Pharmacy Policy Bulletin

Title: Parathyroid Hormone (Natpara®)

Policy #: Rx.01.172

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria **for Natpara ® (parathyroid hormone)** as provided under the member's prescription drug benefit.

Description:

Hypoparathyroidism is a disorder characterized by hypocalcemia and deficiency of parathyroid hormone (PTH). Hyperphosphatmeia, hypercalciuria and reduced concentrations of 1,25-dihydroxyvitamin D are additional characteristics of hypoparathyroidism. Calcium and vitamin D supplementation is the standard therapy for hypoparathyroidism, with the goal of achieving serum calcium levels in the low-normal range and avoiding hypercalciuria. Thiazide diuretics may be used as adjunctive therapy to increase distal tubule calcium reabsorption.

Natpara® is recombinant human PTH (rhPTH), identical to endogenous human PTH. PTH increases serum calcium by increasing renal tubular calcium reabsorption, increasing intestinal calcium absorption, and by increasing bone turnover which releases calcium into the circulation. PTH maintains calcium and phosphate homeostasis. PTH increases in serum calcium occur in a dose dependent manner.

Natpara® is indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism. It has not been studied in hypoparathyroidism due to calcium-sensing receptor mutation or post-surgical hypoparathyroidism.

Policy:

INITIAL CRITERIA: Natpara® (parathyroid hormone) is approved when there is documentation of ALL of the following:

1. Member is 18 years of age or older; and
2. Diagnosis of hypocalcemia for patients with hypoparathyroidism NOT caused by either of the following:
    a. Calcium-sensing receptor mutations; or
    b. Acute post-surgical hypoparathyroidism; and
3. Member is not well controlled on calcium supplements and active forms of vitamin D; and
4. Used as an adjunct to calcium and vitamin D; and
5. Member has normal thyroid-stimulating hormone concentrations if not on thyroid hormone replacement therapy (or if on therapy, the dose had to have been stable for greater than or equal to 3 months); and
6. Member has normal magnesium and serum 25-hydroxyvitamin D concentrations; and
7. Prescribed by or in consultation with an endocrinologist

Initial authorization duration**:** 6 months

REAUTHORIZATION CRITERIA: Natpara® (parathyroid hormone) is re-approved when there is documentation of positive clinical response to therapy (i.e., member has achieved and maintained serum calcium levels in the ideal range; member has achieved reduction in oral calcium and vitamin D intake).

Reauthorization duration**:** 2 years

Black Box Warning as shown in the drug Prescribing Information:

Potential risk of osteosarcoma

In male and female rats, parathyroid hormone caused an increase in the incidence of osteosarcoma (a malignant bone tumor) that was dependent on dose and treatment duration. A risk to humans could not be excluded

Because of the potential risk of osteosarcoma, prescribe Natpara® only to patients who cannot be well-controlled on calcium and active forms of vitamin D and for whom the potential benefits are considered to outweigh the potential risk

Avoid use of Natpara® in patients who are at increased baseline risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, patients with hereditary disorders predisposing to osteosarcoma or patients with a history of prior external beam or implant radiation therapy involving the skeleton)

Natpara® is available only through a restricted program called the Natpara REMS Program

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Cusano NE, Rubin MR, Sliney J, Bilezikian JP. Mini-review: new therapeutic options for hypoparathyroidism. Endocrine. 2012;41:410-14.

Natpara® (parathyroid hormone) [package insert]. Lexington, MA. Shire-NPS Pharmaceuticals, Inc. December 2018. Available from: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=d11fba31-0a6c-11e3-8ffd-0800200c9a66&type=display. Accessed September 29, 2021.

Parathyroid hormone. Micromedex. Available from: http://www.micromedexsolutions.com. Accessed September 29, 2021.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	**Generic Name**
Natpara®	parathyroid hormone

Cross References:

Off-Label Use Rx.01.33

Policy Version Number:	7.00
P&T Approval Date:	September 23, 2021
Policy Effective Date:	January 01, 2022
Next Required Review Date:	September 23, 2022

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.