



INLAND EMPIRE HEALTH PLAN

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Drug: Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Serostim, Zorbtive, (Somatropin)

Class: Human Growth Hormone

Formulary Medication: Omnitrope

Effective Date: September 1999, *Updated:* November 2009

Policy/Criteria: Human Growth Hormone may be considered medically necessary if the following conditions are met:

1. Use in one of the following indication:

Children-Growth Hormone Deficiency (GHD)

- Congenital GHD*: short stature associated with lack of adequate endogenous growth hormone secretion
- Acquired GHD*: short stature associated with lack of adequate growth hormone due to tumors of the hypothalamic, pineal, and pituitary region and optic gliomas
- Chronic Renal Insufficiency (CRI)*: short stature associated with CRI before renal transplant
- Turner Syndrome: short stature in patients with Turner Syndrome
- Prader-Willi Syndrome: short stature in patients with Prader-Willi Syndrome
- Small for Gestational Age (SGA) Children: infants born small for gestational age who have not caught up in height

* Growth Hormone Deficiency (GHD) and Chronic Renal Insufficiency(CRI) are CCS-covered diagnoses. All of the criteria above must be met for CCS coverage and must be prescribed by a CCS paneled pediatric endocrinologist (GHD) at a CCS approved endocrine center or physician from CCS authorized Renal Center (CRI)

Adult-Growth Hormone Deficiency

- Pituitary disease from known causes including pituitary tumor, pituitary surgical damage, trauma, hypothalamic disease and reconfirmed childhood GHD
- HIV-associated wasting (Cachexia)

2. Growth hormone therapy is determined to be medically necessary, if the following criteria are met:

- Two provocative stimulation tests of growth hormone release (at least 1 month apart) with growth hormone level of less than 10ng/mL (not required for Turner Syndrome) (for children GHD only) (Stimulation test requirement is necessary for CCS coverage only)
- Height more than 2 SD below the mean and a height velocity over 1 year more than 1 SD below the mean for chronological age, or a decrease in height SD of more than 0.5 over 1 year in children over 2 years of age (for children GHD, TS, Prader-Willi, SGA, and CRI)
- Diagnosis of TS by genetic testing (for Turner Syndrome only)
- Confirmed diagnosis of Prader-Willi syndrome by genetic testing; obesity cannot be used as the sole diagnosis for growth hormone indication (for Prader-Willi syndrome only)
- Failure to catch up growth by age 2-3 years (height 2 or more standard deviations below the mean for age and sex) (for SGA children only)
- GHD as a result of hypothalamic or pituitary disease; a peak response of less than 5 ng/mL to at least two provocative stimulation tests (insulin, levodopa, L-Arginine) (for Adult GHD only)
- Treatment failure or intolerance of appetite stimulants and /or anabolic agents Involuntary weight loss of greater than 10% of normal baseline body weight or body mass index less than 20 kg/m², without any concurrent illness or medical conditions other than HIV infection that may contribute to the condition (for adult AIDS wasting);
- Patient must be evaluated by an endocrinologist (for all children and adult GHD)

3. Recommended dosage if approved:

PEDIATRIC

- GHD: 0.3mg/kg per week, divided into daily or 6 times-per-week subcutaneous injections
- CRI: Dosage at 0.35mg/kg per week, divided into 6 or 7 doses is recommended¹⁰
- TS: Recommended starting dose: 0.05mg/kg/day
- Prader Willi syndrome: 0.035mg/kg/day

ADULT

- Daily dosage: 3 to 4 mcg/kg/day
- Maximum daily dose: 25mcg/kg for patients up to 35 years of age and 12.5 mcg/kg for older patients
- Growth Hormone Research Society consensus recommends a starting dose of 150 to 300 mcg per day regardless of body weight

4. Monitoring:

- Should be performed by a pediatric endocrinologist in partnership with the pediatrician or primary care physician and should be conducted on a 3 to 6 month basis
- Increase in height and change in height velocity should be assessed
- Monitoring of serum IGF-I and IGFBP-3 levels

5. Therapy End Point:

PEDIATRIC

- Treatment to continue until final height or epiphyseal closure has been documented.
- Bone age >14 to 15 years (girls) and >15 to 16 years (boys)
- Growth rate <2.5cm/ year
- Achievement of mid-parental adult height

ADULT

- IGF-I level above normal
- Decrease in LDL, increase in HDL, and a change in body composition
- Decrease in body fat and an increase in bone density
- If a patient shows no improvement when maximum dose is achieved, treatment should be discontinued
- Contraindications: active malignancy, intracranial hypertension, second and third trimester of pregnancy, or the development of diabetic retinopathy

Formulary Position:

Omnitrope is the preferred Growth Hormone for Growth Hormone Deficiency

Note: Although Omnitrope is the preferred Growth Hormone, these particular branded growth hormone products will be covered for these FDA approved indications:

- Genotropin will be covered for Turner's Syndrome and Prader-Willi Syndrome
- Norditropin will be covered for Noonan's Syndrome
- Serostim will be covered for AIDS associated cachexia or wasting
- Zorbtive will be covered for Short Bowel Syndrome

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