

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)

This request is:

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- Medicaid
- 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)

| wember | | | | |
|----------------------|-------------------------------|---------------------------|------------|--|
| Last Name: ID #: | | First Name: | | |
| | | | | |
| | ian: | | | |
| Requesting Provider: | | Prov. Phone: | Prov. Fax: | |
| Provider Address: | | | | |
| Provider NPI: | | | | |
| Provider Signature: | | Date: | | |
| Product Informa | ation | | | |
| New request | Continuation request | | | |
| Drug product: | ☐ Increlex 10 mg/mL injection | Start date (or date of ne | ext dose): | |
| | | Date of last dose (if ap | plicable): | |
| | | Dosing frequency: | | |
| | | | | |

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
- 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 \ge 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

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All fields must be complete and legible for review. Your office will receive a response via fax. No changes made since 12/2017 Last reviewed 07/2020



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 CMSaccepted 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?

| 🗌 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)
- 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 \geq 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



Requests for continuation of therapy:

- A. Are Epiphyses open? (must be confirmed for patients 10 years of age and older, submit radiograph)
 - 🗌 No
- B. Rate of growth is faster than pretreatment:
 - 🗌 Yes
 - No, Rationale for use:
- C. What is the patient's bone age?