

Medical Policy

An Independent Licensee of the
Blue Cross and Blue Shield Association.

Title: Adult Growth Hormone**Professional**

Original Effective Date: February 5, 1986

Revision Date(s): January 1, 2002;

September 14, 2006; November 2, 2006;

February 2, 2007

Current Effective Date: March 1, 2007

DESCRIPTION

Human growth hormone (GH), also known as somatotropin, is synthesized in the anterior pituitary throughout life. Growth hormone binds to the surface of cells and stimulates the production of insulin growth factor-I (IGF-I). Insulin growth factor is responsible for many of the growth promoting effects attributed to growth hormone. Growth hormone stimulates all aspects of cartilage growth, and one of its major effects is to simulate the growth of the epiphyseal cartilage plates of long bones. Other body tissues respond to the metabolic effect of growth hormone with increases in bone width and the growth of visceral and endocrine organs, skeletal and cardiac muscle, skin, and connective tissue. It also plays a role in the distribution and metabolism of fat in the body.

POLICY

1. Growth hormone therapy is excluded for insureds over the age of 18 with the following exception:
 - a. Those Insureds over the age 18 with:
 - Imaging demonstrated hypothalamic or pituitary disease or injury and
 - Laboratory proven growth hormone deficiency
 - b. Those Insureds over the age of 18 who have had childhood onset of growth hormone deficiency and have had that deficiency demonstrated by testing during childhood.
2. Growth hormone deficiency must be documented by the following criteria:
 - a. Biochemical testing by means of a subnormal response to standard growth hormone stimulation test (peak growth hormone values <5ng/ml to provocative stimuli). Insulin tolerance test with documented hypoglycemia (blood sugars less than 40mg/dl or 50% decrease from baseline) with symptoms is the standard test. When Insulin Tolerance test is contraindicated in a given insured, Growth Hormone Releasing Hormone/arginine can be used as an alternate testing procedure. L-dopa, glucagon or clonidine is not acceptable secretagogues in adults.

OR

- b. A below normal level of IGF-1 (less than 84 µg/liter) constitutes laboratory proof of growth hormone deficiency when associated with panhypopituitarism with documented multiple hormone deficiencies (3 or more deficiencies: secondary hypothyroidism, ACTH deficiency, gonadotropin deficiency, diabetes insipidus) as a result of pituitary or hypothalamic disease secondary to tumor, surgery, inflammation, radiation therapy, severe head trauma or structural abnormality (septo-optic dysplasia, ectopic neurohypophysis). Growth hormone stimulation testing is not necessary in these cases.
3. Continuation of approval for growth hormone therapy requires some indication of a clinical response to the growth hormone during the first 12 months of therapy; weight loss, improvement on lipid profile, increased bone mass, increased muscle strength or increase of IGF1 into the normal range. Children with severe growth hormone deficiency who continue growth hormone therapy into adulthood or adults with hypopituitarism of recent onset will not exhibit the sequelae of adult growth hormone deficiency and will not show the improvements listed above.

NOTE: If consultant decides that growth hormone treatment will be given for the rest of the life of the patient, it will no longer be necessary for Medical Review to re-review for medical necessity. It will be necessary, however, to review for benefits.

UTILIZATION

If growth hormone is approved for an adult, and there has been demonstrative clinical improvement maintained for 1 year or more, periodic review beyond that will be unnecessary for these adults.

CODING

CPT/HCPCS

- 90772 Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
- J2940 Injection, somatrem, 1 mg
- J2941 Injection, somatropin, 1 mg
- Q0515 Injection, sermorelin acetate, 1 microgram (effective 01/01/2006)
- S9558 Home injectable therapy; growth hormone, including administrative services, professional pharmacy services, coordination of care, and all necessary supplies and equipment, per diem

DIAGNOSIS

These diagnoses are otherwise subject to medical policy as stated above

253.0	Acromegaly and gigantism
253.1	Other and unspecified anterior pituitary hyperfunction
253.2	Panhypopituitarism
253.3	Pituitary dwarfism
253.4	Other anterior pituitary disorders
253.6	Other disorders of neurohypophysis
253.7	Iatrogenic pituitary disorders
253.8	Other disorders of the pituitary and other syndromes of diencephalohypophyseal origin

REVISIONS

February 2, 2007 with effective date of	In "Policy" section 2.b. added, "A below normal level of IGF-1 (less than 84ng/ml) constitutes laboratory proof of growth hormone deficiency when associated with" to the beginning of the paragraph as recommended by the Medical Director.
March 1, 2007	In "Reference" section, added Hartman ML, Crowe BJ, Biller BM, HoKK, Clemmons DR, Chipman JJ, et al. Which patients do to require a GH stimulation test for the diagnosis of adult GH deficiency? J Clinical Endocrinol Metab. 2002;87:477-85, for the above statement.

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2. Finkelstein BS, Imperiale TF, Speroff T et al. Effect of growth hormone therapy on height in children with idiopathic short stature: a meta-analysis. Arch Pediatr Adolesc Med 2002; 156(3):230-40.
3. Genotropin, Package Insert
4. Hartman ML, Crowe BJ, Biller BM, HoKK, Clemmons DR, Chipman JJ, et al. Which patients do not require a GH stimulation test for the diagnosis of adult GH deficiency? J Clinical Endocrinol Metab. 2002;87:477-85.
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8. Pasquino AM, Pucarelli I, Roggini M et al. Adult height in short normal girls treated with gonadotropin-releasing analogs and growth hormone. J Clin Endocrinol Metab 2000; 85(2):619-22.
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Government Agency; Medical Society; and Other Authoritative Publications

1. AACE Growth Hormone Task Force. American Association of Clinical Endocrinologists medical guidelines for hormone use in adults and children—2003 update. *Endocrine Practice* 2003; 9(1):65-76.
2. Agency for Healthcare Research and Quality. Evidence Report/Technology Assessment Number 73. Criteria for determining disability in infants and children: short stature. March 2003. <http://www.ahrq.gov/clinic/evrptfiles.htm#short> Accessed on March 18,2005.
3. American Academy of Pediatrics. Considerations related to the use of recombinant human growth hormone in children. American Academy of Pediatrics Committee on Drugs and Committee on Bioethics. *Pediatrics* 1997; 99(1):122-9.
4. Blue Cross and Blue Shield of Kansas Internal Medicine Liaison Committee, August 30, 2006 (see Blue Cross and Blue Shield of Kansas Newsletter, Blue Shield Report. MAC-03-06).
5. Blue Cross and Blue Shield of Kansas Medical Advisory Committee (MAC) meeting, November 2, 2006 (see Blue Cross and Blue Shield of Kansas Newsletter, Blue Shield Report. MAC-03-06).
6. Hayes Medical Technology Directory. Recombinant Growth Hormone Treatment in Growth Hormone- Deficient Adults. Winifred Hayes, Inc. Lansdale, PA. June 2002.
7. Hayes Medical Technology Directory. Recombinant Growth Hormone Treatment in Children. Winifred Hayes, Inc. Lansdale, PA. October 2003.
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10. 2001 TEC Assessment; Tab 11: Recombinant Human Growth Hormone (GH) Therapy in Adults with Age-Related GH Deficiency.

Web site

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