Pharmacy Medical Necessity Guidelines:
Increlex® (mecasermin)

Effective: March 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Increlex (mecasermin) is indicated for the treatment of growth failure in pediatric patients 2 years of age and older with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. Severe Primary IGFD is defined by height standard deviation score ≤-3.0, basal IGF-1 standard deviation score ≤-3.0, and normal or elevated GH.

Increlex is not a substitute to GH for approved GH indications.

COVERAGE GUIDELINES

The plan may authorize coverage of Increlex (mecasermin) for Members, when **ALL** of the following criteria are met:

1. Documented diagnosis of **one (1)** of the following:
    a. Requested use is for the treatment of growth failure in children with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone
    b. Both of the following:
        i. Requested use is for the treatment of growth failure in children with severe primary insulin-like growth factor-1 deficiency
        ii. **ALL** of the following:
            1. Height standard deviation score less than or equal to -3.0
            2. Basal IGF-1 standard deviation score less than or equal -3.0
            3. Normal or elevated growth hormone level

AND

2. The patient is 2 to 17 years of age

AND

3. Prescribed by or in consultation with a pediatric endocrinologist

AND

4. Documentation the patient has open epiphysis

LIMITATIONS

- Coverage of Increlex will be authorized up to the Member's 18th birthday.

CODES

Medical billing codes may not be used for these medications. These medications must be obtained via the Member's pharmacy benefit.

REFERENCES

1. Increlex (mecasermin) [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; March 2024.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

- July 11, 2023: Updated age requirements to through 17 years of age to align with authorization duration rules. Added provider requirements (effective October 1, 2023).
- May 14, 2024: No changes
- March 11, 2025: No changes
- March 10, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services