Inrelex (mecasermin)  
DRUG.00086

Override | Approval Duration
---|---
Prior Authorization | 1 year

Medication

<table>
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<th>Medication</th>
<th>Increlex (mecasermin)</th>
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**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**

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).

Key References: