PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Increlex (mecasermin)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
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. 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.

DATE	ACTION/DESCRIPTION
10/18/2021	Increlex policy creation

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: 04/01/2022
Creation date: 10/18/2021