Pharmacy Medical Necessity Guidelines: Natpara® (parathyroid hormone)

Effective: May 8, 2018

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This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

Fax Numbers:
RXUM: 617.673.0988

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Natpara (parathyroid hormone) is indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism

Because of the potential risk of osteosarcoma, Natpara (parathyroid hormone) is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone.

Natpara (parathyroid hormone) was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations.

Natpara (parathyroid hormone) was not studied in patients with acute post-surgical hypoparathyroidism.

Natpara (parathyroid hormone) is only available through a restricted Risk Evaluation and Mitigation Strategies (REMS) program due to the potential risk of osteosarcoma. Only certified healthcare providers may prescribe and only certified pharmacies may dispense Natpara (parathyroid hormone). Patients should be counseled on the appropriate use and risks associated with treatment, receive a copy of the Patient Brochure, and sign the Natpara (parathyroid hormone) REMS Patient-Prescriber Acknowledgment Form.

**COVERAGE GUIDELINES**

The plan may authorize coverage of Natpara (parathyroid hormone) for Members when all the following criteria for a particular regimen are met and limitations do not apply:

1. Documented diagnosis of hypocalcemia secondary to hypoparathyroidism

   **AND**

2. The prescriber is an endocrinologist

   **AND**

3. Documentation that previous treatment with calcium supplements and active forms of vitamin D was not successful in treating the hypocalcemia

   **AND**

4. Documentation Natpara (parathyroid hormone) will be given in conjunction with calcium supplements

   **AND**

5. Submission of lab studies documenting sufficient 25-hydroxyvitamin D stores and serum calcium levels above 7.5 mg/dL
LIMITATIONS
1. Initial approval will be limited to 6 months. A new prior authorization may be submitted at that
time for continuation of therapy. Subsequent authorization requests may be given in 12-month
intervals based on the submission of medical records documenting tolerance and effectiveness of
therapy.
2. The plan does not cover Natpara (parathyroid hormone) for Members with an increased baseline
risk for osteosarcoma such as Paget's disease, children and young adults less than 25 years of age
with open epiphyses (x-rays should document epiphyseal closure), persons with prior history of
external beam or implant radiation involving the skeleton, or persons with hereditary syndromes
predisposed to osteosarcoma (Li-Fraumeni syndrome (LFS), hereditary retinoblastoma (RB),
Rothmund-Thomson syndrome (RTS) type 2, Werner syndrome (WS), Bloom syndrome (BS),
RAPADILINO syndrome, and Diamond Blackfan anemia (DBA).
3. The plan does not cover Natpara (parathyroid hormone) for the treatment of Members with acute
post-surgical hypoparathyroidism.
4. The plan does not cover Natpara (parathyroid hormone) for Members with hypoparathyroidism
caused by calcium-sensing receptor mutations.
5. Coverage of Natpara (parathyroid hormone) is limited to 28-day supplies as follows:
   - Two multi-dose, dual-chamber glass cartridges per 28 days.

CODES
Medical billing codes may not be used for these medications. These medications must be obtained via
the Member’s pharmacy benefit.

REFERENCES
   pathophysiology, target-organ involvement, treatment, and challenges for future research. J Bone
2. Calvert GT, Randall RL, Jones KB, et al. At risk populations for osteosarcoma: The syndromes and
   2015 July 15.
4. Linglart A, Rothenbuhler A. From synthesis to replacement of parathyroid hormone. Lancet
   hormone (1-84) in hypoparathyroidism (REPLACE): a double-blind, placebo-controlled,
6. Natpara (parathyroid hormone) [prescribing information]. Bedminster, NJ: NPS
   Biopharmaceuticals, Inc; 2016 June.
7. Natpara Academy of Managed Care Pharmacy (AMCP) Formulary Submission Dossier. Bedminster,
8. NPS Pharmaceuticals, Inc. Natpara (parathyroid hormone) for injection. Recombinant human
   parathyroid hormone. BLA 12551. Risk Evaluation and Mitigation Strategy (REMS). Initial REMS

APPROVAL HISTORY
August 11, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
   - January 1, 2016: Administrative change to rebranded template.
   - July 12, 2016: No changes
to Tufts Health RITogether.
   - July 11, 2017: No changes
   - May 8, 2018: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION
Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan
benefits and are published to provide a better understanding of the basis upon which coverage
decisions are made. They are used in conjunction with a Member’s benefit document and in
coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.