

Clinical Pharmacy Program Guidelines for Natpara

Program	Prior Authorization
Medication	Natpara (parathyroid hormone analog)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	6/2015
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

1. Background:

Natpara is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.¹

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. It is available only through a restricted program called the Natpara REMS Program.
- 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.

Natpara has a black box warning for potential risk of osteosarcoma. Please see full prescribing information for additional details.

2. Coverage Criteria:

<p>A. <u>Hypoparathyroidism</u></p> <p>1. <u>Initial Therapy</u></p> <p style="padding-left: 20px;">a. Natpara will be approved based on <u>all</u> of the following criteria:</p> <p style="padding-left: 40px;">(1) <u>All</u> of the following:</p> <p style="padding-left: 60px;">a. Diagnosis of hypocalcemia resulting from chronic hypoparathyroidism</p>

Confidential and Proprietary, © 2020 UnitedHealthcare Services Inc.

- b. 25-hydroxy vitamin D level is above the lower limit of the normal laboratory reference range
- c. Patient is currently on active vitamin D (calcitriol) therapy
- d. Total serum calcium level (albumin corrected) is above 7.5 mg/dL

-AND-

(2) **One** of the following

- a. Patient is currently on calcium supplementation of 1-2 grams per day of elemental calcium in divided doses

-OR-

- b. Patient has a contraindication to calcium supplementation

-AND-

(3) Prescribed by **one** of the following:

- a. Endocrinologist
- b. Nephrologist

Authorization will be issued for 12 months.

2. Reauthorization

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

- (1) Total serum calcium level (albumin corrected) within the lower half of the normal range (approximately 8 to 9 mg/dL)

-AND-

- (2) Patient continues to take concomitant calcium supplementation that is sufficient to meet daily requirements

-AND-

(3) Prescribed by **one** of the following:

- a. Endocrinologist
- b. Nephrologist

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Natpara® [package insert]. Bedminster, NJ: NPS Pharmaceuticals; June 2020.
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. Hypoparathyroidism. In: UpToDate, Rosen, Clifford, et al (ED). UpToDate, Waltham, MA, 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, placebo-controlled, randomized, phase 3 study. The lancet Diabetes & endocrinology. 2013 Dec;1(4):275-83. PMID: 24622413

Program	Prior Authorization - Natpara (parathyroid hormone analog)
Change Control	
Date	Change
6/2015	New Policy
9/2016	Updated policy template and clinical criteria to align with Employer & Individual.
3/2017	Changed initial authorization duration to 12 months
9/2017	Annual review. Removed medical record submission requirement. Removed requirement of concomitant active vitamin D therapy for reauthorization. Updated references.
9/2018	Annual review with no changes to coverage criteria.
9/2019	Annual review with no changes to coverage criteria. Updated references.
9/2020	Annual review with no changes to coverage criteria. Added Additional Clinical Rules section. Updated references.