Pharmacy Medical Necessity Guidelines: Increlex® (mecasermin)

Effective: January 1, 2021

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:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

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 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. 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.

COVERAGE GUIDELINES

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

Initial Therapy

1. Documented diagnosis of **one (1) of the following**:
    a. Severe primary insulin-like growth factor-1 (IGF-1) deficiency as defined by all of the following: A height standard deviation score less than or equal to -3.0, a basal insulin-like growth factor-1 (IGF-1) standard deviation score less than or equal to -3.0, and normal or elevated growth hormone level
    b. Growth hormone gene deletion and has developed neutralizing antibodies to growth hormone

AND

2. The Member is 2 to 18 years of age

AND

3. Prescribed by or in consultation with a pediatric endocrinologist

AND

4. Documentation bony epiphyses are open

Reauthorization Criteria

1. Documented diagnosis of **one (1) of the following**:
    a. Severe primary insulin-like growth factor-1 (IGF-1) deficiency as defined by all of the following: A height standard deviation score less than or equal to -3.0, a basal insulin-like growth factor-1 (IGF-1) standard deviation score less than or equal to -3.0, and normal or elevated growth hormone level
    b. Growth hormone gene deletion and has developed neutralizing antibodies to growth hormone

AND

2. The Member is 2 to 18 years of age

AND

3. Prescribed by or in consultation with a pediatric endocrinologist

AND

4. Documentation the Member has experienced a therapeutic response as evidenced by a growth curve chart

AND

5. Documentation bony epiphyses are open

LIMITATIONS

- Initial authorization of Increlex (mecasermin) will be provided for 12 months. Reauthorization of Increlex (mecasermin) will be provided for 12-month intervals.
- Members new to the plan stable on Increlex (mecasermin) should be reviewed against Reauthorization Criteria.
- The plan does not provide coverage of Increlex (mecasermin) for conditions resulting in secondary forms of IGF-1 deficiency that include, but are not limited to, the following:
  - Growth hormone deficiency
  - Malnutrition
  - Hypothyroidism
  - Chronic steroid therapy

CODES

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

REFERENCES

1. Bajpai A, Menon PS. Insulin like growth factors axis and growth disorders. Indian J Pediatr 2006;73:67-71
2. Clark RG. Recombinant human insulin-like growth factor I (IGF-I): risks and benefits of normalizing blood IGF-I concentrations. *Frontiers of Hormone Research* 2004; 62 Suppl 1:93-100.
3. Frysak Z, Schovanek J, Iacobone M, Karasek D. Insulin-like Growth Factors in a clinical setting: Review of IGF-I. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub. 2015 Sep;159(3):347-51.
4. Increlex (mecasermin) [package insert]. Brisbane, CA: Tercica, Inc.; 2016 March.
5. McEvoy GK, ed. AHFS 2012 Drug Information. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc; 2012.
6. Rosenfeld RG, Rosenbloom AL, Guevara-Aguirre J. Growth hormone (GH) insensitivity due to primary GH receptor deficiency. *Endocr.* 1994; 15(3):369-390.
7. U.S. National Institutes of Health. Clinical Trials. Prepubertal Children with Growth Failure Associated with Primary Insulin-Like Growth Factor-1 (IGF-1) Deficiency. Available at: clinicaltrials.gov/ct/gui/show/NCT00125164. Accessed 2018 July 17.

APPROVAL HISTORY

August 8, 2006: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. December 12, 2006: Removed IPLEX® (mecasermin rinfabate) from title and pharmacy coverage guidelines. Added, "Tufts Health Plan does not cover IPLEX® (mecasermin rinfabate)" to the limitations section.
2. November 13, 2007: No changes
3. November 11, 2008: No changes
4. November 10, 2009: Removed non-covered IPLEX® (mecasermin rinfabate) from limitations section of medical necessity guidelines as product has been discontinued.
5. September 14, 2010: No changes
6. September 13, 2011: No changes
7. September 11, 2012: No changes
8. August 6, 2013: No changes
9. August 12, 2014: No changes
10. August 11, 2015: No changes
11. January 1, 2016: Administrative change to rebranded template.
12. August 9, 2016: No changes
13. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
14. August 8, 2017: No changes
15. August 7, 2018: No changes. Administrative update to move information about initial and subsequent approval requirements to the Limitations section.
16. September 10, 2019: No changes

17. September 15, 2020: Effective January 1, 2021, changed provider specialty requirements to be prescribed by or in consultation with a pediatric endocrinologist. Changed "Radiographs documenting open epiphyses are required for Members who are Tanner stage III or greater" to "Documentation bony epiphyses are open." Modified reauthorization criteria.

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.