Effective Date **6/1/2023**
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Coverage Policy Number **IP0310**

Mecasermin

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for mecasermin subcutaneous injection (**Increlex**®).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Mecasermin (Increlex) is considered medically necessary when ONE of the following is met:

1. **Insulin-Like Growth Factor-1 (IGF-1) Deficiency – Severe, Primary Disease.** Individual meets **ALL** of the following criteria:
    A. Age 2 years or older
    B. Bony epiphyses are open
    C. Height standard deviation score is less than or equal to -3.0, prior to the initiation of mecasermin therapy

D. Basal IGF-1 standard deviation score is less than or equal to -3.0, prior to the initiation of mecasermin therapy
E. Growth hormone concentration is normal or elevated, prior to the initiation of mecasermin therapy
F. Will not be receiving concurrent treatment with growth hormone
G. Medication is prescribed by or in consultation with an endocrinologist.

2. **Growth Hormone Gene Deletion.** Individual meets **ALL** of the following criteria:
   A. Age 2 years or older
   B. Bony epiphyses are open
   C. Has developed neutralizing antibodies to growth hormone
   D. Will not be receiving concurrent treatment with growth hormone
   E. Medication is prescribed by or in consultation with an endocrinologist

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When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of mecasermin (Increlex) is considered medically necessary for **ALL** covered diagnoses when the above medical necessity criteria are met AND there is documentation of beneficial clinical response as evidenced by growth curve chart

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Mecasermin (Increlex) is considered **NOT** medically necessary for the following use:

1. **Idiopathic (i.e. of unknown origin) Short Stature**, also called non-growth hormone deficient short stature in children or adolescents.

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Amyotrophic Lateral Sclerosis (ALS)**
2. **Autism Spectrum Disorder**
3. **Bone Loss Associated with Anorexia**
4. **Phelan- McDermid Syndrome**
5. **Prevention of Retinopathy of Prematurity**
6. **Rett Syndrome**
7. **Treatment of Secondary Forms of IGF-1 Deficiency** (such as chronic treatment with pharmacologic doses of anti-inflammatory drugs, GH deficiency, hypothyroidism, or malnutrition)

At this time there is insufficient or no published evidence to support use of mecasermin (Increlex) in the above listed conditions.

Background

Increlex, an insulin-like growth factor (IGF-1), is indicated for the treatment of growth failure in pediatric patients ≥ 2 years of age with the following conditions:[1]

- **Primary IGF-1 deficiency**, for patients with severe disease, defined as:
  - Height standard deviation score ≤ -3.0; AND
  - Basal IGF-1 standard deviation score ≤ -3.0; AND
  - Normal or elevated growth hormone level.
- **Growth hormone gene deletion**, in patients who have developed neutralizing antibodies to growth hormone.

Increlex is given by subcutaneous injection twice daily, shortly before or after a meal or snack. Treatment with Increlex should continue until the epiphyses fuse indicating full growth potential has been achieved.[2] It is a limitation of use that Increlex is not a substitute to growth hormone for approved growth hormone indications. Increlex is not indicated in secondary forms of IGF-1 deficiency, such as growth hormone deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory corticosteroids.[1]

References

1. Increlex® subcutaneous injection [prescribing information]. Cambridge, MA: Ipsen; December 2019.
2. Cohen J, Blethen S, Kuntze J, et al. Managing the child with severe primary insulin-like growth factor-1 deficiency (IGFD): IGFD diagnosis and management. *Drugs R D*. 2014;14(1):25-29.
3. Rosenbloom AL. Is there a role for recombinant insulin-like growth factor-I in the treatment of idiopathic short stature? *Lancet.* 2006;368:612-616.
4. Ipsen. rhGH and rhIGF-1 combination therapy in children with short stature associated with IGF-1 deficiency. In: ClinicalTrials.gov. Bethesda (MD): National Library of Medicine (US). Available at: rhGH and rhIGF-1 Combination Therapy in Children With Short Stature Associated With IGF-1 Deficiency - Full Text View - ClinicalTrials.gov. NCT00572156. Accessed on November 28, 2022.