

# Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to:  Commercial (Traditional)  Commercial (Individual/Optimized)  
 Medicaid

This request is:  Urgent (life threatening)  Non-Urgent (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

## Increlex<sup>®</sup> (mecasermin)

### Member

Last Name: \_\_\_\_\_ First Name: \_\_\_\_\_  
 ID #: \_\_\_\_\_ DOB: \_\_\_\_\_ Gender: \_\_\_\_\_  
 Primary Care Physician: \_\_\_\_\_  
 Requesting Provider: \_\_\_\_\_ Prov. Phone: \_\_\_\_\_ Prov. Fax: \_\_\_\_\_  
 Provider Address: \_\_\_\_\_  
 Provider NPI: \_\_\_\_\_ Contact Name: \_\_\_\_\_  
 Provider Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### Product Information

New request  Continuation request  
 Drug product:  Increlex 10 mg/mL injection  
 Start date (or date of next dose): \_\_\_\_\_  
 Date of last dose (if applicable): \_\_\_\_\_  
 Dosing frequency: \_\_\_\_\_  
 Patient's weight: \_\_\_\_\_

The recommended starting dose of Increlex is 0.04 to 0.08 mg/kg twice daily. If well-tolerated for at least one week, the dosage can be increased 0.04 mg/kg per dose to the maximum dose of 0.12 mg/kg twice daily.

### Precertification Requirements

**Before this drug is covered, the patient must meet all of the following criteria:**

1. Age is 2 years to 18 years
2. Increlex must be prescribed by or after consultation with an endocrinologist
3. Diagnosis of severe primary insulin-like growth factor-1 (IGF-1) deficiency OR primary growth hormone deficiency caused by growth hormone gene deletions with development of neutralizing antibodies to growth hormone
  - a. Provide documentation of:
    - i. Baseline height < 3<sup>rd</sup> percentile or > 2 standard deviations (SD) below the mean for gender and age
    - ii. IGF-1 ≥ 3 SD below the normal range for age and sex
    - iii. History of lower than normal growth velocity
  - b. Severe primary insulin-like growth factor deficiency requires additional documentation of:
    - i. Growth hormone concentration is normal or increased, OR
    - ii. Confirmation by molecular genetic testing of growth hormone receptor mutations
  - c. Primary growth hormone deficiency caused by growth hormone gene deletion requires additional documentation of:
    - i. Prior treatment with growth hormone (typically 3-6 month trial) and subsequent antibody development
4. Epiphyses are open (must be confirmed for patients 10 years of age and older, submit radiograph)
5. Patient's bone age must be:
  - a. Less than 16 years for males
  - b. Less than 14 years for females

**Continuation of Increlex requires:**

1. Epiphyses are open
2. Rate of growth with Increlex is greater than pretreatment rate of growth
3. Patient's bone age must be:
  - a. Less than 16 years for males
  - b. Less than 14 years for females

**Duration of Authorization:**

If all precertification requirements are met approval will be granted for one year.

**Note:** Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

**New request**

**Priority Health Precertification Documentation**

**A. What condition is this drug being used for?**

- Severe primary insulin-like growth factor-1 (IGF-1) deficiency (Primary IGFD)
- Growth hormone (GH) gene deletion
- Other: \_\_\_\_\_ *please provide rationale for use:* \_\_\_\_\_

**B. Was the patient has evaluated by (prescribed by or after consultation with) an endocrinologist?**

- Yes
- No

**C. Is the patient self-injecting?**

- Yes
- No

**D. Are Epiphyses open? (must be confirmed for patients 10 years of age and older, submit radiograph)**

- Yes
- No

**E. What is the patient's bone age? \_\_\_\_\_**

**F. Has the patient had prior treatment with growth hormone which resulted in subsequent antibody development?**

- Yes
- No

**Please also provide documentation of the following:**

- a) Baseline height < 3<sup>rd</sup> percentile or > 2 standard deviations (SD) below the mean for gender and age
- b) IGF-1 ≥ 3 SD below the normal range for age and sex
- c) History of lower than normal growth velocity

**Diagnosis of Severe primary insulin-like growth factor deficiency requires additional documentation of:**

- a) Growth hormone concentration is normal or increased, OR
- b) Confirmation by molecular genetic testing of growth hormone receptor mutations

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**Requests for continuation of therapy:**

A. **Are Epiphyses open? (must be confirmed for patients 10 years of age and older, submit radiograph)**

Yes

No

B. **Rate of growth is faster than pretreatment:**

Yes

No, *Rationale for use:* \_\_\_\_\_

C. **What is the patient's bone age?** \_\_\_\_\_