Clinical Policy: Parathyroid Hormone (Natpara)

Reference Number: PA.CP.PHAR.282
Effective Date: 10/2018
Last Review Date: 01/2026

Description
Parathyroid hormone (Natpara®) is a parathyroid hormone.

FDA Approved Indication(s)
Natpara is indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

Limitation(s) 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.
- 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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Natpara is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hypocalcemia Secondary to Hypoparathyroidism (must meet all)**:**

1. Diagnosis of hypocalcemia secondary to hypoparathyroidism;
2. Prescribed by or in consultation with an endocrinologist;
3. Age ≥ 18 years;
4. Natpara is prescribed as an adjunct to calcium supplements and active forms of vitamin D, unless contraindicated;
5. Recent (dated within the last 30 days) serum calcium level is >7.5 mg/dL;
6. Recent (dated within the last 30 days) lab result shows sufficient 25-hydroxyvitamin D stores [≥50 nmol/L (≥20 ng/mL)];
7. Failure of a 12-week trial of calcium supplements and active forms of vitamin D (e.g., calcitriol) at up to maximally indicated doses, unless contraindicated or clinically significant adverse events are experienced;
   **Prescriber must indicate that the hypocalcemia is not well controlled with calcium supplements and active forms of vitamin D (see examples in Appendix D below)*;
8. Dose does not exceed 100 mcg/day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Hypocalcemia Secondary to Hypoparathyroidism (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy as evidenced by one of the following (a or b):
   a. Recent (dated within the last 90 days) serum calcium level is within 8-9 mg/dL;
   b. Recent serum calcium level is >9 mg/dL and Natpara dose is being decreased;
3. If request is for a dose increase, new dose does not exceed 100 mcg/day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
calcitriol (Rocaltrol®)	0.25 mcg PO QD initially; dose may be increased at 2- to 4-wk intervals	2 mcg/day
calcium carbonate (Caltrate®, OsCal®, Tums®)	1-3 g PO QD in divided doses	3 g/day
calcium citrate (Cal-Citrate®, Cal-C-Caps®)	1-3 g PO QD in divided doses	3 g/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications

- Contraindication(s): hypersensitivity to any component of the product
- Boxed warning(s): potential risk of osteosarcoma

Appendix D: General Information

- As stated in the prescribing information, the prescriber should confirm 25-hydroxyvitamin D stores are sufficient and serum calcium is above 7.5 mg/dL before starting Natpara.
- The goal of Natpara treatment is to achieve serum calcium within the lower half of the normal range (8 to 9 mg/dL) and to reduce the required doses of calcium and vitamin D supplementation.
- Examples of a "failure" of calcium and vitamin D supplementation can include: large swings in calcium levels, calcium phosphate product cannot be maintained within an acceptable range, high risk of renal complications due to hypercalciuria or calcium containing stones, evidence of renal complications such as nephrolithiasis or having a condition causing poor calcium and vitamin D absorption.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Hypocalcemia secondary to hypoparathyroidism	50 mcg SC QD; increase in increments of 25 mcg every 4 weeks	100 mcg/day

VI. Product Availability

Multiple-dose, dual-chamber glass cartridges: 25 mg/dose, 50 mcg/dose, 75 mcg/dose and 100 mcg/dose

VII. References

1. Natpara Prescribing Information. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; February 2023. Available at: https://www.natpara.com. Accessed December 6, 2025.
2. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed November 29, 2023.
3. Brandi ML, Bilezikian JP, Shoback D, et al. Management of hypoparathyroidism: summary statement and guidelines. J Clin Endocrinol Metab. June 2016;101(6):2273–83.
4. Khan AA, Bilezikian JP, Brandi ML, et al. Evaluation and management of hypoparathyroidism summary statement and guidelines from the second international workshop. J Bone and Mineral Research. December 2022;37(12):2568-85.
5. Khan AA, Ali DS, Bilezikian JP, et al. Best practice recommendations for the diagnosis and treatment of hypoparathyroidism. Metabolism. October 2025;171:156335. doi: 10.1016/j.metabol.2025.156335.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date
Policy Created	10/2018
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/2019
1Q 2020 annual review: references reviewed and updated.	01/2020
1Q 2021 annual review: references reviewed and updated.	01/2021
1Q 2022 annual review: no significant changes; references reviewed and updated	01/2022
1Q 2023 annual review: no significant changes; references reviewed and updated.	01/2023
1Q 2024 annual review: added HCPCS code [C9399]; references reviewed and updated.	01/2024
1Q 2025 annual review: no significant changes; Takeda plans to discontinue global manufacturing of Natpara by the end of 2024; references reviewed and updated.	01/2025
1Q 2026 annual review: no significant changes; updated initial and continued auth durations from 6 months to 12 months; references reviewed and updated.	01/2026