

Medical and Behavioral Health Policy

Section: Medicine

Policy Number: II-12

Effective Date: 11/27/2013

Blue Cross and Blue Shield of Minnesota medical policies do not imply that members should not receive specific services based on the recommendation of their provider. These policies govern coverage and not clinical practice. Providers are responsible for medical advice and treatment of patients. Members with specific health care needs should consult an appropriate health care professional.

GROWTH HORMONE TREATMENT

Description: Biosynthetically produced forms of human growth hormone are used to augment growth in children who are genetically predisposed to short stature and in individuals with endogenous growth hormone (GH) deficiency.

Definitions: **Growth velocity:** Rate of growth a child experiences over a period of time. Normal growth velocities are based on age and gender.

Bone age: Relative maturity of a child's skeletal system compared to standards for chronological age. Bone age tests are performed by obtaining an x-ray of several growth sites (e.g., wrist, hand) and comparing those findings to standards for normal bone age by gender.

Constitutional growth delay: Temporary delay in the skeletal growth and height of a child, with no other physical abnormalities causing the delay. These children are small for their ages, but grow at a normal rate.

Policy:

- I. Recombinant human growth hormone (GH) may be considered **MEDICALLY NECESSARY** for **ANY** of the following indications:
 - A. Children with a confirmed diagnosis of growth hormone deficiency determined by the following:
 - 1. Hypoglycemia in newborn accompanied by a diagnosis of hypopituitarism/panhypopituitarism, **OR**
 - 2. Failure to respond to at least **TWO** of the following standard GH stimulation tests, with failure defined as a peak GH level of less than 10 ng/ml after stimulation:
 - a. Insulin; OR
 - b. L-dopa; OR
 - c. Arginine; OR
 - d. Clonidine; OR
 - e. Glucagon;

AND

3. Documentation of at least **TWO** of the following clinical features of GH deficiency:
 - a. Growth velocity less than the 3rd percentile for bone age (greater than two standard deviations below the mean); OR
 - b. Height less than the 3rd percentile for age (greater than two standard deviations below the mean); OR
 - c. Delayed bone age
 - B. Children with chronic renal insufficiency when **ALL** of the following conditions are met:
 1. Growth retardation with height less than the 3rd percentile for age (greater than two standard deviations below the mean); **AND**
 2. Growth velocity less than the third percentile for bone age (greater than two standard deviations below the mean); **AND**
 3. Bone age at least two standard deviations below the mean for age and gender; **AND**
 4. Pretreatment bone age less than 13 years for females and less than 15 years for males; **AND**
 5. No obvious clinical evidence of another unrelated etiology for growth retardation
 - C. Patients with AIDS wasting
 - D. Adults with proven GH deficiency when **ALL** of the following criteria are met:
 1. Pituitary disease documented by surgery or other insult (e.g., postpartum hemorrhage, cranial irradiation); **AND**
 2. Evidence of and treatment for other hormonal deficiencies (e.g., steroid replacement therapy, thyroid replacement therapy); **AND**
 3. Provocative testing indicates absolute deficiency of growth hormone (<3 ng/mL); **AND**
 4. Presence of clinical features associated with growth hormone deficiency (e.g., increased fat mass with abdominal preponderance, decreased lean body mass, decreased muscle mass and strength, decreased exercise capacity, impaired sense of well-being)
 - E. Patients with Turner's syndrome
 - F. Patients with growth failure due to Prader-Willi syndrome
 - G. Patients with short stature due to Noonan syndrome
 - H. Promotion of wound healing in burn patients
 - I. Prevention of growth delay in children with severe burns
 - J. Patients with short bowel syndrome receiving specialized nutritional support in conjunction with optimal management of short bowel syndrome
 - K. Children with short stature due to SHOX (short stature homeobox-containing gene) deficiency.
- II. Recombinant human growth hormone (GH) therapy is considered **INVESTIGATIVE** for the following indications, including, but not limited to:

- A. Pediatric patients born small for gestational age (SGA) who fail to show catch-up growth by age 2 years
- B. Children with height standard deviation score of -2.25 or below who are not growth hormone deficient (i.e., idiopathic short stature)
- C. Constitutional growth delay
- D. In conjunction with gonadotropin-releasing hormone (GnRH) analogs as a treatment of precocious puberty
- E. GH therapy in older adults without proven deficiency (i.e., anti-aging treatment)
- F. Anabolic therapy except for AIDS provided to counteract acute or chronic catabolic illness (e.g., surgery outcomes, trauma, cancer, chronic hemodialysis, chronic infectious disease) producing catabolic (protein wasting) changes in both adult and pediatric patients
- G. Anabolic therapy to enhance body mass or strength for professional, recreational, or social reasons
- H. Glucocorticoid-induced growth failure
- I. Short stature due to Down's syndrome
- J. Treatment of altered body habitus (e.g., buffalo hump) associated with antiviral therapy in HIV- infected patients
- K. Treatment of obesity
- L. Treatment of cystic fibrosis
- M. Treatment of idiopathic dilated cardiomyopathy
- N. Treatment of juvenile idiopathic or juvenile chronic arthritis
- O. Treatment of fibromyalgia

III. Documentation Requirements for Renewal of Pre-Certification/Pre-Authorization

- A. Renewal for the following diagnoses must include documentation (i.e., growth charts) to support improvement in growth:
 - 1. Turner's syndrome
 - 2. Renal failure
 - 3. Growth hormone deficiency
 - 4. Prader-Willi syndrome
 - 5. Noonan syndrome
 - 6. SHOX deficiency
- B. Renewal for Adult Growth Hormone Deficiency or AIDS Wasting or Cachexia must include documentation supporting improvement in symptoms.

Coverage:

Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a

specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Coding: *The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

HCPCS:

J2940 Injection, somatrem, 1 mg

J2941 Injection, somatropin, 1 mg

S9558 Home injectable therapy; growth hormone, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

Policy History: **Developed February 28, 1986**

Most recent history:

Reviewed November 10, 2010

Reviewed November 9, 2011

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Cross Reference:

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