HealthPartners®

# Growth Deficiency Therapy

These services may or may not be covered by all HealthPartners plans. Please see your plan documents for your own coverage information. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage.

## Administrative Process

Growth hormone and IGF-1 growth factors require prior approval from HealthPartners Pharmacy Administration. Coverage varies with patient age and its indication for use.

## Coverage for Children

Coverage based on the indication for use:

1. Short stature. Coverage is reserved for prescribing by Pediatric Endocrinologists, for children meeting specific growth measurements and specific measures of growth hormone activity. Coverage is approved for an initial 6-month trial to assess response, and then annually until specific height criteria are met. Coverage is reserved for preferred growth deficiency products.

   Short Stature. Coverage is reserved for patients meeting one or more of these growth measurement criteria:
   a. current height <= minus 2.5 standard deviations below normal
   b. Children with a target adult height of <= minus 2 standard deviations below their midparental height
   c. Children with a height velocity <= minus 2 standard deviations for age and Tanner Stage

   Inadequate growth hormone-IGF axis. Coverage is reserved for patients with inadequate activity as determined by one or more of these methods:
   a. Growth hormone provocative testing (GH Peak < 10 mg/ mL)
   b. Serum IGF levels (IGF-1 or IGFBP-3) < 1 standard deviations below normal
   c. IGF generation test (stimulate level 3x baseline or > 250mg/ml)

   Initial approvals. Coverage is approved initially for 6 months. Continuing treatment is approved for children with an increase in height velocity of more than 50% above baseline.

   Continuing treatment. Coverage is reviewed annually. Treatment is covered until one of the following:
   a. Patient height is >= 25% of National Center for Health Statistics (>= 5'8" for boys, and 5'3" for girls).
   b. Mature bone age (>= 17 for boys, and >= 15 for girls)
   c. No response (growth velocity <= 2 cm/ year, calculated over an interval of at least 6 months)

   Preferred products. Preferred growth hormones are listed in the Preferred Drug List (Drug Formulary). IGF-1 growth factors (mecasermin, Increlex and iPlex) are reviewed on a case-by-case basis, for patients failing therapy with growth hormone.
2. Panhypopituitarism. Coverage is reserved for prescribing by Endocrinologists. Coverage is reviewed annually for compliance. Coverage is reserved for preferred growth deficiency products.
3. Prader-Willi. Coverage is reserved for prescribing by Pediatric Endocrinologists. Coverage is reviewed annually. Treatment is covered until the epiphyses are closed. Coverage is reserved for preferred growth deficiency products. Exceptions to these criteria will be reviewed on a case-by-case basis.
4. Turner's Syndrome. Coverage is reserved for prescribing by Pediatric Endocrinologists. Coverage is reviewed annually. Treatment is covered until the bone age is > or = 15 years or growth slows to less than 2 cm per year. Coverage is reserved for preferred growth deficiency products. Exceptions to these criteria will be reviewed on a case-by-case basis.
5. Other diagnoses. Will be reviewed on a case-by-case basis when determined medically necessary. Coverage is reserved for preferred growth deficiency products.

## Coverage for Adults

Patients must have documented childhood onset GHD or adult onset GHD secondary to hypothalamic or pituitary disease or history of cranial irradiation. Treatment must follow most current clinically accepted guidelines.

Prescribing of growth hormone for adults is limited to endocrinologists specializing in the treatment of adult GHD. Cases must be reviewed by a second adult endocrinologist, designated by the HealthPartners Pharmacy and Therapeutics Committee, to confirm criteria have been met. Treatment with a preferred Growth hormone for adults is generally covered per all of the criteria listed below. Preferred growth hormones are listed in the Preferred Drug List (Formulary).

1. GHD exists as defined by low IGF 1 levels based on age-adjusted values and serum growth hormone concentration of less than 5ng/ml (peak levels) following stimulation testing. ITT (Insulin Tolerance Test) is the diagnostic test of choice. Serum glucose level must have fallen by 50% or to less than 40mg/dl for satisfactory stimulation during the ITT. Other testing, such as arginine alone or in combination with GHRH, may be used if ITT is contraindicated. Contraindications to ITT include: age greater than 55, history of heart disease, cerebral vascular disease, or seizure disorder.
2. Complete pituitary hormone function has been tested and replaced when appropriate.
3. The individual demonstrates at least three of the following clinical features of GHD.
    a. Altered body composition with increased body fat mass with abdominal preponderance and decreased lean body mass.
    b. Decreased muscle strength and exercise capacity.
    c. Reduced bone density or presence of a fragility fracture.
    d. Poor sleep;
    e. Impaired sense of well-being.
4. Secondary medical illnesses that affect GH have been ruled out, such as liver disease, kidney disease, and malnutrition.

Growth hormone therapy is reviewed annually. IGF-1 levels are reviewed, and thyroid function tests, lipids, regular body weight, and waist/hip ratio measurements are also recommended. If the patient perceives no benefit, then a trial of GH withdrawal should be considered.

## Definitions

**Growth hormone** is a chemical substance secreted by the pituitary gland. A congenital deficiency of this hormone results in decreased growth in children. Therapy consists of administration of growth hormone. Growth Hormone Deficiency (GHD) may also be found in adults, generally as a result of childhood onset GHD, but occasionally due to adult onset hypothalamic or pituitary disease or injury.

## Products

This information is for most, but not all, HealthPartners plans. Please read your plan documents to see if your plan has limits or will not cover some items. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage. These coverage criteria may not apply to Medicare Products if Medicare requires different coverage. For more information regarding Medicare coverage criteria or for a copy of a Medicare coverage policy, contact Member Services at 952-883-7979 or 1-800-233-9645.

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Bibliography of related research that supports this policy is available on request.