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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	December 7, 2011
Subject:	Increlex	**Page:**	1 of 4

Last Review Date: June 16, 2022

Increlex

Description

Increlex (mecasermin)

Background
The active ingredient of Increlex is identical to the natural hormone, insulin-like growth factor-1 (IGF-1), which the body produces in response to stimulation by growth hormone. Without adequate IGF-1, children cannot achieve height within the normal range. Insulin-like growth factor-1 is a key hormonal mediator on statural growth (1).

If insulin-like growth factor-1 deficiency (IGFD) is determined to be primary and severe, treatment with Increlex may help improve the child's growth. Severe Primary IGFD is defined by height standard deviation score ≤ -3.0 and basal IGF-1 standard deviation score ≤ -3.0 and normal or elevated growth hormone (GH). Severe Primary IGFD includes classical and other forms of growth hormone insensitivity. Patients with Primary IGFD 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 (1).

Regulatory Status
FDA-approved indication: 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 (1).

Limitations of Use:

Increlex is not a substitute for GH for approved GH indications (1).
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. Increlex is not a substitute for GH treatment. Thus, Increlex treatment should be monitored by physicians who are experienced in the diagnosis and management of patients with growth disorders (1).

Increlex is contraindicated in patients with active or suspected neoplasia. Therapy should be discontinued if evidence of malignancy develops. Increlex is contraindicated in patients with closed epiphyses. Intravenous administration of Increlex is contraindicated (1).

Safety and effectiveness in pediatric patients below the age of 2 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Increlex may be considered **medically necessary** in the treatment of patients 2 years of age and older for severe primary insulin-like growth factor deficiency or growth hormone gene deletion and if the conditions indicated below are met.

Increlex may be considered **investigational** for patients less than 2 years old and all other indications.

Prior-Approval Requirements

Age 2 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Severe primary insulin-like growth factor-1 (IGF-1) deficiency
    a. Height standard deviation score ≤ -3.0

b. Basal IGF-1 standard deviation score ≤ -3.0
c. Normal or elevated growth hormone (GH)

2. Growth Hormone (GH) gene deletion
   a. Developed neutralizing antibodies to growth hormone (GH)

AND ALL of the following:
1. Open epiphyses
2. **NO** evidence of active tumor or neoplasm
3. **NOT** for intravenous administration

Prior – Approval *Renewal* Requirements
Same as above

Policy Guidelines
Pre - PA Allowance
None

Prior - Approval Limits

Duration 12 months

Prior - Approval *Renewal* Limits
Same as above

Rationale

Summary
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. Increlex is not a substitute for GH for approved GH indications. Increlex is contraindicated in patients with active or suspected neoplasia. Therapy should be discontinued if evidence of malignancy develops. Increlex is contraindicated in patients with closed epiphyses. Intravenous administration of Increlex is contraindicated. Safety and effectiveness in pediatric patients below the age of 2 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Increlex while maintaining optimal therapeutic outcomes.

References

1. Increlex [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals Inc.; December 2019.

Policy History

Date	Action
December 2011	New policy based on sole product rhIGF-1 product commercially available. Another product branded as Iplex was discontinued in July 2009 and no claims were submitted in 2009
December 2012	Annual policy review-no change in policy statement and editorial updates
June 2014	Annual editorial review and reference update
September 2015	Annual review and reference update
September 2016	Annual editorial review and reference update Policy number change from 5.08.13 to 5.30.07
December 2017	Annual editorial review and reference update
November 2018	Annual review and reference update
December 2019	Annual review and reference update
December 2020	Annual review and reference update
June 2021	Annual review
June 2022	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.