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:
Increlix 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

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	CCI adopted EH Policy: 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 CCI P&T Revision History: 5/16, 1/18 Clarified and added Exclusion criteria to match FDA Label; Specified other criteria to match FDA Label	Exclusion Criteria Other Criteria	10/15/2019