UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2066-10
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, 9/2024
Effective Date	11/17/2024

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]:

A. **Hypoparathyroidism**

1. **Initial Therapy**

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

(1) Diagnosis of hypocalcemia resulting from chronic hypoparathyroidism

-AND-

(2) Patient is currently on adequate supplemental calcium and active vitamin D (e.g., calcitriol) therapy as evidenced by serum calcium (albumin corrected) > 7.5 mg/dL

-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) Documentation of positive clinical response [e.g., total serum calcium level (albumin corrected) within the lower half of the normal range (approximately 8 to 8.5 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. 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
3. Goltzman, David. Hypoparathyroidism. In: Post TW, ed. *UpToDate*. UpToDate; 2023. Accessed July 26, 2024.

Program	Prior Authorization/Medical Necessity - Natpara (parathyroid hormone analog)
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.
9/2024	Annual review. Updated initial authorization criteria and initial authorization duration to 12 months. Updated references.