SPECIALTY GUIDELINE MANAGEMENT

INCRELEX (mecasermin)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no contraindications or exclusions to the prescribed therapy.

A. FDA-Approved Indications

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

   Severe primary IGF-1 deficiency is defined by:
   - Height standard deviation (SD) score ≤ –3.0 and
   - Basal IGF-1 SD score ≤ –3.0 and
   - Normal or elevated GH.

   Severe primary IGF-1 deficiency includes classical and other forms of GH insensitivity. Patients with primary IGF-1 deficiency may have mutations in the GH receptor (GHR), post-GHR signaling pathway including the IGF-1 gene. They are not GH deficient, and therefore, they cannot be expected to respond adequately to exogenous GH treatment. Increlex is not intended for use in subjects with secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids. Thyroid and nutritional deficiencies should be corrected before initiating Increlex treatment.

   Limitations of use: Increlex is not a substitute to GH for approved GH indications.

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review (where applicable):

A. Pretreatment growth hormone provocative test result (laboratory report or medical record documentation)
B. Pretreatment and/or current IGF-1 level (laboratory report or medical record documentation)*

* IGF-1 levels vary based on the laboratory performing the analysis. Laboratory-specific values must be provided to determine whether the value is within the normal range.

III. PRESCRIBER SPECIALTIES

Therapy must be prescribed by or in consultation with an endocrinologist.

IV. CRITERIA FOR APPROVAL

The criteria below apply to members who are not currently receiving Increlex through a paid medical or prescription benefit.

A. Severe Primary IGF-1 Deficiency

Initial authorization of 12 months may be granted to members with severe primary IGF-1 deficiency or GH gene deletion with neutralizing antibodies to GH when ALL of the following criteria are met:

1. Pretreatment height is ≥ 3 SD below the mean for age and gender.
2. Pretreatment basal IGF-1 level is ≥ 3 SD below the mean for age and gender.
3. Pediatric GH deficiency has been ruled out with a provocative GH test (i.e., peak GH level ≥ 10 ng/mL).
4. Epiphyses are open.

V. CONTINUATION OF THERAPY

The criteria below apply to members who are currently receiving Increlex therapy through a paid medical or prescription benefit. All other members (including new members) must meet initial authorization criteria.

A. Severe Primary IGF-1 Deficiency

Authorization of 12 months may be granted to members with severe primary IGF-1 deficiency or GH gene deletion with neutralizing antibodies to GH when BOTH of the following criteria are met:

1. Epiphyses are open (confirmed by X-ray or X-ray is not available)
2. Member meets either of the following:
   a. Member's growth rate is > 2 cm/year and current IGF-1 level is normal for age and gender.
   b. Member's growth rate is ≤ 2 cm/year and there is a documented clinical reason for lack of efficacy (e.g., on treatment less than 1 year, nearing final adult height/late stages of puberty).

VI. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

VII. REFERENCES

1. Increlex [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; May 2014.