

## mecaserim injection (INCRELEX)

### Diagnosis Considered for Coverage:

- Growth failure in children with severe primary IGF-1 deficiency
- Growth failure in children with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone.

### Coverage Criteria:

#### 1. For growth failure in children with severe primary IGF-1 deficiency:

##### Initial Authorization

- Prescribed by an Endocrinologist, **and**
- Patient is between 2 to 18 years of age, **and**
- Height standard deviation score  $\geq 3.0$  standard deviations below standard range for sex and age, **and**
- Basal IGF-1 standard deviation score  $\geq 3.0$  standard deviations below standard range for sex and age, **and**
- Evidence of normal or elevated growth hormone compared to standard range for sex and age, **and**
- Documentation of delayed bone age by bone age report, **and**
- Not being used in combination with human growth hormone therapy.

Coverage Duration: 1 year

##### Reauthorization

- Patient is between 2 to 18 years of age, **and**
- Documentation of delayed bone age by bone age report, **and**
- Greater than 4 cm growth velocity over the past year.

Coverage Duration: 1 year

#### 2. For growth failure in children with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH:

##### Initial Authorization

- Prescribed by an Endocrinologist, **and**
- Patient is between 2 to 18 years of age, **and**
- Documentation of height  $\geq 3.0$  standard deviations below standard range for sex and age, **and**
- Documentation of basal IGF-1  $\geq 3.0$  standard deviations below standard range for sex and age, **and**

<ul style="list-style-type: none"> <li>• Evidence of growth hormone gene deletion, <b>and</b></li> <li>• Development of neutralizing antibodies to growth hormone, <b>and</b></li> <li>• Documentation of delayed bone age by bone age report.</li> </ul> <p><b><u>Coverage Duration:</u></b> 1 year</p>
<p><b>Reauthorization</b></p> <ul style="list-style-type: none"> <li>• Patient is between 2 to 18 years of age, <b>and</b></li> <li>• Documentation of delayed bone age by bone age report, <b>and</b></li> <li>• Evidence of greater than 4 cm growth velocity over the past year.</li> </ul> <p><b><u>Coverage Duration:</u></b> 1 year</p>
<p><b>Coverage Duration:</b> see above</p>

Effective Date: 11/29/2023