Medical Drug Clinical Criteria

Subject:	Increlex (mecasermin)		
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Table of Contents

Overview

This document addresses the use of mecasermin (Increlex®), a recombinant human insulin-like growth factor-1 (rhIGF-1) drug, FDA approved for the treatment of growth failure in children with severe primary IGF-1 deficiency and growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

Severe Primary IGFD includes classical and other forms of growth hormone insensitivity. In normal children, GH is the regulator of circulating IGF-1. 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.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Increlex (mecasermin)

Initial requests for Increlex (mecasermin) may be approved if the following criteria are met:

I. Documentation is provided that individual is a child with growth failure associated with severe primary IGF-1 deficiency, as defined by:
   A. Height standard deviation (SD) score less than or equal to –3.0; **AND**
   B. Basal IGF-1 SD score less than or equal to –3.0; **AND**
   C. Normal or elevated growth hormone (GH) levels (greater than 10 ng/ml on standard GH stimulation tests) are present;

OR

II. Individual has growth hormone gene deletion with the development of neutralizing antibodies to GH.

Continuation requests for Increlex (mecasermin) may be approved if the following criteria are met:

I. Documentation is provided that growth velocity is greater than or equal to 2 cm total growth in 1 year; **AND**
II. Documentation is provided that final adult height has not been reached.

Requests for Increlex (mecasermin) may not be approved for the following criteria:

I. Individual has secondary IGF-1 deficiency (due to, for example, growth hormone (GH) deficiency, untreated malnutrition, untreated hypothyroidism, or other causes); **OR**
II. Individual has closed epiphyses**; OR**
III. Individual has suspected or known malignancies.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J2170	Injection, mecasermin, 1 mg [Increlex]

ICD-10 Diagnosis

E34.3	Short stature due to endocrine disorder
R62.52	Short stature (child)

Document History

Reviewed: 05/20/2022
Document History:

- 08/01/2022 – Administrative update to add documentation.
- 05/20/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/15/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/15/2020 – Annual Review: No changes. Coding Review: No changes
- 05/17/2019 – Annual Review: No changes. Coding reviewed: no changes
- 11/16/2018 – Select Review: First review of Increlex; no changes. HCPCS Coding Review: no change. ICD-10 coding Review: No change.

References

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2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 7, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. 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;86:361-397.