Mecasermin (Increlex®)

**Effective:** 09/29/2021

<table>
<thead>
<tr>
<th>Place of Service</th>
<th>Self-Administration - May be covered under the pharmacy benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HCPCS:</strong></td>
<td><strong>J2170</strong> per 1 mg</td>
</tr>
<tr>
<td><strong>How supplied:</strong></td>
<td>10 mg per mL sterile solution in multiple dose glass vials (40 mg per vial)</td>
</tr>
</tbody>
</table>

**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

**Technician extension of authority (EOA)**

**Section (2) diagnoses:** None

For member new to Blue Shield (within the past 6 months), approve for Section (2) diagnoses if: None

(1) **Special Instructions and Pertinent Information**

If member has a Prescription Benefit, please refer cases to Pharmacy Services for prior authorization.

If covered under the Medical Benefit, please submit clinical information for prior authorization review via fax. Please include medical rationale why medication cannot be home self-administered.

(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 ≤ negative 3.0, **AND**
2. Basal IGF-1 standard deviation score ≤ 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 ≤ negative 3.0, AND
2. Basal IGF-1 standard deviation score ≤ 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

(7) Policy Update
Date of last review: 3Q2021
Date of next review: 3Q2022
Changes from previous policy version:
- No clinical change to policy following routine annual review.

(8) Previous Policy Update History (effective date) – INTERNAL USE
9-17-2009:
• New policy 3Q2009

9-16-2010:
• No change to policy following routine review

9-15-2011:
• No change to policy following routine review

9-20-2012:
• No change to policy following routine review

9-26-2013:
• No change to policy following routine review
• Updated to new policy format

12-19-2013:
• Effective January 20, 2014: Section (2): Added coverage requirement that patient is not using Increlex in combination with growth hormone therapy.
Rationale: Increlex PI states patients with primary IGF-1 deficiency “are not growth hormone [GH] deficient, and therefore, they cannot be expected to respond adequately to exogenous GH treatment.” In addition, there is no published literature supporting efficacy of GH therapy in patients with primary IGF-1 deficiency.

9-18-2014:
• No change to policy following routine review

9-17-2015:
• No change to policy following routine review
• Section (1): Added new fax number for medical management for prior authorization request
• Added ICD-9 and ICD-10 codes

9-15-2016:
• No change to policy following routine review
• Added NDC code

2-1-2017:
  o Section (9): Added subdenials.
  o Removed Pharmacy Services phone number.

10-1-2017:
  o No change to policy following routine review.
  o Added Tech EOA
  o Section (9): Routine denial language review. Update: I, N, R, V

11-1-2018:
• Removed NDC in Header
• Updated tech EOA box
• Section (2): Removed ICD-9 codes
• Section (4): Updated language approved by legal
• Section (9): Updated Denial Code Q, R, U, V, J, W, L

9-5-2019:
• Section (6): Updated PI.
• Section (9): Denial Codes.
  o Removed Q, F, J.
  o Added X.
  o Updated I, D, R, S, O, T, V, U, N, K, P, W.

10-7-2020:
• Section (9): Denial Codes. Removed N. Updated L.
9-29-2021:
- Section (6): Updated PI.
- Section (9): AA Codes. Added X, Y. Updated I, D, R, S, O, T, U, K

### (9) Coverage AA Codes-- INTERNAL USE

<table>
<thead>
<tr>
<th>AA codes</th>
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<tbody>
<tr>
<td><strong>Growth failure in children with severe primary IGF-1 deficiency</strong></td>
<td></td>
</tr>
<tr>
<td>I (No specialist)</td>
<td>The information sent in does not show you have seen an endocrinologist for your condition. An endocrinologist is a doctor who has extra training in treating hormone and growth disorders.</td>
</tr>
<tr>
<td>X (No info on height)</td>
<td>Increlex is a man-made form of insulin-like growth factor (IGF-1) that helps children grow. When you do not have enough of this hormone, your height is much shorter compared to most children of the same age and sex. A height of at least 3 standard deviations below the normal height of other children shows you may need Increlex to help with growth. We did not receive height information from your doctor. We will need this information before we can coverIncrelex.</td>
</tr>
<tr>
<td>D (No severe height deficiency)</td>
<td>Increlex is a man-made form of insulin-like growth factor (IGF-1) that helps children grow. When you do not have enough of this hormone, your height is much shorter compared to most children of the same age and sex. A height of at least 3 standard deviations below the normal height of other children shows you may need Increlex to help with growth. The information sent in does not show your height is much shorter compared to almost all children of the same age and sex.</td>
</tr>
<tr>
<td>R (no IGF-1 lab)</td>
<td>Increlex is approved by the Food and Drug Administration (FDA) to treat children who are very short for their age because they do not make enough insulin-like growth factor (IGF-1). IGF-1 is a hormone that helps with the growth of bone and tissues, IGF-1 is measured with a blood test. We did not receive an IGF-1 blood test. We will need this test before we can coverIncrelex.</td>
</tr>
<tr>
<td>S (IGF-1 &lt;3 standard deviations)</td>
<td>Increlex is a man-made form of insulin-like growth factor (IGF-1). It is given when you do not make enough IGF-1 on your own. The information sent in shows you are making enough IGF-1.</td>
</tr>
<tr>
<td>O (no bone age study)</td>
<td>Increlex is approved by the Food and Drug Administration (FDA) to treat children who are very short for their age because they do not make enough insulin-like growth factor (IGF-1). IGF-1 is a hormone that helps bone and tissue growth and development. A bone age study can show how fast or slow a child is growing. We did not receive a bone age study from your doctor. We will need this information before we can coverIncrelex.</td>
</tr>
<tr>
<td>T (combo)</td>
<td>The information sent in shows you will be using Increlex along with &lt;manually insert drug&gt;. Increlex has not been studied to be given in this combination.</td>
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For diagnosis of growth failure in children with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH

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to help with growth. The information sent in does not show your height is much shorter compared to almost all children of the same age and sex.

**R**  
(no IGF-1 lab)  
Increlex is approved by the Food and Drug Administration (FDA) to treat children who are very short for their age because they do not make enough insulin-like growth factor (IGF-1). IGF-1 is a hormone that helps with the growth of bone and tissues. IGF-1 is measured with a blood test. We did not receive an IGF-1 blood test. We will need this test before we can cover Increlex.

**S**  
(IGF-1 <3 standard deviations)  
Increlex is a man-made form of insulin-like growth factor (IGF-1). It is given when you do not make enough IGF-1 on your own. The information sent in shows you are making enough IGF-1.

**O**  
(no bone age study)  
Increlex is approved by the Food and Drug Administration (FDA) to treat children who are very short for their age because they do not make enough insulin-like growth factor (IGF-1). IGF-1 is a hormone that helps bone and tissue growth and development. A bone age study can show how fast or slow a child is growing. We did not receive a bone age study from your doctor. We will need this information before we can cover Increlex.

**V**  
(no information on growth gene deletion)  
The Food and Drug Administration (FDA) approvedIncrelex for growth failure in children who are missing the growth hormone gene. We need your doctor to confirm you are missing this gene before we can cover Increlex.

**Y**  
(No information if can have antibodies to growth hormone)  
The Food and Drug Administration (FDA) approved Increlex for growth failure in children who are missing the growth hormone gene and does not respond to growth hormone drugs. There was no information sent in to show if your body responds to growth hormone drugs. We will need this information before we can cover Increlex.

**U**  
(no growth hormone antibodies)  
Children who do not have the growth hormone gene may need Increlex if their body does not respond to growth hormone drugs. The information sent in shows your body does respond to growth hormone drugs.

**T**  
(combo)  
The information sent in shows you will be using Increlex along with <manually insert drug>. Increlex has not been studied to be given in this combination.

**General**

**K**  
(max dosing)  
The requested dose is <DOSE>. This is more than what is approved by the Food and Drug Administration (FDA). Increlex is covered up to 0.12 mg/kg given twice a day.

**P**  
(reauth)  
The information sent in does not show that your child is responding to Increlex. Chart notes must show that a child's rate of growth is more than 4 centimeters per year. The information sent in by your prescriber indicates that your child's rate of growth is <enter rate>.  
*(Internal: Allow if the request if the request is a reauth)*

**W**  
(home self-inject)  
Increlex is a self-administered drug covered under the pharmacy benefit. Self-administered drugs can be safely taken by patients or given by caregivers outside of a medically supervised setting (such as a hospital, physician's office, or home infusion). The information sent in does not give a medical reason why you cannot use this drug at home.

**L**  
(off-label)  
The Food and Drug Administration (FDA) has not approved Increlex for <INDICATION>. <ADD DESCRIPTION if needed>. When a drug is used differently from an FDA approved use it is called an OFF-LABEL USE. The information sent in does not meet the “OFF-LABEL DRUG USE” criteria approved by Blue Shield of California’s Pharmacy and Therapeutics Committee that aligns with the California Health and Safety Code (HSC 1367.21). We may cover off-label use of a drug if it meets one of the following:

- The use of this drug for your condition is supported by American Hospital Formulary Service Drug Information (medical literature).
The use of this drug for your condition is supported by at least two articles published in medical journals that are reviewed by medical experts (peer-reviewed). These articles must show the drug is safe and effective for your condition. Also, there must not be any peer-reviewed articles showing the drug does not work for your condition.

Please talk with your doctor about your treatment options.