

Mecasermin (Increlex®)

Place of Service

Self-Administration - May be covered under the pharmacy benefit

HCPCS: J2170 per 1 mg

Condition(s) listed in policy (see criteria for details)

- [Growth failure in children with severe primary IGF-1 deficiency](#)
- [Growth failure in children with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone](#)

AHFS therapeutic class: Somatropin Agonists

Mechanism of action: Mecasermin is a biosynthetic (rDNA origin) form of human insulin-like growth factor I (IGF-I), the principal mediator of somatotropic effects of human growth hormone (GH); somatotropin

(1) Special Instructions and Pertinent Information

This drug is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

For plans with self-injectables only covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Increlex® (mecasermin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Growth failure in children with severe primary IGF-1 deficiency

1. Height standard deviation score \leq negative 3.0, **AND**
2. Basal IGF-1 standard deviation score \leq negative 3.0, **AND**
3. Normal or elevated growth hormone, **AND**
4. Prescribed by an endocrinologist, **AND**
5. Patient is between 2 to 18 years of age, **AND**
6. Delayed bone age, **AND**
7. Not used in combination with growth hormone therapy

Covered Doses

Up to a maximum of 0.12 mg/kg SC given twice a day

Coverage Period

Cover yearly

Reauthorization:

1. Patient is between 2 to 18 years of age, and

2. Delayed bone age, and
3. Greater than 4 cm growth velocity over the past year

ICD-10:
E34.3

For diagnosis of growth failure in children with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH:

1. Height standard deviation score \leq negative 3.0, **AND**
2. Basal IGF-1 standard deviation score \leq negative 3.0, **AND**
3. Evidence of growth hormone gene deletion, **AND**
4. Development of neutralizing antibodies to GH, **AND**
5. Prescribed by an endocrinologist, **AND**
6. Patient is between 2 to 18 years of age, **AND**
7. Delayed bone age

Covered Doses

Up to a maximum of 0.12 mg/kg SC given twice a day

Coverage Period

Cover yearly

Reauthorization:

1. Patient is between 2 to 18 years of age, and
2. Delayed bone age, and
3. Greater than 4 cm growth velocity over the past year

ICD-10:
E34.3

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Increlex® (mecasermin) must be sent for clinical review and receive authorization prior to drug administration or claim payment

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Increlex is not intended for subjects with secondary forms of IGF-1 deficiency, such as growth hormone deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids.

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied: 10 mg per mL sterile solution in multiple dose glass vials (40 mg per vial)

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Increlex (mecasermin) [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; 12/2019.

(7) Policy Update

Date of last review: 3Q2022

Date of next review: 3Q2023

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*