Clinical Policy: Parathyroid Hormone (Natpara)

Reference Number: LA.PHAR.282
Effective Date: 09.29.23
Last Review Date: 02.21.25
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

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 Louisiana Healthcare Connections® 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 B below).*

8. Dose does not exceed 100 mcg per day.

Approval duration: 6 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
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 per day.

Approval duration: 6 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

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 policies – LA.PMN.53 for Medicaid, or evidence of coverage documents.

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 for all relevant lines of business 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/Boxed Warnings
- 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 mcg/dose, 50 mcg/dose, 75 mcg/dose, 100 mcg/dose

VII. References

1. Natpara Prescribing Information. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; February 2023. Available at: https://www.natpara.com. Accessed October 25,2024.
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.

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	LDH Approval Date
Policy created	05.09.23	08.28.23
Annual review: no significant changes; added HCPCS code [C9399]; references reviewed and updated.	03.21.24	5.23.24
Annual review: no significant changes; Takeda plans to discontinue global manufacturing of Natpara by the end of 2024; references reviewed and updated.	02.21.25	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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