



MEDICAL POLICY

Date Reviewed: 12/97, 02/25/00, 04/26/2002, 08/23/02, 03/27/03, 04/26/03, 03/24/06, 04/24/09, 04/28/10, 04/15/11

Subject: Growth Hormone for Pediatrics (Accretropin, Genotropin, Humatrope, NordiFlex, Nordipen, Norditropin, Nutropin, Omnitrope, Protropin, Saizen, Sermorelin, Serostim, Somatrem, Somatropin, Tev-Tropin, Zorbtive)

Description: Human growth hormone (HGH) is used to treat various growth and metabolic disorders. It is primarily used to increase low endogenous growth hormone levels in both children and adults.

Indications of Coverage:

The use of HGH for pediatric patients (less than eighteen years of age) is considered medically necessary for the treatment of the following conditions when criteria for those conditions are met:

Growth Failure due to Growth Hormone Deficiency (either congenital or due to radiation therapy)

The patient has been evaluated by an endocrinologist

The patient's height is at or below the third percentile on NHANES growth charts and a height velocity (measurement of the speed of growth) measured over one year is at or below the third percentile for chronological age.

The HGH deficiency has been confirmed by growth hormone stimulation tests. HGH deficiency is confirmed by a growth hormone level less than ten micrograms/liter to at least two stimuli of growth hormone release: Insulin, Levodopa, Arginine, Clonidine or Glucagon.

If the above criteria are met, twelve months of HGH is appropriate. The continuing coverage of HGH requires an annual evaluation by an endocrinologist with documentation of a positive response to HGH. A positive response to HGH is defined as an increase over pretreatment annual growth rate of at least two centimeters per year and x-ray documentation that the bony epiphyses (areas of growth near the end of bones) have not closed. **Coverage under this policy ends when the bony epiphyses have closed; see Growth Hormone for Adults policy.**

Growth Failure due to Chronic Renal Insufficiency

The patient has been evaluated by an endocrinologist

The patient's height is at or below the third percentile on NHANES growth charts and a height velocity measured over one year is at or below the third percentile for chronological age.

Nutritional status has been optimized, metabolic abnormalities have been corrected, and steroid use has been minimized.

If the above criteria are met, twelve months of HGH is appropriate. The continuing coverage of HGH requires an annual evaluation by an endocrinologist with documentation of a positive response to HGH. A positive response to HGH is defined as an increase over pretreatment annual growth rate of at least two centimeters per year and x-ray documentation that the bony epiphyses have not closed. **Coverage under this policy ends when the bony epiphyses have closed; see Growth Hormone for Adults policy.**

Prader-Willi Syndrome, Noonan Syndrome, Short stature homeobox (SHOX)–containing gene deficiency or Russell-Silver Syndrome

The diagnosis has been confirmed after evaluation by an endocrinologist.

The continuing coverage of HGH requires an annual evaluation by an endocrinologist with documentation of a positive response to HGH. A positive response to HGH is defined as an increase over pretreatment annual growth rate of at least two centimeters per year and x-ray documentation that the bony epiphyses have not closed. **Coverage under this policy ends when the bony epiphyses have closed; see Growth Hormone for Adults policy.**

Turner Syndrome

The diagnosis has been established and confirmed with appropriate testing.

The patient has been evaluated by an endocrinologist prior to initiation of growth hormone therapy.

The patient's height is at or below the third percentile on NHANES growth charts and a height velocity measured over one year is at or below the third percentile for chronological age.

If the above criteria are met, twelve months of HGH is appropriate. The continuing coverage of HGH requires an annual evaluation by an endocrinologist with documentation of a positive response to HGH. A positive response to HGH is defined as an increase over pretreatment annual growth rate of at least two centimeters per year and x-ray documentation that the bony epiphyses have not closed. **Coverage under this policy ends when the bony epiphyses have closed; see Growth Hormone for Adults policy.**

Small for Gestational Age (SGA) or Intrauterine Growth Retardation (SGA is defined as birth weight or length two or more SD below the mean for gestational age)

The patient has been evaluated by an endocrinologist

The patient is at least two years of age and the patient's height is at or below the third percentile on NHANES growth charts

Growth failure is due to a specific congenital anomaly (for example, IGF-I deficiency) or conditions during pregnancy (for example, maternal diabetes, infections, hypoxia, addictions, or placental dysfunction).

Other causes for growth failure (for example, medication, chronic disease, endocrine disorders) have been ruled out.

If the above criteria are met, twelve months of HGH is appropriate. The continuing coverage of HGH requires an annual evaluation by an endocrinologist with documentation of a positive response to HGH. A positive response to HGH is defined as an increase over pretreatment annual growth rate of at least two centimeters per year and x-ray documentation that the bony epiphyses have not closed. **Coverage under this policy ends when the bony epiphyses have closed; see Growth Hormone for Adults policy.**

Limitations of coverage:

Review contract for exclusions and benefits.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

The use of HGH for Idiopathic Short Stature or Non-Growth Hormone-Deficient Short Stature is not a covered benefit. These conditions are not due to illness or injury.

HGH is considered not medically necessary in patients with a malignancy or in patients with an acute critical illness due to complications from cardiac or abdominal surgery, trauma, or acute respiratory failure.

HGH for pediatric patients whose bony epiphyses have closed is considered not medically necessary unless coverage is available in the Growth Hormone for Adults policy.

The safety and effectiveness of Zorbtive in pediatric patients with Short Bowel Syndrome has not been established.

Documentation required:

Office notes

Growth hormone stimulation tests

Imaging reports

Growth chart

Rationale: Growth hormone is a protein hormone secreted by the pituitary which promotes linear growth, so growth hormone therapy for children promotes this growth by correcting the deficiency. Linear growth continues until the bony epiphyses at the ends of the bones close. This treatment is also sometimes required for children with rare congenital syndromes in order to maintain a more normal growth pattern.

References: American Association of Clinical Endocrinologists: Clinical Medical Guidelines for Growth Hormone in Adults & Children. 2003 Update. Endo Pract 2003; 9:65-73.

Blum Werner F., Crowe Brenda J., Quigley Charmian A, Jung Heike, Cao Dachuang , Ross Judith L, Braun LeeAnn, Gudrun Rappold for the SHOX Study Group. Growth Hormone Is Effective in Treatment of Short Stature Associated with Short Stature Homeobox-Containing Gene Deficiency: Two-Year Results of a Randomized, Controlled, Multicenter Trial. The Journal of Clinical Endocrinology & Metabolism Vol. 92, No. 1 219-228.

Kirk J M W, Betts P R, Butler G E, M D Donaldson C, Dunger D B, Johnston D I, Kelnar C J H, Price D A, Wilton P, the UK KIGS Executive Group on behalf of the participating centres. Short stature in Noonan syndrome: response to growth hormone therapy. *Arch Dis Child* 2001;84:440–443.

Ranke Michael B, Lindberg Anders, Cowell Christopher T, Wikland Kerstin Albertsson, Reiter Edward O, Wilton Patrick, and Price David A. Prediction of Response to Growth Hormone Treatment in Short Children Born Small for Gestational Age: Analysis of Data from KIGS (Pharmacia International. *The Journal of Clinical Endocrinology & Metabolism* 88(1):125–131 Growth Database).

Voss Linda D. Is short stature a problem? The psychological view. *European Journal of Endocrinology*, Vol 155, Issue suppl_1, 39-45.

These guidelines are designed for reference purposes only, do not guarantee coverage, and should not be construed as medical advice. See full Medical Policy Disclaimer.

Approved by the Medical Director

URL addresses for growth charts:

www.cdc.gov/nchs/data/nhanes/growthcharts/set2clinical/cj411067.pdf

www.cdc.gov/nchs/data/nhanes/growthcharts/set2clinical/cj411068.pdf

www.cdc.gov/nchs/data/nhanes/growthcharts/set2clinical/cj411071.pdf

www.cdc.gov/nchs/data/nhanes/growthcharts/set2clinical/cj411072.pdf