

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[®] (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 65 years
2. Increlex must be prescribed by or after consultation with a pediatric 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 < 3rd 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) a pediatric 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 < 3rd 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

**Request to continue a previously authorized approval
Priority Health Precertification Documentation**

- 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?** _____