

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 indications

- 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 use

- none

Coverage Guidelines

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

The individual must meet **all** of the following criteria if initial approval or treated less than 1 year:

- Pretreatment height standard deviation score ≤ -3.0 at baseline; AND
- Pretreatment basal IGF-1 level is below the lower limits of the normal reference range for the reporting laboratory; AND
- Pretreatment growth hormone concentration is normal or increased; AND
- Prescribed by or in consultation with a pediatric endocrinologist

Growth Hormone (GH) Gene Deletion in a Child who has Developed Neutralizing Antibodies to GH

- Initial therapy or has been on Increlex less than a year; AND
- Prescribed by or in consultation with a pediatric endocrinologist

For reauthorization (Severe Primary Insulin-like Growth Factor-1 (IGF-1) Deficiency or Growth Hormone (GH) Gene Deletion in a Child who have Developed Neutralizing Antibodies to GH :

- Patient has been on Increlex for at least 1 year; AND
- Height has increased by 4 cm/year or greater in the most recent year; AND
- Epiphyses are open

Approval duration: 12 months

Dosing Recommendations

- Starting dose is 0.04 to 0.08 mg/kg (40 to 80 micrograms/kg) subcutaneously twice daily. If well tolerated for one week, the dose may be increased by 0.04 mg/kg per dose, to a maximum dose of 0.12 mg/kg given twice daily.

References

1. Increlex® injection [prescribing information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals/Hospira; May 2016.
2. Rosenfeld RG. The IGF system: new developments relevant to pediatric practice. *Endocr Dev*. 2005; 9:1-10.
3. Cohen J, Blethen S, Kuntze J, et al. Managing the child with severe primary insulin-like growth factor-1 deficiency (IGFD): IGFD diagnosis and management. *Drugs R D*. 2014; 14(1):25-29.
4. Elmlinger MW, Kühnel W, Weber MM, Ranke MB. Reference ranges for two automated chemiluminescent assays for serum insulin-like growth factor I (IGF-I) and IGF-binding protein 3 (IGFBP-3). *Clin Chem Lab Med*. 2004; 42(6):654-664.
5. Rosenbloom AL. Is there a role for recombinant insulin-like growth factor-I in the treatment of idiopathic short stature? *Lancet*. 2006; 368:612-616.

Other References Utilized

1. Savage MO, Attie KM, David A, et al. Endocrine assessment, molecular characterization and treatment of growth hormone insensitivity disorders. *Nat Clin Pract Endocrinol Metab*. 2006; 2:395-407.
2. Collett-Solberg PF, Misra M; Drug and Therapeutics Committee of the Lawson Wilkins Pediatric Endocrine Society. The role of recombinant human insulin-like growth factor-I in treating children with short stature. *J Clin Endocrinol Metab*. 2008; 93:10-18.
3. Guevara-Aguirre J, Rosenbloom AL, Vasconez O, et al. Two-year treatment of growth hormone (GH) receptor deficiency with recombinant insulin-like growth factor I in 22 children: comparison of two dosage levels and to GH-treated GH deficiency. *J Clin Endocrinol Metab*. 1997; 82:629-633.
4. Chernausk SD, Backeljauw PF, Frane J, et al. Long-term treatment with recombinant IGF-I in children with severe IGF-I deficiency due to growth hormone insensitivity. *J Clin Endocrinol Metab*. 2007; 92:902-910.
5. Khwaja OS, Ho E, Barnes KV, et al. Safety, pharmacokinetics, and preliminary assessment of efficacy of mecasermin (recombinant human IGF-1) for the treatment of Rett syndrome. *Proc Natl Acad Sci U S A*. 2014; 111(12):4596-4601.