mecasermin (Increlex®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO133

Description

Mecasermin (Increlex) is an injection that is indicated for the treatment of growth failure in children with severe primary insulin-like growth factor (IGF-1) deficiency or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
mecasermin (Increlex)	40 mg/4 mL multiple dose vial	Severe primary insulin-like growth factor (IGF-1) deficiency; Growth hormone (GH) gene deletion with neutralizing antibodies to GH	7.2 mg/kg/30 days

Initial Evaluation

I. Mecasermin (Increlex) may be considered medically necessary when the following criteria below are met:
   A. Member is a between 2-18 years of age; **AND**
   B. Medication is prescribed by, or in consultation with, a pediatric endocrinologist or a pediatric nephrologist; **AND**
   C. Member has evidence of non-closure of the epiphyseal plate confirmed by radiograph; **AND**
   D. A diagnosis of one of the following:
      1. **Severe primary insulin-like growth factor (IGF-1) deficiency**
         i. Member meets ALL of the following:
            a. Height standard deviation score ≤ -3.0; **AND**
            b. Basal IGF-1 standard deviation score ≤ -3.0; **AND**
            c. Normal or elevated growth hormone (GH) level, [serum growth hormone level of ≥ 10 ngm/mL to at least two stimuli (insulin, levodopa, arginine, clonidine, or glucagon)]; **OR**
      2. **Growth hormone (GH) gene deletion**
         i. Member has developed neutralizing antibodies to GH; **AND**
         ii. Member has normal thyroid function (TSH in the range of 0.5-6 uIU/mL); **AND**

iii. Member is not malnourished (BMI < 18 kg/m^2); **AND**
iv. Member does not have active or suspected neoplasia (e.g. cancer)

II. Mecasermin (Increlex) is considered investigational when used for all other conditions, including but not limited to:
   A. Secondary forms of IGF-1 deficiency such as:
      1. GH deficiency
      2. Malnutrition
      3. Hypothyroidism
      4. Chronic treatment with pharmacologic doses of anti-inflammatory steroids

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through the health plan; **AND**
II. Member has shown a response in the first 6 months of the IGF-1 therapy (e.g. increase in height, increase in height velocity); **AND**
III. Member has evidence of non-closure of the epiphyseal plate, confirmed by radiograph

Supporting Evidence

I. Mecasermin (Increlex) is for the long-term treatment of growth failure in children with severe primary insulin-like growth factor-1 (IGF-1) deficiency (primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. Severe primary IGFD is defined by:
   - Height standard deviation score ≤ -3.0
   - Basal IGF-1 standard deviation score ≤ -3.0
   - Normal or elevated GH
II. Insulin-like growth factor (IGF-1) is the principal hormonal mediator of statural growth. Under normal circumstances, growth hormone (GH) binds to its receptor in the liver and other tissues, and stimulates the synthesis/secretion of IGF-1.
   - In target tissues, the type 1 IGF-1 receptor, which is homologous to the insulin receptor, is activated by IGF-1, leading to intracellular signaling, which stimulates multiple processes leading to statural growth.
   - The metabolic actions of IGF-1 are, in part, directed at stimulating the uptake of glucose, fatty acids, and amino acids so that metabolism supports growing tissues.
III. Severe primary IGF-1 deficiency includes members with mutations in the GH receptor (GHR), post-GHR signaling pathway, and IGF-1 gene defects; they are not GH deficient; therefore, they cannot be expected to respond adequately to exogenous GH treatment.
IV. Mecasermin (Increlex) is not a substitute to growth hormone (GH) for approved GH indication.
V. Mecasermin (Increlex) is not indicated for use after epiphyseal closure.

Investigational Use

I. Mecasermin (Increlex) is not intended for use in members with secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids.

References

1. Increlex [package insert].Cambridge, MA: Ipsen Biopharmaceuticals, Inc;2019.
2. UpToDate, Inc. Growth hormone insensitivity syndromes. UpToDate [database online]. Waltham, MA. Updated March 8, 2019. Available at: http://www.uptodate.com/home/index.html. Accessed November 9, 2019.

Policy Implementation/Update:

Date Created	September 2008
Date Effective	October 2008
Last Updated	November 2019
Last Reviewed	12/2008, 11/2019

Action and Summary of Changes	**Date**
Criteria updated to new policy format. Specific changes include: removal of bone age requirement (If male, bone age is less than 16 years of age; or if female, bone age is less than 14 years of age) and update on child 2 years of age or older.	11/2019