Increlex (mecasermin)

**DRUG.00086**

**Override**

<table>
<thead>
<tr>
<th>Override</th>
<th>Approval Duration</th>
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</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>1 year</td>
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</table>

**Medication**

<table>
<thead>
<tr>
<th>Medication</th>
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<tbody>
<tr>
<td>Increlex (mecasermin)</td>
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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:

1. 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**

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

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

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

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

1. Closed epiphyses; **OR**
2. Suspected or known malignancies.

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

1. 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.

CRX-ALL-0146-18
**Market Applicability**

<table>
<thead>
<tr>
<th>Market</th>
<th>DC</th>
<th>FL &amp; FHK</th>
<th>FL MMA</th>
<th>FL LTC</th>
<th>GA</th>
<th>KS</th>
<th>KY</th>
<th>LA</th>
<th>MD</th>
<th>NJ</th>
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<th>NY</th>
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<tbody>
<tr>
<td>Applicable</td>
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*FHK- Florida Healthy Kids

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**

<table>
<thead>
<tr>
<th>State name</th>
<th>Date effective</th>
<th>Mandate details (including specific bill if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
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**Key References:**