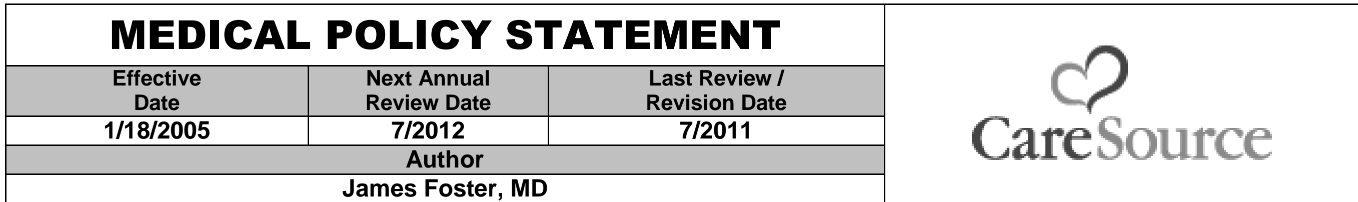

| MEDICAL POLICY STATEMENT | | |
|---|---|---|
| Effective Date | Next Annual Review Date | Last Review / Revision Date |
| 1/18/2005 | 7/2012 | 7/2011 |
| Author | | |
| James Foster, MD | | |



CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative and are not provided mainly for the convenience of the member or provider.

## A. SUBJECT

Growth Hormone

## B. BACKGROUND

This document is to establish a policy to review the medical necessity for Growth Hormone.

The FDA has approved growth hormone (GH) for use in the following conditions:

1. Pediatric and adult growth hormone deficiency
2. Turner’s syndrome
3. Growth retardation due to chronic renal insufficiency
4. AIDS cachexia

## C. POLICY

**For Special Needs Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD).**

CareSource will consider growth hormone therapy medically necessary when the above conditions are met and the following approval criteria are met:

A. Pediatric growth hormone deficiency
   1. Present height is <5th percentile for age/sex
   2. Growth velocity is <10th percentile for bone age and gender
   3. Radiographic documentation of the open growth plates
   4. Bone age is a minimum of one year behind chronological age
   5. Documented failure to respond to 2 growth hormone provocative tests with a GH level <10ng/ml. Unless contraindicated, one of the tests must be the insulin tolerance test; others include levodopa, arginine, clonidine, propranolol and glucagon.
   6. IGF-1 and IGF-BP3 levels below normal for bone age and sex

**OR**

B. Turner's syndrome
   1. Present height is less than <10th percentile for age/sex
   2. Radiographic documentation of the open growth plates
   3. Documented diagnosis of Turner's syndrome

**OR**

C. Growth retardation due to chronic renal insufficiency (CRI)
   1. Patients with documented diagnosis of CRI up to the time of renal transplant
   2. Authorization request for Nutropin therapy
   3. Present height is <5th percentile for age/sex
   4. Growth velocity is <10th percentile for bone age and gender
   5. Radiographic documentation of the open growth plates

**OR**

D. SGA Infant
   1. Child who is greater than age three years and who has persistent short statue (>2 SD below the mean for chronological age)

**OR**

E. Adult growth hormone deficiency
   1. Childhood onset
      a. Patients who were growth hormone deficient during childhood who have GH deficiency confirmed as an adult
      b. Biochemical diagnosis of GH deficiency by negative response to a standard growth hormone stimulation test with GH maximum peak <5ng/ml

**OR**

   2. Adult onset
      a. Patients who have GH deficiency either alone, or with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma.
      b. Biochemical diagnosis of GH deficiency by negative response to a standard growth hormone stimulation test with GH maximum peak <5ng/ml. The insulin tolerance test (ITT) is required unless contraindicated. Results from other stimulation tests (excluding the clonidine test) may be submitted for those patients with a documented contraindication to ITT.
      c. Patient is receiving full supplementation of deficient pituitary hormones such as thyroid, glucocorticoid, or gonadotropic hormones
      d. No evidence of active malignancy
      e. Evaluation of insulin-like growth factor-1 once annually and following any change in dose

**OR**

   3. AIDS wasting or cachexia
      a. Patient must be at least eighteen years old
      b. Patient must have a clear documentation of HIV infection with serum antibodies to HIV
      c. Patient had failed to achieve desirable results with Megace or Marinol
      d. Patient must be on concomitant antiretroviral therapy

e. Patient must have a documented weight loss of at least 10% from baseline premorbid weight
f. Patient should be receiving adequate caloric intake and nutritional counseling
g. Patient should not have any active malignancy other than Kaposi's Sarcoma

**Termination of Therapy**

Growth hormone therapy is considered **no longer reconstructive** when **any** of the following criteria are met:

a. Bone age = 16 years (male), or = 14 years (female) is reached, or
b. Epiphyseal fusion has occurred, or
c. "Mid-parental height" is achieved. Mid-parental height = (father's height + mother's height) divided by 2, plus 2.5 inches (male) or minus 2.5 inches (female).

**If there is no LCD or NCD present reference the CSMG Policy for coverage.**

## D. REVIEW / REVISION HISTORY

Date Issued: 1/18/2005
Date Revised: 3/1/2006, 4/2008, and 7/2008
Date Reviewed: 7/1/2009, 7/1/2011

## E. REFERENCES


1. Ghigo E, Bellone J, Aimaretti G, et al. Reliability of provocative tests to assess growth hormone secretory status. Study in 472 normally growing children. J Clin Endo Metab. 1996; 81: 3323-3327.
2. Hindmarsh PC, Brook CGD. Short stature and growth hormone deficiency. Clin Endocrinol. 1995; 43:133-142.
3. American Academy of Pediatrics. Considerations related to the use of recombinant human growth hormone in children. Ped 1997; 99:122-29.


The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.