

WELLCHOICE™

GROWTH HORMONE PRODUCTS

SOMATROPIN: Genotropin, Norditropin, Nutropin, Nutropin AQ, Nutropin Depot, Humatrope, Saizen, Tev-Tropoin, Zorbtive

SOMATREM: Protropin

SERMORELIN: Geref

CRITERIA FOR APPROVAL:

1. Member will have one of the following diagnoses:

- Long term treatment of children with growth failure due to a lack of endogenous growth hormone secretion;
- Growth failure associated with chronic renal insufficiency: treatment of children who have growth failure associated with chronic renal insufficiency up to the time of renal transplantation;
- Turner Syndrome diagnosed by means of a positive chromosomal analysis;
- growth failure due to Prader-Willi syndrome;
- Growth failure in children born small for gestational age (SGA) who fail to manifest catch-up growth by age 2 and who are determined to be 2 or more standard deviations below the mean for age and sex where other causes of growth failure (ex. growth inhibiting medication, chronic disease, endocrine disorders, emotional deprivation or syndromes, except for Russell-Silver syndrome) have been ruled out.
- The treatment of adults with growth hormone deficiency who have a biochemical diagnosis of somatotropin deficiency syndrome (SDS) and either adult onset or childhood onset. Patients can have SDS either alone or with multiple hormone deficiencies as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma.
- Short Bowel Syndrome (SBS) as a result of surgical resection of the small intestine

2. Member (with diagnosis other than SBS, Turner Syndrome or Prader-Willi Syndrome) will demonstrate a negative response to a standard growth hormone stimulation test (maximum peak growth hormone levels <10 ng/mL). Testing must be performed via levodopa, insulin-induced hypoglycemia, arginine, clonidine or glucagon stimulation.

3. Member with childhood onset growth hormone deficiency will demonstrate open epiphyseal plates upon radiologic examination of left hand and wrist.

4. Member with childhood onset growth hormone deficiency (with diagnosis other than Turner Syndrome or Prader-Willi Syndrome) will demonstrate a pretreatment growth velocity of less than 5 cm per year.

5. Member with childhood onset growth hormone (with diagnosis other than Turner Syndrome or Prader-Willi Syndrome) deficiency will demonstrate a pretreatment height which is below the fifth (5th) percentile for age.

6. Adult member with closed epiphyses (with diagnosis other than SBS) will exhibit signs and/or symptoms of adult growth hormone deficiency which may include increased fat mass, decreased muscle mass, reduced exercise capacity, decreased muscle strength, abnormal blood lipids (hyperlipidemia or hypercholesterolemia), hypoglycemia, decreased physical mobility, decreased bone mass, decreased libido, general malaise).

7. Coverage will not be granted for members who present with the diagnosis of Idiopathic Short Stature (ISS). The use of growth hormone supplementation to treat short stature in persons who are not growth hormone deficient is not medically necessary.

8. In addition the treatment of growth hormone deficiency (if other criteria are met), Geref may be approved for diagnostic use in the determination of the presence of growth hormone deficiency.

LENGTH OF APPROVAL:

Approval in the treatment of growth hormone deficiency, Prader Willi Syndrome and Turner's Syndrome will be granted as requested by the prescriber up to a maximum of 6 months for children and adolescents and 12 months for adults. Approval for use in the treatment of Short Bowel Syndrome will be for 4 weeks.

RENEWAL OF PA:

Renewal of prior authorization will be based upon a progress report from the prescriber indicating response to therapy.

- Member with childhood onset growth hormone deficiency must exhibit a growth velocity during current approval period which is greater than pre-treatment growth velocity.
- Member with adult onset growth hormone deficiency must exhibit an improvement of symptomatology related to growth hormone deficiency (decreased strength, increased fat mass, decreased lean mass, reduced aerobic exercise capacity, decreased muscle strength, abnormal blood lipids, low energy level, decreased physical mobility and difficulty with concentration).
- Member with Short Bowel Syndrome must demonstrate improvement in symptoms (diarrhea, weight loss, dehydration, malnutrition, and malabsorption of fats, vitamins and other nutrients).

FORMULARY ALTERNATIVES INCLUDE:

Not Applicable

REFERENCES:

Clinical Pharmacology, Version 2.11, Copyright 2004, Gold Standard Multimedia
Zorbtive Package insert <http://www.zorbtive.com/pdfs/ZorbtivePI.pdf>