Prior Authorization Criteria for Increlex (mecasermin)

The following criteria were established by the DoD Pharmacy & Therapeutics (P&T) Committee for growth hormone products obtained through the TRICARE Mail Order Pharmacy or retail network pharmacies as part of the TRICARE Pharmacy (TPHARM) Program. This prior authorization is good for a year.

Mecasermin [rDNA origin] injection (Increlex) is used for the long-term treatment of growth failure in children with severe primary insulin-like growth factor (IGF)-1 deficiency (primary IGFD) or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone. Mecasermin is different from growth hormone products (somatrem, somatropin). Severe primary IGFD includes patients with mutations in the growth hormone receptor (GHR), post-GHR signaling pathway, and IGF-1 gene defects; these patients are not growth hormone deficient, and therefore cannot be expected to respond adequately to treatment with growth hormone products (somatrem, somatropin).

Mecasermin presents some unique concerns regarding appropriate patient selection, dosing, administration, potential for misuse, and monitoring for possible low blood glucose levels (hypoglycemia). Patients and/or caregivers must be educated on how to monitor blood glucose levels, adjust mecasermin dosing, and manage hypoglycemia.

Prior Authorization Criteria for Increlex (mecasermin)

Coverage provided for the use of mecasermin for the treatment of:

- Patients with severe primary insulin-like growth factor (IGF)-1 deficiency (IGFD) defined by the following:
  - Height standard deviation score < -3
  - Basal IGF-1 standard deviation score < -3
  - Normal or elevated growth hormone levels OR

- Patients with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone
Patients must meet the following criteria:

- Are receiving ongoing care under the guidance of a health care provider skilled in the diagnosis and management of patients with growth disorders (e.g., pediatric endocrinologist)
- Thyroid and nutritional deficiencies have been corrected before initiating mecasermin treatment
- Have been educated on monitoring and management of hypoglycemia

Coverage NOT provided for:

- Patients with closed epiphyses (bone growth plates)
- Patients with active or suspected neoplasia (therapy should be discontinued if evidence of neoplasia develops)
- Patients with other causes of growth failure (secondary forms of IGF-1 deficiency, such as growth hormone deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroid)

*Criteria approved through the DoD P&T Committee process*
**US Family Health Plan Prior Authorization Request Form**

**for Mecasermin (Increlex)**

**To be completed and signed by the prescriber. To be used only for prescriptions which are to be filled through the Department of Defense (DoD) pharmacy.**

- The provider may call: 1-877-880-7007 or the completed form may be faxed: 1-617-562-5296
- The patient may attach the completed form to the prescription and mail it to: ATTN: Pharmacy, 77 Warren St, Brighton, MA 02135

Prior authorization criteria and a copy of this form are available at: [link]

### Step 1

**Please complete patient and physician information (Please Print)**

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### Step 2

**Please complete the clinical assessment**

1. **Is the patient a child older than two years of age with open epiphyses?**
   - [ ] Yes
   - [ ] No
   - Please proceed to question 2
   - Coverage not approved

2. **Is the patient receiving ongoing care under the guidance of a health care provider skilled in diagnosis and management of growth disorders (e.g., pediatric endocrinologist)?**
   - [ ] Yes
   - [ ] No
   - Coverage not approved
   - Please proceed to question 3

3. **Does the patient have severe primary insulin-like growth factor (IGF)-1 deficiency (IGFD), defined by the following:**
   - [ ] Yes
   - [ ] No
   - Please proceed to question 5
   - Please proceed to question 4
   - Coverage not approved
   - Coverage not approved
   - Height standard deviation score < -3 AND
   - Basal IGF-1 standard deviation score < -3 AND
   - Normal or elevated growth hormone levels

4. **Does the patient have growth hormone gene deletion AND neutralizing antibodies to growth hormone?**
   - [ ] Yes
   - [ ] No
   - Coverage not approved
   - Please proceed to question 5

5. **Does the patient have any of the following:**
   - [ ] Yes
   - [ ] No
   - Coverage not approved
   - Please proceed to question 6
   - Other causes of growth failure (e.g., growth hormone deficiency, malnutrition, hypothyroidism, chronic anti-inflammatory steroid use)
   - Active or suspected neoplasia

6. **Has the patient and/or caregiver been educated on how to monitor blood glucose levels, received a glucometer and necessary testing supplies, and demonstrated knowledge of blood glucose monitoring and hypoglycemia management?**
   - [ ] Yes
   - [ ] No
   - Coverage approved for 1 year
   - Coverage not approved

### Step 3

**I certify the above is correct and accurate to the best of my knowledge (Please sign and date)**

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Latest revision: Aug 2007