# POLICY AND PROCEDURE



**POLICY TITLE:** **Increlex (Mecasermin)**
**DEPARTMENT:** **Clinical Pharmacy Services- Utilization Management**
**ORIGINAL DATE:** ***April 2006***

**Last P & T Committee Approval Date:** *February 2018*

**Product Applicability:** *mark all applicable products below:*

| | |
|---|---|
| **COMMERCIAL** | [ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All |
| **OTHER** | [x ] Self-funded/ASO |

## PURPOSE

The purpose of this policy is to define the prior authorization process for Increlex (Mecasermin).

Increlex (Mecasermin) is indicated for the treatment of growth failure in children with severe primary insulin-like growth-factor 1 (IGF-1) deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

## DEFINITIONS

**Insulin-like Growth Factor-1 (IGF-1) –** a hormone that functions as the major mediator of growth hormone (GH)-stimulated somatic growth, as well as a mediator of GH-independent anabolic responses in many cells and tissues.

**Severe Primary IGF-1 Deficiency** – includes classical and other forms of growth hormone insensitivity, including those with mutations in the GH receptor (GHR), post-GHR signaling pathway, and IGF-1 gene defects. These patients are not GH deficient and therefore would not be expected to respond to GH treatment.

## POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Increlex (Mecasermin), is subject to the prior authorization process.

**PROCEDURE**

**Initial Authorization Criteria:**

*Must meet all of the criteria listed under the respective diagnosis:*

**1. For Growth Failure due to Severe IGF-1 Deficiency**

- Must be prescribed by a pediatric endocrinologist and must be used with appropriate physician (pediatric endocrinologist) follow-up
- Must be age 2 years or older
- Must have a diagnosis of severe IGF-1 deficiency defined as meeting ALL of the following:
  - Height standard deviation score ≤ -3.0 for age and sex
  - Basal IGF-1 standard deviation of ≤ -3.0 based on laboratory reference range
  - Normal or elevated GH defined as stimulated serum GH level (peak level) of >10ng/mL or basal (unstipulated) serum GH level >5ng/mL
- Must not have secondary forms of IGF-1 deficiency, such as growth hormone deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids. If thyroid or nutritional deficiencies exist, this should be corrected before initiation with mecasermin treatment.
- Must not use concomitantly with growth hormone treatment
- Must not have evidence of active or suspectedmalignancy, or have an allergy to mecasermin
- Must not be prescribed for growth promotion in patients with closed epiphyses
- Must include a treatment plan outlining the dose, monitoring parameters, such as when the member is seen for follow-up, methods for determining treatment response and anticipated duration of use

**2. For Growth Hormone Gene Deletion**

- Must be prescribed by a pediatric endocrinologist and must be used with appropriate physician (pediatric endocrinologist) follow-up.
- Must be age 2 years or older
- Must have GH gene deletion in gene GH1
- Must have developed neutralizing antibodies to growth hormone therapy
- Must not have secondary forms of IGF-1 deficiency, such as growth hormone deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids. If thyroid or nutritional deficiencies exist, this should be corrected before initiation with mecasermin treatment.
- Must not have evidence of active or suspected malignancy, or have an allergy to mecasermin
- Must not be prescribed for growth promotion in patients with closed epiphyses
- Request must include a treatment plan outlining the dose, monitoring parameters, such as when the member is seen for follow-up, methods for determining treatment response and anticipated duration of use

**Reauthorization Criteria:**

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at one-year intervals based upon:

- Documentation from provider in the form of a recent progress note indicating growth and maturation as a result of treatment
- Documentation that epiphyses have not closed

**Limitations:**

| Length of Authorization (if above criteria met) | |
|---|---|
| Initial Authorization | Up to 1 year |
| Reauthorization | Same as initial |

If the established criteria are not met, the request is referred to a Medical Director for review.

**REFERENCES**

1. Increlex (mecasermin [rDNA origin] injection) [Product Information], Tercica, Inc. Brisbane, CA. August 2005.
2. Iplex (mecasermin rinfabate [rDNA origin] injection) [Product Information], Insemed Incorporated. Glen Allen, VA. December 2005.
3. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use in Adults and Children – 2003 Update. Endocrine Practice 2003; 64-76.
4. Guevara-Aguirre J, Vasconez O, Martinez V, et al. A randomized, double blind, placebo-controlled trial on safety and efficacy of recombinant human insulin-like growth factor I in children with growth hormone receptor deficiency. *J Clin Endocrinol Metab*. 1995;80(4):1393-1398.
5. Ranke MB, Savage MO, Chatelain PG, et al. Insulin-like growth factor I improves height in growth hormone sensitivity: Two years' results. Horm Res. 1995;44(6):253-264.
6. Clark RG. Recombinant human insulin-like growth factor I (IGF-I): Risks and benefits of Normalizing blood IGF-I concentrations. *Horm Res*. 2004;62 Suppl 1:93-100.
7. Kemp SF. Insulin-like growth factor-I deficiency in children with growth hormone insensitivity. *Biodrugs* 2009;3:155-163

**RECORD RETENTION**
Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

**REVIEW HISTORY**

| DESCRIPTION OF REVIEW / REVISION | DATE APPROVED |
|---|---|
| *Annual Review* | *02/17, 02/18* |