

## GROWTH HORMONE – PROPOSED CLINICAL PA CRITERIA

Growth Hormone therapy is a covered Nevada Medicaid benefit subject to Prior Authorization.

### 1. Coverage and Limitations

#### A. Children (up to age 21)

##### 1. The following apply to all requests for children:

- a. Evaluation by a pediatric endocrinologist or pediatric nephrologist with a recommendation for therapy.
- b. All other causes for short stature are ruled out.
- c. Patient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids or gonadotropic hormone.

Therapy will be approved for any one of the following:

- d. Diagnosis of Turner's Syndrome.
- e. Diagnosis of Prader-Willi Syndrome.
- f. Patient has chronic renal insufficiency (defined as Creatinine Clearance between 5 and 75 ml/min/1.73m<sup>2</sup>).
- g. If the patient has evidence of hypothalamic-pituitary disease of structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma, or cranial irradiation **AND** meeting any **one** of the following:
  - Has failed at least one GH stimulation test (peak GH level <10 nanograms (ng)/mL).
  - Has at least one documented low IGF-1 level (below normal range for patient's age - refer to range on submitted lab document).
  - Has deficiencies in 3 or more pituitary axes (i.e., TSH, LH, FSH, ACTH, ADH).
- h. If the patient is a newborn infant and has evidence of hypoglycemia **AND** either a low GH level (<20 ng/mL) or a low for age IGF-1/IGF Binding Protein #3 level (**no stimulation tests required for infants**).
- i. Children with a history of intrauterine growth restriction (small for gestational age [SGA]) who at age 2 years have a height at least 2 standard deviations (SD) below the mean for the patient's age and gender.
- j. For Idiopathic Short Stature, the following criteria must be met:
  1. Bone age >2 SD below the mean for the age. Epiphyses open.
  2. Height > 2.25 SD below the mean for the age or >2 SD below the mid-parental height percentile, **or** growth velocity <25<sup>th</sup> percentile for bone age.

- k. At least one provocative stimuli test to show failure to raise growth hormone level above 10 ng/ml.

Exception to the requirement for stimuli testing:

Patients meeting j.1 and j.2 above in addition to a documented low serum insulin-like growth factor 1 (IGF-1) and/or insulin-like growth factor binding protein 3 (IGFBP3) will not be required to have stimuli testing.

- 2. Criteria for continuation of growth hormone therapy in children include the following:

- a. Bone age >2 SD below the mean for the age. Epiphyses open.
- b. Growth rate with treatment is at least two centimeters greater than untreated rate. Copy of the growth chart must accompany forms.
- c. Child has not reached the 25<sup>th</sup> percentile of normal height for gender and age.
- d. No diagnosis of an expanding intracranial lesion or tumor formation.
- e. Patient has not undergone renal transplant.

- 3. Reasons for Non-Coverage/Denial include, but are not limited to, the following:

- a. Indications other than those specified in this policy;
- b. Any condition(s) that is contraindicated and/or considered to be experimental;
- c. Patients with expanding lesions or tumor formation;
- d. Patients who have received renal transplantation; or
- e. Patients who do not meet criteria as set by this policy.
- f. Also, growth rate that is less than 2.0 cm/yr of untreated rate; growth that has reached the 25% of normal height for gender; bone age that is over recommended age for gender; or if epiphysis is closed.

An evaluation by a pediatric endocrinologist or a pediatric nephrologist is mandatory for initiation of Growth Hormone therapy and close monitoring either by a pediatric endocrinologist, pediatric nephrologist or the recipient's primary care physician is required throughout therapy.

Prior Authorization will be given for a 6-month time period for initiation of therapy, and 6-12 months for continuation of therapy, dependent upon the growth response of the recipient.

B. Adults (age 21 and older)

Agents selected for treatment must have an FDA-approved indication for the diagnosis being treated as stated in the package insert.

Indications for growth hormone therapy in adults are:

- Adults who were growth hormone deficient as children or adolescents.
1. All of the following criteria must be met:
    - a. The patient is evaluated by an endocrinologist.
    - b. Recipient has a growth hormone deficiency either alone or with multiple hormone deficiencies (hypopituitarism), as a result of EITHER disease of the pituitary or hypothalamus, OR injury to either the pituitary or hypothalamus from surgery radiation therapy, or trauma.
    - c. Recipient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids or gonadotropic hormone. Patient has failed to respond to standard growth stimulation tests. Exception: Complete hypopituitarism
    - d. Patient has failed a growth hormone stimulation test. Failure is generally defined as a maximum peak of <5 ng/ml.

2. AIDS wasting or cachexia

Agents selected for treatment must have an FDA approved indication for the diagnosis being treated as stated in the package insert.

The following criteria must be met for the treatment of AIDS wasting or cachexia:

- a. Patient must be stable on antiretroviral therapy and compliant with therapy.
- b. Documented involuntary weight loss greater than 10% pre-illness baseline or a body mass index of < 20KG/M<sup>2</sup> (weight and diagnosis must be confirmed by faxed chart notes).
  1. Patient has failed to adequately respond to dietary measures.
  2. Patient has failed to respond or is intolerant to appetite-stimulating drugs, (e.g., Megace) and anabolic steroids.
  3. Absence of a concurrent illness or medical condition other than HIV infection that would explain these findings.
- c. No active malignancy other than Kaposi's Sarcoma.

If patient meets the above criteria approve for 12 weeks.

If patient maintains or gains weight, is experiencing no adverse events, and is being monitored on a regular basis by the prescriber, approve for 12 additional weeks.

Subsequent approvals based on these criteria may be granted in 12-week increments.

3. Requests involving the following should be denied:
  - a. Indications other than those specified above.
  - b. Any condition that is considered contraindicated and/or considered to be experimental.
  - c. Recipients who do not meet the written criteria.