

## PHARMACY POLICY STATEMENT

### Nevada Medicaid

<b>DRUG NAME</b>	Increlex (mecasermin)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

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. Increlex is not indicated for use in patients with secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory corticosteroids. It is administered subcutaneously.

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

#### Pediatric Growth Failure

For initial authorization:

1. Member is at least 2 years of age or older; AND
2. Medication must be prescribed by or in consultation with 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  $\leq -3.0$ ;
  - b) Basal IGF-1 standard deviation score  $\leq -3.0$ ;
  - c) Normal or elevated growth hormone (GH); OR
4. Member has documentation of GH gene deletion and development of neutralizing antibodies to GH; AND
5. Member has radiographic evidence of open epiphyses (x-ray results must be included); AND
6. Member has documentation of pretreatment height; AND
7. Member does **NOT** have a history of active malignancy; AND
8. Member is **NOT** being treated concomitantly with growth hormone therapy.
9. **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:

1. Member has a growth rate of at least 2 cm/year; AND
2. Member has radiographic evidence of open epiphyses (x-ray results must be included).

***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.**

DATE	ACTION/DESCRIPTION
10/18/2021	Increlex policy creation
09/15/2023	Added in consultation with option to prescriber specialty; added documentation of pretreatment height; added no history of active malignancy; removed not being treated with growth hormone therapy from reauthorization criteria.

References:

1. Increlex [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; December 2019
2. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for growth hormone and insulilike growth factor-1 treatment in children and adolescents: growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-1 deficiency. *Hormone Research in Paediatrics* 2016;361-397
3. Rosenfeld RG. The IGF system: new developments relevant to pediatric practice. *Endocrine Development* 2005;9:1-10
4. Clark RG. Recombinant human insulin-like growth factor I (IGF-I): risks and benefits of normalizing blood IGF-I concentrations. *Frontiers of Hormone Research* 2004; 62 Suppl 1:93-100
5. Roelfsema V, Clark RG. The growth hormone and insulin-like growth factor axis: its manipulation for the benefit of growth disorders in renal failure. *Journal of the American Society of Nephrology* 2001 Jun;12(6):1297-306

Effective date: 01/01/2026

Revised date: 09/15/2023