Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2021**
Policy Number: PA.CP.PHAR.282	**Effective Date: 01/01/2018** **Revision Date: 01/2021**
Policy Name: Parathyroid Hormone (Natpara)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2021 annual review: references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Parathyroid Hormone (Natpara)

Reference Number: PA.CP.PHAR.282
Effective Date: 10..2018
Last Review Date: 01.2021 Revision Log

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 health plans affiliated with 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: 6 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 Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.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: 6 months

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.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 policies – 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 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

- 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.; July 2020. Available at: https://www.natpara.com. Accessed October 27, 2020.
2. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed October 27, 2020.
3. 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created	10/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	
1Q 2020 annual review: references reviewed and updated.	01/2020	
1Q 2021 annual review: references reviewed and updated.	01/2021	