fail to demonstrate catch-up growth by age 2 to 4 years and criteria 1 through 5 are met:
    1. Documentation that patient was born SGA, defined as a birth weight and/or length of 2 or more standard deviations below the mean for gestational age and gender (including infants born with intrauterine growth restriction or Russell-Silver Syndrome resulting in SGA).
    2. Documented short stature/growth failure (subnormal growth rate) by 2 years of age when height is 2 or more standard deviations below the mean for the patient's age and gender.

3. Documentation that other causes for short stature such as growth inhibiting medication, endocrine disorders, and emotional deprivation or syndromes have been ruled out.
4. Must provide an initial bone age and demonstration of open growth plates.
5. Minimum age requirement: 2 years old.

E. Growth failure associated with Turner's or Noonan's Syndrome and criteria 1 and 2 are met:
1. Must provide an initial bone age and demonstration of open growth plates.
2. Documented short stature/growth failure (subnormal growth rate) when height is below the 10th percentile for the patient's age and gender.

F. Short stature or growth failure in children with short stature homeobox-containing gene (SHOX) deficiency and criteria 1 and 2 are met:
1. Must provide an initial bone age and demonstration of open growth plates.
2. Documented short stature/growth failure (subnormal growth rate) when height is at least 2 standard deviations below the normal mean for the patient's age and gender.

G. Growth failure associated with Chronic renal insufficiency (CRI) and criteria 1 through 3 are met:
1. Must provide an initial bone age and demonstration of open growth plates.
2. Documented short stature/growth failure (subnormal growth rate) when height is below the 5th percentile for the patient's age and gender, and untreated growth velocity with a minimum of 1 year of growth data is below the 25th percentile for the patient's age and gender.
3. Patient requires weekly dialysis or has a glomerular filtration rate (GFR) < 75 ml/min / 1.73 m^2.

H. Pediatric burn patients and criterion 1 is met:
1. Burns are over at least 40% of the total body surface area.

II. Treatment must be prescribed by or in consultation with a pediatric endocrinologist, pediatric nephrologist, or trauma/burn surgeon.

III. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Acute Critical Illness due to complications following open heart surgery, abdominal surgery, or multiple accidental trauma, or those with acute respiratory failure.
- Children with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment.
- Active Malignancy.

- Active Proliferative or Severe Non-Proliferative Diabetic Retinopathy.
- Children with closed epiphyses (except for GHD in adolescents during transition period).

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- The quantity is limited to a maximum of a 30 day supply per fill.

APPROVAL LENGTH

- **Authorization:**
  - Pediatric burn: One time for up to 12 months.
  - All other diagnoses: Up to 12 months or until maximum bone age is met (up to 16 years of age for males or 14 years of age for females), whichever is shorter.
- **Re-Authorization:**
  - Pediatric burn: N/A
  - All other diagnoses: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the patient's growth velocity is greater than 2.5 cm/year. Must also include documentation of a through b below, if applicable:
    a. Bone age must be obtained annually when chronological age reaches 15 in males or 13 in females. Therapy must not exceed a bone age of 16 in males or 14 in females.
    b. If diagnosis is chronic renal insufficiency (CRI), patient must still require weekly dialysis or have a glomerular filtration rate (GFR) < 75 ml/min / 1.73 m^2.

APPENDIX

N/A

REFERENCES

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