UHA
HEALTH INSURANCE

Growth Hormone Therapy

I. Policy

University Health Alliance (UHA) will reimburse for growth hormone therapy when it is determined to be medically necessary and when it meets the medical criteria guidelines (subject to limitations and exclusions) indicated below.

II. Criteria/Guidelines

Initial therapy with human growth hormone is covered (subject to Limitations/ Exclusions and Administrative Guidelines) for one of the following indications:

A. Children with evidence of growth hormone deficiency (GHD) must meet the following criteria:

1. Biochemical Criteria:

    a. Documentation of abnormal responses to two growth hormone (GH) stimulation tests defined as less than 10 nanograms per milliliter (ng/mL) or as otherwise determined by the testing lab; or

    b. At least one GH stimulation test response less than15 ng/ml, and both IGF-I and IGF-BP3 levels below normal for age and gender; or

    c. One GH stimulation test response below 10 ng/ml with defined CNS pathology, history of cranial irradiation or genetic conditions associated with GHD; or

    d. Two or more documented pituitary hormone deficiencies other than GH; or

    e. Abnormally low GH level documented in association with neonatal hypoglycemia; and

2. Auxologic Criteria

    a. Height equal to or less than two standard deviations below the mean for age and gender; or

    b. Height equal to or less than one standard deviation below the mean and growth velocity less than one standard deviation below the mean for age and gender; and

        A. A minimum of one year of growth data is required with measurements at least six months apart and performed by an endocrinologist; or

        B. Patient must have four or more height determinations measured at least six months apart, by the patient's primary care physician, over a period of at least two years. Results must show a consistent growth pattern; and

    c. Radiologic documentation of open growth plates in patients over 12 years of age.

B. Children with idiopathic short stature, familial short stature, or small for gestational age infants with failure of catch-up growth by the age of two must meet the following criteria:

1. Auxologic Criteria:

    a. Height less than or equal to 2.25 standard deviations below the mean for age and gender measured in accordance with criteria noted above; and

    b. Growth velocity equal to or less than one standard deviation below the mean for age and gender measured in accordance with criteria noted above; and

c. Radiologic documentation of open growth plates in patients over 12 years of age

C. **Turner's syndrome, Noonan's syndrome, Prader-Willi syndrome:** Patients must meet the following criteria:

1. Open growth plates in patients over 12 years of age; and
2. Height below the tenth percentile for age.

D. **Children with chronic renal insufficiency:** Patients must meet the following criteria:

1. Creatinine clearance less than or equal to 75 mL/min per 1.73 m^2 or serum creatinine greater than 3.0 mg/dl, or dialysis dependent; and
2. Radiographic documentation of open growth plates in patients over 12 years of age.

E. **Acquired Immune Deficiency Syndrome** (**AIDS) wasting:** Patients must meet the following criteria:

1. Greater than 10 percent of baseline weight loss that cannot be explained by a concurrent illness other than HIV infection; and
2. Simultaneous treatment with antiviral agents.

F. **Burn patients:** Patients must meet the following criteria:

1. Extensive 3rd-degree burns; or
2. Burns greater than or equal to 40 percent total body surface area.

G. **Short bowel syndrome:** Patients must meet the following criteria**:**

1. Receiving specialized nutritional support; and
2. Optimal management of short bowel syndrome.

H. **Adults with evidence of GH deficiency**

1. Irreversible hypothalamic/pituitary structural lesions or ablation: No further testing needed
2. Defect in GH synthesis: No further testing needed
3. GH deficiency in childhood, circumstances other than 1 or 2 above: Only about 25% children with GH deficiency will be found to have GH deficiency as adults. Therefore, once adult height has been achieved, patients should be retested for GH deficiency after at least a one month break in GH therapy to determine if continuing replacement therapy is necessary in accordance with one of the following criteria:
    a. Three or more pituitary hormone deficiencies and IGR-1 level below laboratory's range of normal: no further testing necessary;
    b. Peak GH level in response to insulin tolerance test less than or equal to 5.0 ng/ml and IGF-1 level below laboratory's range of normal;
    c. Peak GH level in response to glucagon stimulation test less than or equal to 3.0 ng/ml and IGF-1 level below laboratory's range of normal;
    d. Peak GH level in response to arginine stimulation test less than or equal to 0.4 ng/ml and IGF-1 level below laboratory's range of normal

    Note: Levadopa and clonidine stimulation tests are not acceptable for documenting persistence of GH deficiency into adulthood

I. Continuation of therapy must meet additional criteria. Continuation of therapy is covered (subject to Administrative Guidelines) when the continuation of therapy criteria listed in the chart below (in Administrative Guidelines) are met.

J. Monitoring of GH therapy is covered within the following guidelines:

1. To test of the adequacy of GH treatment, UHA covers measuring a serum IGF-1 two months after starting therapy. No prior authorization required.
2. Once serum IGF-1 is in the normal range, UHA covers repeat testing every 6 to 12 months. No prior authorization required.

NOTE:

This UHA payment policy is a guide to coverage, the need for prior authorization and other administrative directives. It is not meant to provide instruction in the practice of medicine, and it should not deter a provider from expressing his/her judgment.

Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or members' individual benefit plans may apply, and this policy is not a guarantee of payment. UHA reserves the right to apply this payment policy to all UHA companies and subsidiaries.

UHA understands that opinions about and approaches to clinical problems may vary. Questions concerning medical necessity (see Hawaii Revised Statutes §432E-1.4) are welcome. A provider may request that UHA reconsider the application of the medical necessity criteria considering any supporting documentation.

III. Limitations and Exclusions

A. Initial authorization will be for up to 12 months if above criteria are met, with exception of burn patients. Initial authorization for burn patients will be up to four weeks.

B. Continuation of GH therapy will be considered medically necessary within the limitations outlined in the table in section IV, below.

1. Continuation of therapy for burn patients, AIDs wasting, and short bowel syndrome does not meet criteria for approval.

IV. Administrative Guidelines

A. Prior authorization is required for GH therapy.

B. To request prior authorization, please submit via UHA's online portal. If login has not been established, you may contact UHA at 808-532-4000 to establish one.

Indication	Initial Authorization Period
Pediatric short stature Turner's Syndrome Noonan's Syndrome Prader-Willi Syndrome Chronic Renal Insufficiency Adult GHD	Up to 12 months
Burn patients	Up to 12 months
Short bowel syndrome	Four weeks
AIDS wasting	Up to 12 months

Indication	Continuation of therapy
Growth hormone deficiency Pediatric short stature Turner's Syndrome Noonan's Syndrome Prader-Willi Syndrome Chronic Renal Insufficiency	Approved in 12 month increments with current documentation of: 1. Growth velocity greater than or equal to two centimeters per year; and 2. Open growth plates in children over 12 years of age; and 3. Height less than fifth percentile of normal adult height for gender (150 centimeters for girls; 165 centimeters for boys).
Adult GHD	Can be approved in 12 month increments.
Burn patients Short bowel syndrome AIDS wasting	No further authorization shall be given.

Codes	Description
J2941 and NDC number	Injection, somatropin, 1 mg

V. Policy History

Policy Number: MPP-0076-120301

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