

Pharmacy Policy Bulletin

Title: Mecasermin (Increlex®)

Policy #: Rx.01.54

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▶ **Intent:**

The intent of this policy is to communicate the medical necessity criteria for **mecasermin (Increlex®)** as provided under the member's prescription drug benefit.

▶ **Description:**

Mecasermin (Increlex®) is indicated for the long-term treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

Mecasermin is a recombinant form of human insulin-like growth factor I (rhIGF-I) that mediates anabolic and growth-promoting effects of growth hormone. Endogenous Insulin Growth Factor1 (IGF-1) is required for normal growth and brain development. IGF-1 is in part directed towards stimulating the uptake of glucose, fatty acids, and amino acids so that metabolism supports growing tissues. Mecasermin increases insulin sensitivity by mimicking some actions of insulin.

▶ **Policy:**

Mecasermin (Increlex®) is approved when all of the following inclusion criteria are met:

1. Diagnosis of growth failure in children with ONE of the following:
 - a. Severe primary insulin-like growth factor-1 deficiency (IGF-D); or
 - b. Growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH

AND

2. Member is 2 years of age or older; AND
3. Height standard deviation (SD) score of less than or equal to 3.0 SD scores below normal (growing at or below the third percentile for age and sex);AND
4. Baseline IGF-1 (SD) score of less than or equal to 3.0 SD scores below normal (based on age- and sex-related reference ranges); AND

5. Normal or elevated GH level (based on GH stimulation testing) or (for children with GH gene deletion) measured titers of GH-neutralizing antibodies;AND
6. Open epiphyses (bone growth plates) (bone age less than 14 years for girls and less than 16 years for boys); AND
7. Prescribed an endocrinologist

CONTINUATION CRITERIA

Continuation of mecasermin (Increlex®) is approved when all of the following are met:

1. Growth velocity greater than or equal to 2.5cm/year; AND
2. Yearly evaluation by an endocrinologist; AND
3. Expected adult height is not obtained; AND
4. Documentation of expected adult height goal

Authorization length: 1 year

▸ Black Box Warning:

None

▸ Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▸ References:

Increlex (mecasermin) [prescribing information]. Basking Ridge, NJ. Ipsen Biopharmaceuticals, Inc. March 2016. Available online at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=a8b27a1b-a611-4f91-ad22-76d4b390c3ae&type=display#section-10.1>. Accessed on November 15, 2018.

Mecasermin. Micromedex Solutions [Internet database]. Available at: www.micromedexsolutions.com. Accessed November 26, 2018.

▸ Applicable Drugs:

i Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Increlex®	mecasermin

▸ Cross References:

N/A

Policy Version Number:	8.00
P&T Approval Date:	October 11, 2018
Policy Effective Date:	January 1, 2019
Next Required Review Date:	October 11, 2019

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.