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PHARMACY / MEDICAL POLICY – 5.01.519

Increlex (mecasermin); Recombinant Human Insulin-Like Growth Factor-1

Effective Date:	Dec. 1, 2023	RELATED MEDICAL POLICIES:
Last Revised:	Nov. 20, 2023	5.01.500 Growth Hormone Therapy
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

Insulin-like growth factor-1 (IGF-1) acts a bit like a go-between in the growth process as IGF-1 is the hormone that is naturally produced in the liver and certain other tissues. The pituitary gland, located in the brain, stimulates the production of growth hormone, which is then released into the blood. When growth hormone reaches the liver, it causes the liver to create IGF-1. Then, IGF-1 acts as the link between growth hormone that is in the blood and the growth processes inside cells. The levels of IGF-1 increase during childhood, peak during puberty, and then decline. Children whose bodies don't create enough IGF-1 are very short for their age. IGF-1 that is made in a lab may be used to help children grow when other causes of slow growth have been ruled out. This policy describes when IGF-1 may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
Increlex (mecasermin)	**Increlex (mecasermin) may be considered medically necessary for its Food and Drug Administration (FDA)-approved indication for the treatment of growth failure in children if the individual meets ALL of the following criteria:** • Diagnosis of growth failure due to severe primary insulin-like growth factor-1 (IGF-1) deficiency (growth hormone receptor mutations [e.g., Laron syndrome], post-growth hormone receptor signaling pathway mutations, or IGF-1 gene defects) OR growth hormone (GH) gene deletion with neutralizing antibodies to GH **AND** • The individual's height is below the 3rd percentile on growth charts for their age and gender related height (i.e., height is greater than 2.25 standard deviations [SD] below the mean) **AND** • The individual's baseline IGF-1 concentration is ≥ 3 SD below normal (based on lab reference range for age and sex) **AND** • The individual's baseline growth hormone concentration is normal or elevated based on at least one stimulation test **AND** • Bone age is < 13 years for females or < 15 years for males

Drug	Not Medically Necessary
Increlex (mecasermin)	**Use of Increlex (mecasermin) to treat idiopathic short stature is considered not medically necessary.**

Drug	Investigational
Increlex (mecasermin)	**Use of Increlex (mecasermin) to treat all other indications is considered investigational, including but not limited to:** • Less severe forms of IGF-1 deficiency • Secondary forms of IGF-1 deficiency (GH deficiency, malnutrition, hypothyroidism, or chronic corticosteroid therapy) • Growth failure due to other identifiable causes (e.g., Prader-Willi syndrome, Turner syndrome, Noonan syndrome)

Drug	Investigational
	• Diabetes mellitus • Acquired immunodeficiency syndrome (AIDS)-associated wasting • Women with anorexia nervosa • Obesity in postmenopausal women • Advanced chronic renal failure • Cystic fibrosis • Amyotrophic lateral sclerosis (ALS) • Severe head injury • Use in combination with GH

Length of Approval	
Approval	**Criteria**
Initial authorization	**Increlex (mecasermin) may be approved up to 12 months.**
Re-authorization criteria	**Future re-authorization of Increlex (mecasermin) may be approved up to 12 months as long as the drug-specific coverage criteria are met, and chart notes demonstrate that the individual continues to show a positive clinical response to therapy as supported by ALL of the following criteria:** • Growth velocity is ≥ 2.5 cm / year **AND** • Bone age is ≤ 14 years for females or ≤ 16 years for males

Note: Policy and guidelines for the use of growth hormone (somatropin) are contained in a separate medical policy (see **Related Policies**).

Coding

Code	Description
Reviewed for Medical Necessity	
HCPCS	
J2170	Injection, mecasermin (Increlex), 1 mg

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Benefit Application

Enrollees receiving mecasermin should be reviewed on at least an annual basis to assure proper application of benefits.

Increlex (mecasermin) may be managed through either the pharmacy or medical benefit.

Evidence Review

Description

Increlex (mecasermin) is produced by recombinant DNA technology and has an identical amino acid sequence to endogenous human insulin-like growth factor-1 (IGF-1). Mecasermin is approved for the treatment of growth failure in children with severe primary IGF-1 deficiency (growth hormone receptor mutations, post-growth hormone receptor signaling pathway mutations, or IGF-1 gene defects) and in those with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. It is estimated that 30,000 to 60,000 children in the United States (US) and Western Europe have primary IGF-1 deficiency. Of these individuals, approximately 20%, or 6,000 to 12,000, have severe primary IGF-1 deficiency.

The current somatomedin hypothesis of statural growth involves GH release by the anterior pituitary that is controlled in a stimulatory fashion by GH-releasing hormone and in an inhibitory fashion by somatostatin. Circulating GH then binds to GH receptors in the liver resulting in production of IGF-1, IGF binding proteins, and acid labile subunit. Virtually all circulating IGF-1 is bound to IGF binding proteins and acid labile subunit. This tertiary complex reduces extravascular passage and increases the half-life of IGF-1. Circulating IGF-1 then stimulates multiple processes leading to statural growth and metabolic changes that support this growth. GH also stimulates prechondrocyte differentiation and local production of IGF-1 (autocrine and paracrine) that in turn stimulate clonal expansion, maturation of chondrocytes, and growth.

Approximately 15% to 20% of growth is thought to be the result of this local effect of GH versus that resulting from circulating hepatic IGF-1.

Mecasermin is not a substitute for GH treatment and is not indicated for the treatment of secondary IGF deficiency resulting from GH deficiency, malnutrition, hypothyroidism or chronic corticosteroid therapy.

Rationale

Severe primary IGF-1 deficiency or GH gene deletion with neutralizing antibodies to GH are rare disorders currently without therapeutic alternatives. A small quantity of low-quality evidence consistently supports the efficacy and safety of Increlex (mecasermin) for the treatment of children with these conditions to increase statural growth. According to the Food and Drug Administration (FDA) review report for mecasermin, approval was granted based on four small (n= 6 to 23) and one long-term clinical studies (4 open-label and 1 double-blind placebo-controlled). Because of the rarity of severe primary IGF-1 deficiency, the individuals and data from the 4 smaller studies were "rolled into" the larger long-term study.

Chernausek et al. reported long-term efficacy and safety results from a multicenter, open-label, uncontrolled study in 76 children with severe IGF-1 deficiency associated with growth hormone insensitivity. It should be noted that the inclusion criteria used for the study were less stringent than defined by the FDA for identification of individuals with severe deficiency. A total of 76 individuals initially received mecasermin 0.04-0.08 mg/kg SC twice daily, and if the dose was tolerated for at least a week without hypoglycemic episodes it was titrated by 0.04 mg/kg/dose to 0.12 mg/kg twice daily. The primary study endpoint was change from baseline in height velocity. During the first year of treatment, height velocity increased from a mean baseline of 2.8 cm/yr to 8.0 cm/yr, in 59 evaluable individuals ($P<0.0001$). Height velocity was lower in subsequent years but remained above baseline for up to 8 years. Height velocity was dose dependent or fastest in those receiving the maximal dose (0.012 mg/kg twice daily). Bone age increased modestly an average of 5.8 yrs over 5.1 years ($P=0.01$).

A smaller (n=8) open-label uncontrolled study in which individuals with severe primary IGF-1 deficiency were treated with mecasermin 0.08-0.12 mg/kg twice daily as tolerated for up to 7.5 years showed similar results. During the first year of treatment, height velocity increased from a mean baseline of 4.0 cm/yr to 9.3 cm/yr (mean height velocity standard deviation score [SDS] +3.8) and 6.2 cm/yr (mean height velocity SDS +0.5) in the second year of treatment. Mean change in height velocity SDS was +1.4 after 6-7 years of therapy.

The most commonly reported adverse events reported with use of mecasermin at recommended doses in children with severe primary IGF-1 deficiency were hypoglycemia, lymphoid tissue hypertrophy, and injection-site lipohypertrophy. Hypoglycemia was minimized by consumption of a meal or a snack within 20 minutes of administration of the drug, and lipohypertrophy was minimized by rotation of the injection site with each dose. Rarely, intracranial hypertension was also reported.

Labeled contraindications include closed epiphyses, suspected or active neoplasia, intravenous (IV) administration, and hypersensitivity to any component. Labeled warnings and precautions include that the product contains benzyl alcohol as a preservative, which has been associated with neurological toxicity in neonates; sensitivity reactions have been reported; treatment should be directed by physicians experienced in the diagnosis and management of individuals with growth disorders; mecasermin should be administered shortly (± 20 min) before or after a meal or snack because mecasermin has insulin-like hypoglycemic effects; hypertrophy of lymphoid tissue with complications (e.g., snoring, sleep apnea) has been observed; intracranial hypertension has been reported; rapid growth may cause slipped capital femoral epiphysis or worsen scoliosis; and allergic reactions have been reported.

The recommended starting dose of mecasermin is 0.04-0.08 mg/kg subcutaneously (SC) twice daily. If well-tolerated (without hypoglycemia) for at least one week, the dose may be increased in 0.04 mg/kg/dose increments up to the maximum dose of 0.12 mg/kg SC twice daily. Doses greater than 0.12 mg/kg twice daily have not been studied in children with primary IGF-1 deficiency and should not be used to avoid potential hypoglycemia.

2009 Update

A literature search of the MEDLINE database conducted from August 2008 through June 2009 did not identify any additional published studies that would prompt reconsideration of the policy statements.

2010 Update

A literature search of the MEDLINE database conducted from July 2009 through April 2010 did not identify any additional published studies that would prompt reconsideration of the policy statements.

2011 Update

A literature search of the MEDLINE database conducted from May 2010 through January 2011 did not identify any additional published studies that would prompt reconsideration of the policy statements.

2012 Update

A literature search of the MEDLINE database conducted from January 2011 through February 2012 did not identify any additional published studies that would prompt reconsideration of the policy statements.

2013 Update

A literature search of the MEDLINE database conducted from January through December 2012 did not identify any additional published studies that would prompt reconsideration of the policy statements.

2014 Update

A literature search conducted from January 2013 through February 2014 and no new evidence was found that would change this policy.

2015 Update

A literature search conducted from January 2014 through March 2015 and no new evidence was found that would change this policy.

2016 Update

A literature search conducted from July 1, 2015, through December 5, 2016, and no new evidence was found that would change this policy.

2017 Update

A literature search conducted from October 1, 2016, through November 1, 2017, and no new evidence was found that would change this policy.

2018 Update

A literature search conducted from November 1, 2017, through October 31, 2018, and no new evidence was found that would change this policy.

2019 Update

A literature search conducted from November 1, 2018, through October 31, 2019, and no new evidence was found that would change this policy.

2020 Update

A literature search conducted from November 1, 2019, through November 2020, and no new evidence was found that would change this policy.

2021 Update

Reviewed prescribing information and conducted a literature search conducted from July 1, 2020 through June 30, 2021 and no new evidence was found that would change this policy.

2022 Update

Reviewed Increlex (mecasermin) prescribing information and reviewed the management of growth hormone insensitivity syndromes. No new evidence was found that would change this policy.

2023 Update

Reviewed Increlex (mecasermin) prescribing information and conducted a literature search on the management of growth hormone insensitivity syndromes from October 31, 2022 through November 1, 2023. No new evidence was found that would change this policy.

References

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History

Date	Comments
08/12/08	Add to Prescription Drug Section - New PR Policy.
07/14/09	Replace Policy - Policy updated with literature search, no change to the policy statement.
06/08/10	Replace Policy - Policy updated with literature search, no change to the policy statement.
03/08/11	Replace Policy - Policy updated with literature review; no change in policy statement. Policy guidelines updated for improved clarity and administrative simplicity.
04/25/12	Replace policy. Policy updated with literature review; policy statements unchanged. Reference 15 added.
04/16/13	Replace policy. Policy updated with literature review; policy statements unchanged.
05/05/14	Annual Review. Policy updated with literature review; policy statements unchanged.
05/27/15	Annual Review. Policy updated with literature review, policy statements unchanged. Notation added that this policy is managed and administered through the pharmacy benefit.
10/28/16	Formatting update. Coding table reformatted and moved to Policy Guidelines section.
01/01/17	Annual Review, approved December 13, 2016. Policy updated with literature review, policy statements unchanged.
12/01/17	Annual Review, approved November 21, 2017. No new evidence was found, and policy statements unchanged.
12/01/18	Annual Review, approved November 21, 2018. No new evidence was found, and policy statements unchanged.

Date	Comments
01/01/20	Annual Review, approved December 10, 2019. Policy updated with literature review through October 2019, policy statements unchanged.
01/01/21	Annual Review, approved December 17, 2020. No new evidence was found, and policy statements unchanged.
09/01/21	Annual Review, approved August 3, 2021. No changes to policy statement.
11/01/22	Annual Review, approved October 10, 2022. No changes to policy statement. Changed the wording from "patient" to "individual" throughout the policy for standardization.
12/01/23	Annual Review, approved November 20, 2023. No changes to policy statement.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

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Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx.

Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

Language Assistance

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MO LOU SILAFIA: Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totogi, mo oe, Telefoni mai: 800-722-1471 (TTY: 711).

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