

## Pharmacy Policy Bulletin

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**Title:** Mecasermin (Increlex™)

**Policy #:** FS.CLIN.29

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This pharmacy policy will be reviewed regularly and updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

### Intent

**Mecasermin (Increlex™)** is indicated for the long-term treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

The use of mecasermin (Increlex™) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

### Description:

**Mecasermin (Increlex™)** contains human insulin-like growth factor-1 (rhIGF-1) produced by recombinant deoxyribonucleic acid (DNA) technology. Insulin-like growth factor-1 (IGF-1) is the main mediator of growth hormone (GH) physiological actions, including those related to linear growth.

### Policy

Authorizations will be placed for a period of 1 year unless otherwise specified.

#### INITIAL CRITERIA

**Mecasermin (Increlex™)** is approved when **all** of the following inclusion criteria are met:

- Documentation of **one** of the following indications:
  - Growth failure in children who have severe primary insulin-like growth factor-1 deficiency (IGFD)
  - Growth failure in children who have growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH
- The individual has a height standard deviation (SD) score of less than or equal to 3.0 SD scores below normal (growing at or below the third percentile for age and sex).
- The individual has a baseline IGF-1 (SD) score of less than or equal to 3.0 SD scores below normal (based on age- and sex-related reference ranges).

- The individual has a normal or elevated GH level (based on GH stimulation testing) or (for children with GH gene deletion) measured titers of GH-neutralizing antibodies.
- The individual has open epiphyses (bone growth plates) (bone age less than 14 years for girls and less than 16 years for boys).
- The individual is two years of age or older.
- The individual has been prescribed mecasermin (Increlex™) by an endocrinologist or pediatric endocrinologist.

**RE-AUTHORIZATION CRITERIA**

- Documentation of a growth velocity greater than or equal to 2.5cm/year
- Documentation of clinical re-evaluation by the treating endocrinologist at least yearly

**Guidelines**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any products that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References**

Increlex™ (mecasermin). American Hospital Formulary Service (AHFS). Drug Information 2008. [STAT!Ref Web site]. 03/24/08. Available at: [www.online.statref.com](http://www.online.statref.com) [via subscription only]. Accessed October 27, 2011.

Mecasermin (Increlex™)[prescribing information]. Brisbane, CA: Tercica; 2007. Available at: [www.increlex.com/increlex\\_pi.pdf](http://www.increlex.com/increlex_pi.pdf). Accessed October 27, 2011.

Micromedex Healthcare Series [Internet database]. Increlex™ (mecasermin). Greenwood Village, CO: Thomson Micromedex. Available at: [www.thomsonhc.com](http://www.thomsonhc.com) [via subscription only].

**Applicable Drugs**

** Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.**

Drug Name	Strength and/or formulation
Mecasermin (Increlex)	All

**Cross References**

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**Policy version number:** 3.0  
**P&T approval date:** 9/8/2011  
**Policy effective date:** 12/1/2011  
**Next required review date:** 9/8/2012

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