

Increlex[®] (mecasermin [rDNA origin])



When requesting Increlex[®](mecasermin [rDNA origin]), the individual requiring treatment must be diagnosed with the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indications¹

- Increlex[®](mecasermin [rDNA origin]) is indicated for the treatment of growth failure in children with severe primary insulin-like growth factor-1 (IGF-1) deficiency.
- Increlex[®](mecasermin [rDNA origin]) is indicated for the treatment of growth hormone gene deletion who have developed neutralizing antibodies to growth hormone.

Approved Off-label Compendial use²

- No off-label uses meet evidence standards

Coverage Guidelines

Severe Primary Insulin-like Growth Factor-1 (IGF-1) Deficiency

The individual must meet **all** of the following criteria for initial approval:

- No active or suspected neoplasia¹
- Epiphyses are open¹
- Pretreatment height is ≥ 3 standard deviations below the mean for age and gender
- Pretreatment basal IGF-1 level is ≥ 3 standard deviations below the mean for age and gender
- Normal or elevated growth hormone levels¹
- Secondary forms of IGF-1 deficiency have been ruled out such as:
 - o growth hormone deficiency
 - o malnutrition
 - o hypothyroidism
 - o chronic treatment with pharmacologic doses of anti-inflammatory steroids¹

For reauthorization:

- No active or suspected neoplasia¹
- Epiphyses are open¹
- Diagnosis is severe primary IGF-1 Deficiency
- Must show response on therapy with Increlex[®](mecasermin [rDNA origin]) (i.e. rate of growth is faster than pretreatment)

Growth Hormone Gene Deletion

- No active or suspected neoplasia¹
- Epiphyses are open¹

Approval duration: 12 months

Additional Information for Prescribers¹

- Intravenous administration of Increlex[®] is contraindicated.
- Increlex[®] (mecasermin [rDNA origin]) is not a substitute to growth hormone for approved growth hormone indications.
- Thyroid and nutritional deficiencies should be corrected before initiating treatment with Increlex[®] (mecasermin [rDNA origin]).
- Increlex[®] (mecasermin [rDNA origin]) has insulin-like hypoglycemic effects and it should be administered shortly before or after (± 20 minutes) a meal or snack. It should not be administered when a meal or snack is omitted. Glucose monitoring is recommended until a well tolerated dose is established.
- Funduscopic examination is recommended at the initiation and periodically during therapy with Increlex[®] (mecasermin [rDNA origin]) to assess for intracranial hypertension.
- Individuals should have periodic examinations to rule out lymphoid tissue hypertrophy and receive appropriate therapy if necessary.
- Slipped capital femoral epiphysis can occur in individuals who experience rapid growth. Any pediatric individual with the onset of a limp or complaints of hip or knee pain should be carefully evaluated.
- Monitor for the progression of preexisting scoliosis.

References

1. Increlex[®] prescribing information. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; March 2016. Accessed April 6, 2017. <http://increlex.com/pdf/hcp-full-prescribing-information.pdf>
2. Klasco RK (Ed): DRUGDEX[®] system. Thomson Micromedex, Greenwood Village, CO. Accessed February 15, 2017. <https://www.micromedexsolutions.com>