Pharmacy Policy

Natpara™ (parathyroid hormone)

Policy Number: 9. 063
Version Number: 2.0
Version Effective Date: 07/17/2017

Product Applicability

☐ All Plan Products

Well Sense Health Plan
☒ New Hampshire Medicaid
☒ NH Health Protection Program
☐ __________________________

Boston Medical Center HealthNet Plan
☒ MassHealth
☒ Qualified Health Plans
☐ Senior Care Options
☐ __________________________

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

Policy Summary

The Plan may authorize coverage of Natpara™ when the criteria below are met.

Description of Item or Service

Natpara® is a recombinant human parathyroid hormone and is used as an adjunct to vitamin D and calcium for adults 18 years of age or older with hypoparathyroidism who cannot be well controlled on calcium and active forms of vitamin D alone to control hypocalcemia. The efficacy of Natpara® was evaluated in a 24-week, randomized, double-blind, placebo-controlled, multicenter trial. One hundred and twenty-four patients were randomized to receive Natpara® or placebo; 56% of patients received 100 mcg of Natpara® per day, 26% received 75 mcg of Natpara® per day, and 18% received 50 mcg of Natpara® per day; others received placebo. For efficacy analysis, patients that fulfilled three components of a three-part response criterion were considered responders. A responder was defined as an individual who had: at least a 50% reduction from baseline in the dose of active vitamin D, at least a 50% reduction from baseline in the dose of oral calcium supplementation and an albumin-corrected total serum calcium concentration between 7.5 mg/dL and 10.6 mg/dL. At the end of treatment, significantly (p-value <0.001) more patients treated with Natpara® (54.8%)
Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrollees. 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.

Natpara® compared to placebo (2.5%) met the response criterion. Forty-two percent of patients randomized to Natpara were independent of active forms of vitamin D and were on no more than 500 mg of oral calcium, compared with 2.5% of patients randomized to placebo. There were no differences in the proportion of patients with a calcium level between 7.5 mg and 10.6 mg at end of treatment between patients randomized to Natpara® and placebo.

The most common adverse reactions associated with Natpara® and occurring in greater than 10% of individuals were: paresthesia, hypocalcemia, headache, hypercalcemia, nausea, hypoesthesia, diarrhea, vomiting, hypercalciuria and pain in extremity.

Limitations of Use:

- Because of the potential risk of osteosarcoma, Natpara® is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone.
- Natpara® was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations.
- Natpara® was not studied in patients with acute post-surgical hypoparathyroidism.

The dose of Natpara® should be individualized to achieve a serum calcium level in the lower half of the normal range. The starting dose of Natpara® is 50 mcg injected once daily in the thigh.

Natpara® should be reserved for patients with hypoparathyroidism whose hypocalcemia cannot be well controlled on calcium and active forms of vitamin D alone.

**Policy**

The Plan may authorize coverage of Natpara™ for treatment of specific conditions when the following criteria are met:

<table>
<thead>
<tr>
<th>Medication</th>
<th>BMC HealthNet Plan</th>
<th>Well Sense Health Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MassHealth</td>
<td>QHP</td>
</tr>
<tr>
<td>Natpara</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

**Prior Authorization – (Duration of Approval – Initial up to 6 months)**

A prior authorization request will be required for all prescriptions of Natpara™. These requests will be approved when the following criteria are met.

Natpara will be approved based on all of the following criteria:

**Initial Therapy**

1. Documentation of all of the following:
   a. Diagnosis of hypocalcemia resulting from chronic hypoparathyroidism
   b. 25-hydroxy vitamin D serum level is above the lower limit of the normal laboratory reference range

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c. Member is currently on active vitamin D (calcitriol) therapy

d. Total serum calcium level (albumin corrected) is above 7.5 mg/dL; **AND**

2. Age is 18 years or older; **AND**

3. 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; **AND**

4. Natpara is prescribed by, or in consultation with either an endocrinologist or a nephrologist

**Reauthorization (approved for 12 months)**

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 active vitamin D (calcitriol) therapy and calcium supplementation.

**Quantity Limits Apply – see Appendix A**

**Limitations**

The Plan will **not** approve coverage of Natpara™ in the following instances:

- When the above criteria has not been met.
- Members < 18 years of age.

**Clinical Background Information and References**


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Appendix A: Quantity Limitations for Natpara™

<table>
<thead>
<tr>
<th>Medication Name and Strength</th>
<th>Maximum Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Natpara Injection – 25mcg, 50mcg, 75mcg, 100mcg</td>
<td>2 cartridges per 28 days</td>
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</table>

<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date</th>
<th>Policy Owner</th>
<th>Approved by</th>
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<tbody>
<tr>
<td>03/10/2016</td>
<td>07/06/2016</td>
<td>Pharmacy Services</td>
<td>Pharmacy &amp; Therapeutics (P&amp;T) Committee</td>
</tr>
<tr>
<td>05/17/2016</td>
<td>07/06/2016</td>
<td>Pharmacy Services</td>
<td>New Hampshire DHHS (NH DHHS)</td>
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Policy Revisions History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date</th>
<th>Approved by</th>
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<tbody>
<tr>
<td>03/09/2017</td>
<td>P&amp;T Annual Review; No changes required</td>
<td>07/17/2017</td>
<td>P&amp;T Committee NH DHHS</td>
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Next Review Date

03/08/2018

Other Applicable Policies

9.002 Mandatory Generic Substitution Program
9.015 Quantity Limitation Program

Reference to Applicable Laws and Regulations, If Any

N/A

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.

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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.

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