



RATIONALE FOR INCLUSION IN PA PROGRAM

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 pediatric patients 2 years of age and older 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 corticosteroids. 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).



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INCRELEX (mecasermin)

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

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.; March 2024.