

Increlex (mecasermin)

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

| Medication |
|-----------------------|
| Increlex (mecasermin) |

APPROVAL CRITERIA

Initial requests for Increlex (mecasermin) may be approved if the following criteria are met:

- I. Documentation is provided that individual is a child with growth failure associated 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) are present;
- OR**
- II. Individual has growth hormone gene deletion with the development of neutralizing antibodies to GH.

Continuation requests for Increlex (mecasermin) may be approved when the following criteria are met:

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

Requests for Increlex (mecasermin) may not be approved for the following criteria:

- I. Individual has secondary IGF-1 deficiency (due to, for example, growth hormone (GH) deficiency, untreated malnutrition, untreated hypothyroidism, or other causes); **OR**
- II. Individual has closed epiphyses; **OR**
- III. Individual has suspected or known malignancies; **OR**
- IV. When the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 7, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
4. Grimberg A, DiVall SA, Polychronakos C, et.al. Guidelines for growth hormone and insulin-like growth factor-I treatment in children and adolescents: Growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-I deficiency. *Horm Res Paediatr*. 2016;86:361-397.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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