Reference number(s)
1740-A

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.

FDA-Approved Indications
Increlex is indicated for the treatment of growth failure in pediatric patients 2 years of age and older with severe primary insulin-like growth factor-1 (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.

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

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review for continuation of therapy requests:
A. Total duration of treatment (approximate duration is acceptable)
B. Date of last dose administered
C. Approving health plan/pharmacy benefit manager
D. Date of prior authorization/approval
E. Prior authorization approval letter

III. CRITERIA FOR INITIAL APPROVAL

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 ALL of the following criteria are met:
A. Pretreatment height is ≥ 3 standard deviations (SD) below the mean for age and gender
B. Pretreatment basal IGF-1 level is ≥ 3 SD below the mean for age and gender
C. Pediatric GH deficiency has been ruled out with a provocative GH test (i.e., peak GH level ≥ 10 ng/mL)
D. Epiphyses are open

IV. CONTINUATION OF THERAPY

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

A. The member's growth rate is > 2 cm/year [2] or 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).
B. Epiphyses are open (confirmed by X-ray or X-ray is not available).

V. REFERENCES

1. Increlex [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; October 2023.