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

Increlex 1740-A SGM P2024

© 2024 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.



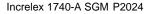
IV. CONTINUATION OF THERAPY

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:

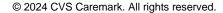
- A. The member's growth rate is > 2 cm/year ² or there is a documented clinical reason for lack of efficacy (e.g., on treatment less than 1 year, nearing final adult height/late stages of puberty).
- B. Epiphyses are open (confirmed by X-ray or X-ray is not available).

V. REFERENCES

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



pharmaceutical manufacturers that are not affiliated with CVS Caremark.



This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of