CVS Caremark®

|  |
| --- |
| Reference number(s) |
| 1740-A |

# Specialty Guideline Management Increlex

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Increlex | mecasermin |

## 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 Indications1

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.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests:

* Growth chart
* Pretreatment insulin-like growth factor-1 (IGF-1) level (laboratory report or medical record documentation)\*
* Growth hormone provocative test result(s) (laboratory report or medical record documentation)

Continuation of therapy requests:

* Total duration of treatment (approximate duration is acceptable)
* Date of last dose administered
* Approving health plan/pharmacy benefit manager
* Date of prior authorization/approval
* Prior authorization approval letter

\* 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.

## Coverage Criteria

### Severe Primary IGF-1 Deficiency1

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:

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

## 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 both of the following criteria are met:

* The member’s growth rate is > 2 cm/year 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).
* Epiphyses are open (confirmed by X-ray or X-ray is not available).

## References

1. Increlex [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; March 2024.
2. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for growth hormone and insulin-like growth factor-I treatment in children and adolescents: growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-I deficiency. Horm Res Paediatr. 2016;86:361-397.
3. Franklin SL, Geffner ME. Growth hormone: the expansion of available products and indications. Pediatr Clin North Am. 2011;58:1141-1165.