



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Increlex

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Effective Date: 6/9/2025

Last Review Date: 5/19/2025

Applies to:  Illinois  Florida Kids  Maryland  New Jersey  
 Pennsylvania Kids  Virginia  Kentucky PRMD

### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Increlex under the patient's prescription drug benefit.

### Description:

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  $\leq -3.0$  and
- Basal IGF-1 SD score  $\leq -3.0$  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.

### Applicable Drug List:

Increlex

### Policy/Guideline:

#### 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)



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#### 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.

#### **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 the following criteria are met:

- Pretreatment height is  $\geq 3$  standard deviations (SD) below the mean for age and gender
- Pretreatment basal IGF-1 level is  $\geq 3$  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  $\geq 10$  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 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).

#### **Approval Duration and Quantity Restrictions:**

**Approval:** 12 months

#### **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.