BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Natpara

Policy Number: 9.309
Version Number: 1
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth - MCO ☒ MassHealth - ACO ☐ 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:

- **Natpara (parathyroid hormone)**

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

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	1. Diagnosis of hypocalcemia resulting from chronic hypoparathyroidism; **AND** 2. 25-hydroxy vitamin D serum level is above the lower limit of the normal laboratory reference range; **AND**

[+] *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.

	3. Member is currently on active vitamin D (calcitriol) therapy; **AND** 4. Total serum calcium level (albumin corrected) is above 7.5 mg/dL; **AND** 5. **One** of the following a. Member is currently taking calcium supplementation of 1-2 grams per day of elemental calcium in divided doses; **OR** b. Member is receiving other formulation of calcium supplementation.
Age Restriction	18 years of age or older
Prescriber Restriction	Prescribed by or in consultation with either an endocrinologist or a nephrologist
Coverage Duration	Initial: 6months Reauthorization: 12 months
Other criteria	Reauthorization 1. Submission of medical records (e.g., chart notes, laboratory values) documenting total serum calcium level (albumin corrected) within the lower half of the normal range (approximately 8 to 9 mg/dL); ***AND*** 2. Member continues to take concomitant calcium supplementation. Note: Active vitamin D supplementation may be discontinued if lab values improve/stabilize while on therapy.

Clinical Background Information and References

1. Natpara® [package insert]. Bedminster, NJ: NPS Pharmaceuticals; July 2017.

2. Abramowicz, M, Zuccotti, G, Pflomm, JM, et al. Recombinant Human Parathyroid Hormone (Natpara). The medical letter on drugs and therapeutics. 2015 June; 57(1470):87-88.

3. Goltzman, David et al. Hypoparathyroidism. UpToDate. Reviewed January 2019. Last updated: Oct. 10, 2017

4. Mannstadt, M, Clarke, BL, Vokes, T, et al. Efficacy and safety of recombinant human parathyroid hormone (1-84) in hypoparathyroidism (REPLACE): a double-blind, placebocontrolled, randomized, phase 3 study. The lancet Diabetes & endocrinology. 2013, Dec; 1(4):275-83. PMID: 24622413

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	9.063 Natpara Policy retired, new policy created	1/1/2021	P&T Committee

Next Review Date

2021

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.