

Specialty Pharmacy Program

Increlex[®] (mecasermin)

CLINICAL BACKGROUND

Increlex is recombinant human insulin-like growth factor-1 (IGF-1), the principal hormonal mediator of statural growth. Increlex is indicated for the long-term treatment of growth failure in children with severe primary insulin-like growth factor-1 (IGF-1) deficiency (primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. Severe primary IGFD is defined by 1) height standard deviation score ≤ -3.0 ; 2) basal IGF-1 standard deviation score ≤ -3.0 ; and 3) normal or elevated GH level. Severe primary IGFD includes patients with mutations in the GH receptor (GHR), post-GHR signaling pathway, and IGF-1 gene defects. These patients are not GH deficient, and therefore, they cannot be expected to respond adequately to exogenous GH treatment.

Increlex is not intended for use in patients with secondary forms of IGF-1 deficiency or other causes of growth failure (eg, GH deficiency, malnutrition, hypothyroidism). Increlex is not a substitute for GH treatment. Increlex should also not be used for growth promotion in patients with closed epiphyses or in patients with active or suspected cancer. Increlex has not been studied in children less than two years of age or in adults.

APPROVAL DURATION

Approval duration: 1 year

APPROVAL CRITERIA

FDA-Approved Indication(s)

1. Treatment of growth failure in children with severe primary insulin-like growth factor-1 (IGF-1) deficiency (primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.