Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Increlex® (mecasermin)

Effective: March 10, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

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 gene deletion who have developed neutralizing antibodies to growth hormone. Severe Primary IGFD is defined by height standard deviation score ≤-3.0, basal IGF-1 standard deviation score ≤-3.0, and normal or elevated growth hormone.

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

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Increlex 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

1. Coverage of Increlex will be authorized up to the patients' 18th birthday.
2. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Increlex (mecasermin [rDNA origin]) [prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals Inc; May 2025.

Approval And Revision History

September 13, 2022: Reviewed by the 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
- May 11, 2025: No changes (eff 3/11/25)
- March 10, 2026: No changes, administrative update to remove Carelink

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.