UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1163-10
Program	Prior Authorization/Notification
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 on active vitamin D (e.g., calcitriol) therapy prior to starting Natpara

-AND-

(3) **One** of the following

a. Patient is currently on calcium supplementation

-OR-

b. Patient has a contraindication to calcium supplementation

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Natpara** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Natpara therapy

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.
- Medical Necessity may be in place

4. References:

1. Natpara® [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; February 2023.

Program	Prior Authorization/Notification - Natpara (parathyroid hormone analog)
Change Control	
10/2015	New program.
9/2016	Annual Review. No changes.
9/2017	Annual review with no changes to coverage criteria. Updated reference.
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. Added state mandate footnote.
9/2023	Annual review with no changes to coverage criteria. Updated reference.
9/2024	Annual review. Updated initial authorization duration to 12 months.