

Policy Name:	Increlex (mecasermin)	Policy #:	1231P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Increlex.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Increlex under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Criteria for Treatment of Primary Insulin-Like Growth Factor-1 Deficiency

- 1.1 Prescribed by a specialist familiar with the diagnosis and treatment of primary insulin-like growth factor-1 deficiency
- 1.2 Age 2 years or older
- 1.3 Basal insulin-like growth factor-1 standard deviation score -3 for age and sex
- 1.4 Height standard deviation score -3 for age and sex
- 1.5 Normal or near normal growth hormone levels (> 10 ng/dL following stimulation, or basal level > 5 ng/dL)
- 1.6 Approval Time: 12 months
- 1.7 Renewal requires documentation of:
 - Growth velocity 2 cm per year and epiphyses are open

2. Criteria for Treatment of Growth Failure in Children with Growth Hormone Gene Deletion who have Developed Neutralizing Antibodies to Growth Hormone

- 2.1 Prescribed by a specialist familiar with the diagnosis and treatment of growth hormone deficiencies
- 2.2 Age 2 years or older
- 2.3 Diagnosis of growth hormone gene deletion who have developed neutralizing antibodies to growth hormone
- 2.4 Approval Time: 12 months
- 2.5 Renewal requires documentation of:
 - Growth velocity 2 cm per year and epiphyses are open

3. Exclusions

- 3.1 Idiopathic Short Stature (ISS)
- 3.2 Idiopathic short stature is considered a clinical description and not a diagnosis of an illness, injury or disease. Due to this, coverage of mecasermin for the treatment of idiopathic short stature (ISS) is not considered medically necessary.

- 3.3 ISS is generally considered a normal variant of growth
 - Long-term benefits of intervention are unclear
 - Predictions of adult height, with or without treatment, are imprecise
- 3.4 Most patients with ISS have normal psychosocial functioning
 - Short stature could not be established as the cause of problems with peer relationships
 - The effects have not been adequately studied
 - Short stature has a minimal impact on peer perceptions of social behavior, friendship, or peer acceptance

HCPCS Codes

J2170	Injection, mecasermin, 1 mg
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References

1. Increlex (mecasermin [rDNA origin]) [prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals Inc; March 2024.
2. 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 Mar;14(1): 25–29.
3. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency. *Horm Res Paediatr* 2016; 86:361.
4. Rughani A, Zhang D, Vairamani K, et al. Severe growth failure associated with a novel heterozygous nonsense mutation in the GHR transmembrane domain leading to elevated growth hormone binding protein. *Clin Endocrinol (Oxf)* 2020; 92:331.

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DISCLAIMER

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