Increlex (mecasermin)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Increlex (mecasermin) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

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

Severe primary IGF-1 deficiency is defined by:

- Height standard deviation (SD) score ≤ –3.0 and
- Basal IGF-1 SD score ≤ –3.0 and
- Normal or elevated GH.

Severe primary IGF-1 deficiency includes classical and other forms of GH insensitivity. Patients with primary IGF-1 deficiency may have mutations in the GH receptor (GHR), post-GHR signaling pathway including the IGF-1 gene. They are not GH deficient, and therefore, they cannot be expected to respond adequately to exogenous GH treatment. Increlex is not intended for use in subjects with secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids. Thyroid and nutritional deficiencies should be corrected before initiating Increlex treatment.

Limitations of use: Increlex is not a substitute to GH for approved GH indications.

POLICY

Required Documentation

The following information is necessary to initiate the prior authorization review for continuation of therapy requests:

A. Total duration of treatment (approximate duration is acceptable)
B. Date of last dose administered
C. Approving health plan/pharmacy benefit manager
D. Date of prior authorization/approval
E. Prior authorization approval letter

Criteria for Initial Approval

Severe Primary IGF-1 Deficiency

Authorization of 12 months may be granted to members with severe primary IGF-1 deficiency or GH gene deletion with neutralizing antibodies to GH when ALL of the following criteria are met:

A. Pretreatment height is ≥ 3 standard deviations (SD) below the mean for age and gender.
B. Pretreatment basal IGF-1 level is ≥ 3 SD below the mean for age and gender.
C. Pediatric GH deficiency has been ruled out with a provocative GH test (i.e., peak GH level ≥ 10 ng/mL).
D. Epiphyses are open.

Continuation of Therapy

Severe Primary IGF-1 Deficiency

Authorization of 12 months may be granted for the continuation of therapy of severe primary IGF-1 deficiency or GH gene deletion with neutralizing antibodies to GH when ALL of the following criteria are met:

A. The member's growth rate is > 2 cm/year or there is a documented clinical reason for lack of efficacy (e.g., on treatment less than 1 year, nearing final adult height/late stages of puberty).
B. Epiphyses are open (confirmed by X-ray or X-ray is not available).

Increlex is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

REFERENCES

- Increlex [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; December 2019.
- Caremark Clinical Programs Review. Focus on growth hormones, growth hormone releasing hormone, Increlex, Somavert. December 18, 2006.

POLICY HISTORY

Policy #: 05.04.09
Policy Creation: April 2020
Reviewed: January 2021
Revised:
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