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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	October 25, 2015
Subject:	Natpara	**Page:**	1 of 5

Last Review Date: September 6, 2024

Natpara

Description

Natpara (parathyroid hormone)

Background
Natpara (parathyroid hormone) is a hormonal injection administered once daily that helps to regulate the body's calcium levels. Natpara is used as add-on therapy to manage hypocalcemia of hypoparathyroidism in patients who do not respond to calcium and vitamin D alone. It works by raising serum calcium through increased tubular reabsorption, increased intestinal absorption and increased bone turnover. Hypoparathyroidism is caused by loss of function of the parathyroid glands and occurs most commonly as a result of surgical removal of the parathyroid glands and more rarely as a result of autoimmune or congenital diseases (1).

Regulatory Status
FDA-approved indication: Natpara is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism (1).

Limitations of Use: (1)

1. Natpara is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone due to potential risk of osteosarcoma.
2. Natpara was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations.
3. Natpara was not studied in patients with acute post-surgical hypoparathyroidism.

Natpara has a boxed warning for risk of osteosarcoma (malignant bone tumor) that is dose and duration dependent. Patients at increased baseline risk (such as those with Paget's disease or with certain hereditary disorders) should avoid use of Natpara. Due to the unusual risk of osteosarcoma associated with Natpara, the drug is only available through a Risk Evaluation and Mitigation Strategy (REMS) program (1).

Serum calcium levels should be closely monitored when adjusting therapy due to the risk for hypercalcemia and hypocalcemia. Adjustments to calcium and vitamin D supplementation should be made accordingly. In patients who are concomitantly taking digoxin, calcium levels should be monitored more frequently due to the risk for digoxin toxicity that is associated with hypercalcemia (1).

Safety and efficacy of Natpara have not been established in pediatric patients (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Natpara may be considered **medically necessary** if the conditions indicated below are met.

Natpara may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Hypocalcemia due to hypoparathyroidism

AND ALL of the following:

1. Patient has **NOT** been controlled by calcium supplements alone or calcium supplements plus calcitriol (activated vitamin D)

2. Used in conjunction with calcium supplements alone or calcium supplements plus calcitriol (activated vitamin D)
3. Serum 25-hydroxyvitamin D level is within the normal range prior to initiation of therapy
4. Total serum calcium is above 7.5 mg/dL prior to initiation of therapy
5. Serum magnesium is within the normal range prior to initiation of therapy
6. Prescriber has been certified by Natpara REMS program

AND NONE of the following:

1. Calcium-sensing receptor mutations
2. Acute post-surgical hypoparathyroidism (within 6 months of surgery)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Hypocalcemia due to hypoparathyroidism

AND ALL of the following:

1. Used in conjunction with calcium supplements alone or calcium supplements plus calcitriol (activated vitamin D)
2. Serum 25-hydroxyvitamin D level is within the low-normal range
3. Total serum calcium is between 8-9 mg/dL, or the dose of Natpara, calcitriol, or calcium supplement is being adjusted to achieve total serum calcium levels within low-normal range
4. Serum magnesium is within the normal range

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 6 cartridges per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Natpara is recombinant parathyroid hormone used in the management of hypocalcemia secondary to hypoparathyroidism. Natpara is associated with an increased risk of osteosarcoma and is only available through a REMS program. During therapy, serum calcium levels should be monitored to assess for hypocalcemia and hypercalcemia. The safety and efficacy of Natpara in patients less than 18 years of age has not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Natpara while maintaining optimal therapeutic outcomes.

References

1. Natpara [package insert]. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; February 2023.

Policy History

Date	Action
October 2015	New Policy
December 2015	Annual review
September 2016	Annual editorial review and reference update Policy number change from 5.07.21 to 5.30.21
December 2017	Annual review and reference update
November 2018	Annual editorial review and reference update
December 2019	Annual review and reference update
June 2020	Annual editorial review. Addition of PA quantity limit per FEP
September 2021	Annual review and reference update
September 2022	Annual review
December 2022	Annual review
September 2023	Annual review and reference update
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.