ConnectiCare

Commercial/Healthcare Exchange PA Criteria
Effective: December 2004

Prior Authorization: Growth Hormone

Products Affected: For coverage of Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton and Zorbtive

Medication Description:

Covered Uses:

- **Indicated for Growth Failure in children**: All except Serostim and Zorbtive
- **Indicated for Growth Failure associated with CKD**: Nutropin, Nutropin AQ
- **Indicated for Growth Failure associated with Noonan Syndrome**: Norditropin
- **Indicated for Growth Failure associated with Prader-Willi syndrome**: Genotropin, Humatrope, Omnitrope, Norditropin
- **Indicated for Growth failure associated with SHOX deficiency**: Humatrope, Zomacton
- **Indicated for Treatment of growth failure in children born small for gestational age who fail to manifest catch-up growth by 2 years of age** (Genotropin, Omnitrope) or by 2 to 4 years of age (Humatrope, Norditropin, Zomacton)
- **Indicated for Growth failure associated with Turner syndrome**: Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, Omnitrope, Zomacton
- **Indicated for Growth Hormone deficiency in adults**: Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, Omnitrope, Saizen, Zomacton
- **Indicated for Idiopathic Short Stature (not approved)**: Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, Omnitrope, Zomacton
- **Indicated for Short Bowel Syndrome**: Zorbtive
- **Indicated for Wasting or cachexia associated with HIV**: Serostim

Exclusion Criteria:

1. Acute critical illness after open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure due to the risk of increased mortality with use of pharmacologic doses of somatropin
2. Pediatric patients with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment due to the risk of sudden death
3. Active Malignancy
4. Active proliferative or severe non-proliferative diabetic retinopathy
5. Pediatric patients with closed epiphyses
6. Saizen is reconstituted with Bacteriostatic Water for Injection, USP (0.9% Benzyl Alcohol) should not be administered to patients with a known sensitivity to Benzyl Alcohol
7. Idiopathic Short Stature is not considered to be medically necessary because it is not an illness, injury or disease.
8. Investigational/Experimental Indications: Growth hormone therapy for all other indications is considered to be experimental and investigational and therefore not covered by the plan.

Required Medical Information:

1. Documentation of follow up notes including growth charts
2. Growth velocity in the most recent year
3. Growth hormone stimulation test result if appropriate

4. Genetic testing confirm diagnosis if appropriate
5. All other appropriate lab / testing confirming pituitary deficiencies, renal function, open epiphyses, etc.
6. Current height and weight
7. Bone age for initiation if appropriate

Age Restrictions: The safety and effectiveness in patients aged 65 and over have not been evaluated in clinical studies for all of the medications listed above.

A. **Serostim:** Safety and effectiveness in pediatric patients with HIV have not been established. Available evidence suggests that somatropin clearance is similar in adults and children, but no pharmacokinetic studies have been conducted in children with HIV.
B. **Zorbtive:** The safety and effectiveness in the treatment for short bowel syndrome in pediatric patients have not been established.

Prescriber Restrictions: Prescribed by or in consultation with an endocrinologist.

Coverage Duration:

- If the above criteria below are met initial authorization is limited to 6 months.
- Subsequent authorization (up to 1 year) will be granted with documented efficacy.
- The quantity is limited to a maximum of a 30-day supply per fill.

Other Criteria:
Growth hormone (Norditropin for Commercial members and Freedom Formulary Members) is medically necessary when the following criteria are met:

Growth Hormone Use in Children

A. Treatment of growth hormone deficiency in children (including pituitary dwarfism as well as growth hormone deficiency following cranial irradiation), where:
• Patient must be evaluated by a pediatric endocrinologist
• The patient's baseline height must be < the third percentile (i.e. >2 standard deviations below the mean for gender and age, a measure of the degree of short stature
• Children aged <3 years must have a pretreatment growth rate of <7 cm per year, and children aged 3 years and older must have a growth rate <4 cm per year
• The patient must have a documented growth hormone deficiency as defined by a diminished serum growth hormone response to stimulation testing of <10ng/ml. The results of two or more of the following stimulation tests are required to support the diagnosis of growth hormone deficiency: levodopa, insulin, arginine, clonidine and glucagon.
• Note: Reauthorization is contingent upon response as shown by growth curve chart. Yearly reassessment for reauthorization of coverage is required.

B. Treatment of growth delay in children with chronic renal failure, where:
• Patient must be evaluated by a pediatric endocrinologist or nephrologist
• Patients nutritional status has been optimized, metabolic abnormalities have been corrected, and steroid usage has been reduced to a minimum
• Patient has growth retardation with height SDS between –2 and –3 SDS below the mean for chronological age and sex and decreased growth rate (GV measured over 1 year below 25th percentile for age and sex)
• Growth hormone therapy is not recommended for post-transplantation.
• Note: Reauthorization is contingent upon response as shown by growth curve chart. Yearly reassessment for reauthorization of coverage is required.

C. Turner's Syndrome:
• Growth hormone therapy is recommended for girls with short stature associated with Turner's syndrome, demonstrated by chromosome analysis.
• Note: Reauthorization is contingent upon response as shown by growth curve chart. Yearly reassessment for reauthorization of coverage is required.

D. Prader-Willi Syndrome:
• Growth hormone therapy is recommended for children with growth failure associated with Prader-Willi syndrome confirmed by appropriate genetic testing.
• Note: Reauthorization is contingent upon response as shown by growth curve chart. Yearly reassessment for reauthorization of coverage is required.

E. Growth failure with Noonan Syndrome
• Note: Reauthorization is contingent upon response as shown by growth curve chart. Yearly reassessment for reauthorization of coverage is required.

F. Short children born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) including those with Silver-Russell syndrome:
• Patient must be evaluated by a pediatric endocrinologist
• Patient must be 2 years of age.
• Patient must have been born SGA, which is defined as birth weight and/or length that is >2 SD below the mean for gestational age and gender, and with failure to manifest catch up growth by age 2. (Growth charts from birth through age 2 should be submitted for evaluation.)
• Note: Reauthorization is contingent upon response as shown by growth curve chart. Yearly reassessment for reauthorization of coverage is required.

Growth Hormone Use in Adults

A. Treatment of growth hormone deficiency in adults (childhood or adult onset), where:
• Patient must be evaluated by an endocrinologist
• Patient must have a documented diagnosis of growth hormone deficiency that is one of the following:
1. Childhood onset: or
2. Adult onset: growth hormone deficiency alone or with multiple hormone deficiencies, such as hypopituitarism, as a result of hypothalamic or pituitary disease, radiation therapy, surgery or trauma
• GHD has been confirmed by growth hormone stimulation tests and rule-out of other hormonal deficiency, as follows:
1. Growth hormone response of <5 ng/mL to one growth hormone stimulation test
Rule-out and appropriate supplementation for other hormonal deficiencies such as thyroid, cortisol or sex steroids.

B. AIDS related wasting, where:
• Patient must be HIV-positive and have wasting or cachexia;
• Patient must have one of the following: documented, involuntary weight loss of >10% of pre-illness baseline body weight or body mass index (BMI) <20 kg/m2, in the absence of a concurrent illness or medical condition other than HIV infection that would explain these findings, and who have failed to adequately respond or are intolerant to anabolic steroids (i.e. Megace).
• Patient must have been on antiretroviral therapy for >30 days prior to beginning somatropin therapy and will continue antiretroviral therapy throughout the course of somatropin treatment.

• Therapy with somatropin for AIDS related wasting should be limited to 24 weeks. (Repeat 12-24-week courses may be authorized in patients who have received a previous 12 or 24-week course of somatropin for HIV Infection with wasting or cachexia provided that they have been off somatropin for at least one month and meet the above criteria. There are no safety and efficacy data from controlled trials in patients treated with somatropin continuously for greater than 48 weeks or for patients who start, stop, and then restart treatment.)

C. Short bowel syndrome, where:
• Somatropin is recommended for adults with short bowel syndrome who are receiving specialized nutritional support (intravenous parenteral nutrition). Patient must be aged > 18 years old and therapy is limited to one 4-week course per year. Growth hormone treatment of short bowel syndrome for more than four weeks duration has not been adequately studied for this indication.

Note: In addition to the above criteria, Genotropin, Humatrope, Nutropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton or Zorbtive will be approved if the patient has had an intolerance to, or treatment failure of, Norditropin.

References:

1. American Association of Clinical Endocrinologists. Medical Guidelines for Clinical Practice for Growth Hormone Use in Adults and Children-2003 Update. Endocrine Practice. 2003:9:64-76.
2. Genotropin [package insert]. Kalamazoo, MI: Pharmacia & Upjohn, Inc;
3. Humatrope [package insert]. Indianapolis, IN: Eli Lilly and Company;
4. Norditropin [package insert]. Princeton, NJ: Novo Nordisk Pharmaceuticals Inc;
5. Nutropin [package insert]. San Francisco, CA: Genentech, Inc;
6. Nutropin AQ [package insert]. San Francisco, CA: Genentech, Inc;

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	12/2004

2	Annual Review	New Policy Template Revision History: 1/14, 4/15, 1/16, 5/16, 11/16	All	03/02/2020
3	Update	Added Norditropin to the following: Indicated for Growth Failure associated with Prader-Willi syndrome. Added the following continuation criteria to Prader-Willi Syndrome and Growth failure with Noonan Syndrome: Note: Reauthorization is contingent upon response as shown by growth curve chart. Yearly reassessment for reauthorization of coverage is required.	Covered Uses Other Criteria	10/15/20