BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Increlex®

Policy Number: 9.317
Version Number: 2.0
Version Effective Date: 9/1/2021

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ MassHealth MCO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Increlex® (mecasermin)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications unless otherwise excluded.
Exclusion Criteria	Secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacological doses of anti-inflammatory steroids; closed epiphyses; malignant neoplasm or history of malignancy.
Required Medical Information	1. A diagnosis of growth failure due to severe primary insulin-like growth factor-1 (IGF-1) deficiency including:

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	• Height standard deviation score ≤ -3.0 ; ***AND*** • Basal IGF-1 standard deviation score ≤ -3.0; ***AND*** • Normal or elevated growth hormone ; ***OR*** 2. A diagnosis of growth failure due to growth hormone gene deletion and has developed neutralizing antibodies to growth hormone
Age Restrictions	Pediatric patients 2 years of age or older
Prescriber Restriction	The prescriber must be an endocrinologist
Coverage Duration	12 months
Other criteria	Reauthorization: Documentation that there has been an increase in height velocity with no significant adverse events.

Applicable Coding:

Code	Medication
J2170	Increlex (mecasermin injection)

Clinical Background Information and References

1. Increlex [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc. ; August 2005.
2. Mecasermin. In DrugDex® System (internet database). Version 5.1, Greenwood Village, Colo. Thomson Micromedex. Accessed June 2007.
3. Mecasermin (recombinant human insulin-like growth factor-1): Drug Information. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on April 1, 2019.)

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.091 Increlex Policy retired, new policy created	1/1/2021	P&T Committee
5/13/2021	P&T Annual review: No changes	9/1/2021	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.