Clinical Policy: Mecasermin (Increlex)
Reference Number: ERX.SPMN.234
Effective Date: 01/17
Last Review Date:

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that mecasermin (Increlex®) is medically necessary for members meeting the following criteria:

I. Initial Approval Criteria
   A. Growth Failure (must meet all):
      1. Prescribed by an endocrinologist;
      2. Documented diagnosis of growth failure with one of the following (a or b):
         a. Severe primary IGF-1 deficiency as defined by all:
            i. Height SDS ≤−3.0,
            ii. Basal IGF-1 SDS ≤−3.0,
            iii. Normal or elevated GH level;
         b. Growth hormone (GH) gene deletion with development of neutralizing antibodies to GH.

      Approval duration: 3 months

   B. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy.

II. Continued Approval
   A. Growth Failure (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
      2. Demonstrated a therapeutic response toIncrelex, including growth of > 2 cm/year if member has been on Increlex therapy for at least a year.

      Approval duration: 6 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
      2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

Background
Increlex is an insulin growth factor-1 (IGF-1) analogue FDA approved to treat growth failure in pediatric patients ≥ 2 years of age with 1) severe primary IGF-1 deficiency (IGFD) or 2) growth hormone deficiency (GHD) resulting from GH gene deletion who have developed neutralizing antibodies to GH.¹ Under normal circumstances, GH binds to tissue receptors and stimulates insulin growth factor-1 (IGF-1) secretion.¹ IGF-1, in turn, activates IGF-1 receptors leading to
 intracellular signaling and statural growth. IGFD is defined by a height standard deviation score (SDS) of less than -3.0 and a basal IGF-I SDS of less than -3.0 in the presence of normal or elevated GH. Severe primary IGF-I deficiency includes cases of mutations in the GH receptor (GHR), post-GHR signaling pathway, and IGF-I gene. Patients with IGFD are not GH deficient, and therefore, cannot be expected to respond adequately to exogenous GH treatment.

Appendices
Appendix A: Abbreviation Key
GH: growth hormone
GHD: growth hormone deficiency
IGF-1: insulin-like growth factor -1
IGFD: insulin-like growth factor deficiency
SDS: standard deviation score

Coding Implications
The following codes are for informational purposes only. They are current at time of review of this policy. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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<tr>
<th>CPT®* Codes</th>
<th>Description</th>
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ICD-10-CM Diagnosis Codes that Support Coverage Criteria

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Reviews, Revisions, and Approvals
Policy created. 12/16  Approval Date: 01/17

References

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of
physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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