CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	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 ≤ –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 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

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