

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

# Increlex (mecasermin)

DRUG.00086

Override	Approval Duration
Prior Authorization	1 year

Medication
Increlex (mecasermin)

## APPROVAL CRITERIA

Increlex (mecasermin) may be approved for the treatment of individuals greater than 2 years of age with the following indications:

- I. Growth failure in children with severe primary IGF-1 deficiency, as defined by:
  - A. Height standard deviation (SD) score less than or equal to -3.0; **AND**
  - B. Basal IGF-1 SD score less than or equal to -3.0; **AND**
  - C. Normal or elevated growth hormone (GH) levels (greater than 10 ng/mL on standard GH stimulation tests, see Anthem® medical policy DRUG.00009 for additional information) are present;

**OR**

- II. Growth hormone gene deletion with the development of neutralizing antibodies to GH.

Continuation of treatment with Increlex (mecasermin) may be approved when the following criteria have been met:

- I. Growth velocity is greater than or equal to 2 cm total growth in 1 year; **AND**
- II. Final adult height has not been reached.

Increlex (mecasermin) may **not** be approved for individuals with the following contraindications:

- I. Closed epiphyses; **OR**
- II. Suspected or known malignancies.

Increlex (mecasermin) may **not** be approved for the treatment of all other indications, including but not limited to:

- I. When any of the approval criteria above are not present; **OR**

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- II. Growth velocity is less than 2 cm total growth in 1 year; **OR**
- III. Final adult height has been reached; **OR**
- III. Secondary IGFD (for example, due to GH deficiency, untreated malnutrition, untreated hypothyroidism or other causes).

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

1. United States Food and Drug Administration. Increlex Package Insert. Available at: [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/021839s016lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021839s016lbl.pdf). Accessed on February 1, 2018.

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