



# Comprehensive Medical and Dental Program Authorization Guideline

**TITLE**

Criteria for Use of Recombinant Growth Hormone in Children Prior Authorization Guideline

**RESPONSIBLE AREA**

Health Services

**History of Review:** 1/2005, 11/2005, 3/2007, 6/2008, 1/2010, 5/1/2013, 4/24/2014, 1/23/15, 7/1/16, 9/1/17, 12/9/18; 06/03/19

**Approval Date:** 06/03/19

**DESCRIPTION**

This guideline is used in the prior authorization and decision-making process regarding requests for Recombinant Growth Hormone (rGH).

**CLINICAL GUIDELINE**

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

**Use of rGH in Children**

The CMDP Medical Management (MM) Committee recommends that rGH be used only for growth hormone resistant or deficient states and that it should only be prescribed and monitored by a Pediatric Endocrinologist. Because of cost and potential side effects, prudent use is recommended.

**GH Replacement for Deficiency States**

- *Classical growth hormone (GH) deficiency*  
Infants may present with hypoglycemia-related seizures, visual defects, or micropenis.
- *Acquired forms of GH deficiency*  
Head trauma – transection of pituitary stalk/injury to pituitary gland, intracranial lesions, irradiation therapy – greater than 2,400 rads of cranial radiation, therapy that is associated with abnormal spontaneous generation of growth hormone.

Patients are usually treated from ~4 years of age through puberty. There is an expectation that children should have a growth rate of  $\geq 5$  cm (2 inches) per year.

**GH-resistant states with abnormal growth velocity of  $<5$  cm/year**, such as Chronic Renal Failure while awaiting transplantation: The goal is to maintain age-appropriate growth so that with the re-establishment of normal GH responsiveness after transplantation, children might attain a final adult height that is more consistent with their genetic potential.

The response to rGH therapy in growth-resistant states should yield a growth rate of  $\geq 2.5$  cm/6 months



or  $\geq 5$  cm/year. The CMDP MM Committee recommends discontinuing rGH if the rate of growth is  $< 5$  cm/year, generally around the chronological age of 12 or 13.

### **Criteria to Substantiate Medical Necessity for rGH**

The child must have a **diagnosis consistent with a GH deficiency state** and the following criteria must all be met:

- Use must be for an FDA-approved condition,
- The child must have proportionate short stature with height  $< 5$ th percentile on a standardized growth chart,
- The child must have an abnormal growth velocity, as demonstrated on growth chart ( $< 5$  cm/year),
- The child must have a delayed bone age  $> 2$  SD from the norm, as compared with chronological age,
- The child must have failed a growth hormone stimulation test, with a peak  $< 10$  micrograms/ml, **and**
- The child must have an absence of chronic disease, psychosocial dwarfism or malnutrition.

### **OR**

The child must have a **diagnosis consistent with a GH resistant state** and demonstrate an abnormal growth velocity.

- Use must be for an FDA-approved condition,
- The child must have proportionate short stature with height  $< 5$ th percentile on a standardized growth chart,
- The child must have an abnormal growth velocity, as demonstrated on growth chart ( $< 5$  cm/year),

### **Once initial PA is received, continued authorization is required on a semi-annual basis.**

Must document compliance, annualized growth velocity, benefits of continued treatment

### **Considerations for Discontinuing rGH Therapy**

- Decrease in growth velocity while on rGH therapy, i.e.  $< 5$  cm/year,
- Bone age of:
  - $> 14$  years in females
  - $> 16$  years in males
- Poor compliance, **or**
- Attained height of the child/youth that is within genetic potential, as defined by midparental height:
  - For males =  $([\text{mother's height} + 13\text{cm}] + \text{father's height})/2$
  - For females =  $([\text{father's height} - 13\text{cm}] + \text{mother's height})/2$

\*(Calculations must be in cm)

### **REFERENCES**

Review and update lecture to AHCCCS Medical Directors on June 27, 2003 by Dr. Khalid Hasan, Director Pediatric Endocrinology, Phoenix Children's Hospital



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MMC Grand Rounds, Dr. Chirag Kapadia. Interpretation of Growth Curves in Children on January 12, 2010.

**PLEASE NOTE:** State and Federal law take precedence over prior authorization guidelines. CMDP reserves the right to review and update guidelines periodically.