

UNIVERSITY PHYSICIANS HEALTH PLANS
(University Family Care)

PHARMACY REFERRAL GUIDELINE

GROWTH HORMONE THERAPY FOR CHILDREN

Research indicates that recombinant growth hormone (rGH), alone or in combination with anabolic steroids, improves the growth rate in children with growth hormone deficiency.

Growth Hormone therapy should only be prescribed and monitored by a Pediatric Endocrinologist.

University Physicians Health Plans recognizes the medical necessity of rGH for the following clinical settings FOR CHILDREN ONLY.

GROWTH HORMONE REPLACEMENT:

1. For classical growth hormone (GH) deficiency
 - Infants may present with hypoglycemia related seizures, visual defects or micropenis.
2. For acquired forms of GH deficiency
 - Head trauma – transection of pituitary stalk
 - Intracranial lesions
 - Irradiation therapy – greater than 2400 rads of cranial radiation
 - Therapy associated with abnormal spontaneous generation of GH

All patients must have a diagnosis consistent with Growth Hormone deficiency and all of the following:

- Short stature with height <5th percentile on standard growth chart
- Abnormal growth velocity (<5cm/yr) demonstrated on standard growth chart
- Delayed bone age >2 Standard Deviations from norm as compared with chronological age

- Failure on two growth hormone stimulation tests (peak <10ng/ml)
- Absence of chronic disease, psychosocial dwarfism or malnutrition

PROCEDURE:

I. INITIAL REQUEST

All of the following must be submitted:

- A. Patient's height and growth chart.
- B. Documentation of each biological parent's adult height.
- C. Results of Stimulation tests (must be below 10ng/ml with Insulin, Clonidine, Arginine, or Levodopa).
- D. Radiological documentation of bone age. Bone age must be greater than 2 standard deviations from norm as compared with chronological age.
- E. Documentation of absence of other chronic disease.

II. APPROVAL OF GROWTH HORMONE THERAPY

If the patient meets all of the above criteria, Growth Hormone Therapy may be instituted for a period of 6 months.

III. CONTINUED THERAPY

- A. At the six month interval the prescribing physician must submit:
 - 1. Documentation of growth. Should be measured every six months. Must demonstrate a growth velocity of 2 ½ cm every six months or 5 cm per year.
 - 2. Radiological documentation of bone age. See above requirements.
 - 3. Documentation of compliance.

4. Documentation of lack of side effects.
- B. If documentation in "A" meets criteria for continued therapy, approval will be given for an additional 6 months.
- C. On a yearly basis, the prescribing physician must submit:

Pharmacy Guidelines - Growth Hormone

-3-

- (1) Documentation of growth velocity on patient's growth chart.
- (2) Radiological documentation of bone age.
- (3) Documentation of lack of chronic disease.
- (4) Documentation of lack of side effects and compliance.

IV. CRITERIA FOR DISCONTINUING GROWTH HORMONE THERAPY

Growth Hormone therapy will be discontinued when any one of the following has occurred:

1. Decrease in growth velocity while on therapy (less than 5 cm/year).
2. Bone age of > 14 years in females and > 16 years in males.
3. Height attained that is within genetic potential as defined by midparental height (measurements should be made in cm).

For males:

$$\frac{(\text{Mother's height} + 13 \text{ cm}) + \text{father's height}}{2}$$

For females:

$$\frac{(\text{Father's height} - 13 \text{ cm}) + \text{mother's height}}{2}$$

4. Poor compliance is documented.