

Comprehensive Medical and Dental Program Authorization Guidelines

Subject: Criteria for Use of Recombinant Growth Hormone in Children

Unit: Health Services

Purpose

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

This guideline does not represent a standard of care, nor is it intended to dictate an exclusive course of management. Since medical research, physician practice patterns, and health care technology are continuously evolving, please note that the information contained in this guideline may be updated.

Background

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 ≥ 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 ≥ 2.5 cm/6 months or ≥ 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.

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Reviewed: 01/2005, 11/2005, 3/2007, 11/2007, 06/2008, 1/2010, 5/1/13, 4/24/14, 1/23/15, 7/1/16, 9/1/17

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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 < 5th 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 < 5th 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 = $([\text{father's height} - 13\text{cm}] + \text{mother's height})/2$

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*(Calculations must be in cm)

References:

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Signature on file

Medical Director

9/1/2017

Date

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