

Criteria for Growth Hormones for Adults

Adult patients with growth hormone deficiency may be approved for replacement of endogenous growth hormone upon **endocrinologist** documentation of medical necessity. Requests for prior approval will receive review based on the following criteria:

Childhood Onset

Patients who were growth hormone deficient during childhood and who have deficiency confirmed as an adult by a negative response to provocative testing.

Adult Onset:

Patients who have growth hormone deficiency, either alone or with multiple pituitary hormone deficiencies, such as hypopituitarism, as a result of pituitary disease, surgery, hypothalamic disease, radiation therapy, or trauma.

For the above patients:

- Biochemical diagnosis of growth hormone deficiency by means of a negative response to an appropriate stimulation test, ordered by an endocrinologist. The clonidine test is not acceptable for diagnosis in adults.
- No evidence of active malignancy **or other contraindication**.
- Other hormonal deficiencies with adequate replacement therapy.
- Initial dose \leq 0.006 mg/kg daily.
- Maximum dose \leq 0.025 mg/kg daily in patients under 35 years of age
- Maximum dose \leq 0.0125 mg/kg daily in patients over 35 years of age.
- **Baseline and evaluation annually of the following to justify continued use:**
 - ◆ **Insulin-like growth factor-1 (IGF-1) at least once annually and following any change in dosage**
 - ◆ **Fasting lipid profile**
 - ◆ **BUN**
 - ◆ **Fasting glucose**
 - ◆ **Electrolyte levels**
 - ◆ **Baseline bone density testing and then every three (3) years**
 - ◆ **Evaluation of any new osteoarthritis and joint pain**

Approval may be granted initially for a period of up to one year. If an extension of benefits is needed, the physician must submit a progress report, including information regarding efficacy, adverse effects, and compliance. This report must include the date that the patient was last seen.

Requests for prior approval should be sent to the Rational Drug Therapy Program, by fax at 1-800-531-7787 or telephone at 1-800-847-3859.