



Commercial/Healthcare Exchange PA Criteria

Effective: July 27, 2016

Prior Authorization: Increlex

Products Affected: Increlex (mecasermin [rDNA origin]) 10 mg/mL Subcutaneous Solution

Medication Description:

Increlex injection contains insulin-like growth factor (rhIGF-1) produced by recombinant DNA technology. Insulin-like growth factor-1 (IGF-1) is a key hormonal mediator on statural growth. Under normal circumstances, growth hormone binds to its receptor in the liver, and other tissues, and stimulates the synthesis/secretion of IGF-1. In target tissues, the Type 1 IGF-1 receptor, which is homologous to the insulin receptor, is activated by IGF-1, leading to intracellular signaling which stimulates multiple processes resulting in statural growth. The metabolic actions of IGF-1 are in part directed at stimulating the uptake of glucose, fatty acids, and amino acids so that metabolism supports growing tissues.

Covered Uses: Severe Primary IGF-1 Deficiency (Primary IGFD)

Exclusion Criteria:

- Benign or Malignant Neoplasia
- IV administration
- Closed Epiphyses

Required Medical Information:

1. Documented diagnosis
2. Previous therapies tried
3. Confirmed open epiphyses

Age Restrictions: 2 years of age and older

Prescriber Restrictions: Prescribed by or in consultation with a Pediatric Endocrinologist

Coverage Duration: 12 months

Other Criteria:

Severe Primary IGF-1 Deficiency (Primary IGFD)

Approve Increlex if the patient meets the following criteria:

- A. Patient has confirmed open epiphyses; **AND**
- B. Patient has growth hormone gene deletion and has developed neutralizing antibodies to growth hormone; **OR**
- C. Patient has a diagnosis of severe primary insulin-like growth factor-1 deficiency (IGFD) defined by:
 - a. Height standard deviation score ≤ -3.0
 - b. Basal IGF-1 standard deviation score ≤ -3.0
 - c. Normal or elevated growth hormone; **AND**
- D. Patient does not have secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids

Last Res.10.15.2019



Confidential Information

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References:

1. Product Information: INCRELEX(R) subcutaneous injection, mecasermin rDNA origin subcutaneous injection. Ipsen Biopharmaceuticals, Inc. (per FDA), Basking Ridge, NJ. 2012. Accessed June 2019. Revised October 2019.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	6/8/16
2	Policy Update	<p>CCI adopted EH Policy:</p> <p>CCI P&T Review History: 12/05, 6/07, 6/08, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 5/16, 2/17, 1/18</p> <p>CCI P&T Revision History: 5/16, 1/18</p> <p>Clarified and added Exclusion criteria to match FDA Label;</p> <p>Specified other criteria to match FDA Label</p>	<p>Exclusion Criteria</p> <p>Other Criteria</p>	10/15/2019