

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2066-9
Program	Prior Authorization/Medical Necessity
Medication	Natpara [®] (parathyroid hormone analog)
P&T Approval Date	10/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 9/2021, 9/2022, 9/2023
Effective Date	12/1/2023

1. Background:

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

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:

<p>A. <u>Hypoparathyroidism</u></p> <p>1. <u>Initial Therapy</u></p> <p>a. Natpara will be approved based on <u>all</u> of the following criteria:</p> <p>(1) <u>All</u> the following:</p> <ul style="list-style-type: none"> 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 <p style="text-align: center;">-AND-</p> <p>(2) <u>One</u> of the following</p> <ul style="list-style-type: none"> a. Patient is currently on calcium supplementation of 1-2 grams per day of elemental calcium in divided doses <p style="text-align: center;">-OR-</p> <ul style="list-style-type: none"> 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 6 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

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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.

4. **References:**

1. Natpara® [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; February 2023.
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: Post TW, ed. *UpToDate*. UpToDate; 2023. Accessed August 2, 2023.

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

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Change Control	
10/2015	New program.
9/2016	Annual Update. Updated references.
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 reference.
9/2020	Annual review with no changes to coverage criteria. Updated reference.
9/2021	Annual review with no changes to coverage criteria. Updated references.
9/2022	Annual review with no changes to coverage criteria. Updated references.
9/2023	Annual review with no changes to coverage criteria. Updated references.