Increlex (mecasermin) is indicated for the treatment of growth failure in pediatric patients 2 years of age and older with severe primary IGF-1 deficiency or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. It is administered subcutaneously. Growth hormone deficiency involves inadequate secretion of growth hormone from the pituitary gland.

Increlex (mecasermin) will be considered for coverage when the following criteria are met:

**Pediatric Growth Failure**

For **initial** authorization:
1. Member is at least two years of age or older;
2. Medication must be prescribed by a pediatric endocrinologist; AND
3. Member has a diagnosis of Severe Primary Insulin-like Growth Factor-1 Deficiency (IGFD) confirmed by all of the following:
   a) Height standard deviation score ≤ –3.0;
   b) Basal IGF-1 standard deviation score ≤ –3.0;
   c) normal or elevated growth hormone (GH); OR
4. Member has documentation of GH gene deletion who have developed neutralizing antibodies to GH; AND
5. Documentation the bone epiphyses are open;
6. Member is not treated with other growth hormone therapy
7. **Dosage allowed/Quantity limit:** Initial dose of 0.04 to 0.08 mg/kg (40 to 80 micrograms/kg) twice daily. If well-tolerated for at least one week, the dose may be increased by 0.04 mg/kg per dose, to the maximum dose of 0.12 mg/kg given twice daily

*If all the above requirements are met, the medication will be approved for 12 months.*

For **reauthorization:**
Increlex will be reauthorized when chart notes show all of the following:
1. Member has a growth rate of at least 2 cm/year;
2. Documentation the bone epiphyses are open; AND
3. Member is not treated with other growth hormone therapy

*If all the above requirements are met, the medication will be approved for an additional 12 months.*

CareSource considers Increlex (mecasermin) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.
<table>
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<tr>
<th>DATE</th>
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<tr>
<td>10/18/2021</td>
<td>Increlex policy creation</td>
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<td>10/06/2022</td>
<td>Updated benefit to medical due to OH single PBM.</td>
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References:


Effective date: 10/01/2022
Creation date: 10/06/2022