UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Natpara

Program	Prior Authorization
Medication	Natpara (parathyroid hormone analog)
Issue Date	6/2015
Pharmacy and Therapeutics Approval Date	9/2017
Effective Date	11/2017

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.

2. Coverage Criteria:

A. Hypoparathyroidism

1. **Initial Therapy**

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

(1) All of the following:

a. Diagnosis of hypocalcemia resulting from chronic hypoparathyroidism
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 active vitamin D (calcitriol) therapy and calcium supplementation unless contraindicated.

-AND-

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

a. Endocrinologist
b. Nephrologist

Authorization will be issued for 12 months.

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3. References:

1. Natpara® [package insert]. Bedminster, NJ: NPS Pharmaceuticals; July 2016.
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. Updated references.