PRIOR AUTHORIZATION POLICY

POLICY: Hypoparathyroidism – Natpara Prior Authorization Policy
- Natpara® (parathyroid hormone subcutaneous injection – Shire-NPS/Takeda)

REVIEW DATE: 04/24/2024; selected revision 10/30/2024

OVERVIEW

Natpara, a replica of the endogenous parathyroid hormone, is indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with **hypoparathyroidism**.[1]

Limitations of Use: Due to 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.[1] Natpara was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations; and Natpara was not studied in patients with acute post-surgical hypoparathyroidism.

Before initiating and during therapy with Natpara, 25-hydroxyvitamin D stores should be sufficient.[1] In addition, before initiating Natpara, serum calcium concentration should be > 7.5 mg/dL In the pivotal study, a responder to Natpara therapy was defined as an individual who had: ≥ 50% reduction from baseline in the dose of active vitamin D, ≥ 50% reduction from baseline in the dose of oral calcium supplementation, and an albumin-corrected total serum calcium concentration between 7.5 mg/dL and 10.6 mg/dL.

Natpara has a Boxed Warning about the potential risk of osteosarcoma.[1] Parathyroid hormone has been shown to increase the incidence of osteosarcoma in male and female rats; the risk was dependent on dose and treatment duration. A risk to humans could not be excluded. Natpara is available only through a restricted Risk Evaluation and Mitigation Strategy (REMS) program; only certified healthcare providers can prescribe and only certified pharmacies can dispense Natpara.

Note: Natpara continues to be unavailable except for select patients through a Special Use Program. On October 4, 2022, the manufacturer (Takeda) released a statement that it will discontinue manufacturing Natpara globally at the end of 2024 due to unresolved supply issues.[2] Takeda will not re-commercialized Natpara in the US (or globally). Beyond 2024, Takeda intends to supply available doses until inventory is depleted or expired.[2]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Natpara. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Natpara as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Natpara to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Natpara is recommended in those who meet the following criteria:
FDA-Approved Indication

1. **Chronic Hypoparathyroidism.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient cannot be well-controlled on calcium supplements and active forms of vitamin D alone; AND
     - **ii.** Patient's 25-hydroxyvitamin D stores are sufficient (before initiating Natpara therapy) according to the prescriber; AND
     - **iii.** Patient's serum calcium concentration is > 7.5 mg/dL before initiating Natpara therapy; AND
     - **iv.** Medication is prescribed by or in consultation with an endocrinologist or a nephrologist.
   - **B)** Patient is Currently Receiving Natpara. Approve if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient cannot be well-controlled on calcium supplements and active forms of vitamin D alone; AND
     - **ii.** Patient's 25-hydroxyvitamin D stores are sufficient (during Natpara therapy) according to the prescriber; AND
     - **iii.** Patient is responding to Natpara therapy, according to the prescriber.
       Note: Response to Natpara therapy include reduction in the patient's oral calcium dose; reduction in the patient's active vitamin D dose; maintenance of a stable albumin-corrected total serum calcium concentration.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Natpara is not recommended in the following situations:

1. **Acute Post-Surgical Hypoparathyroidism.** Natpara was not studied in patients with acute post-surgical hypoparathyroidism.

2. **Hypoparathyroidism Caused by Calcium-Sensing Receptor Mutations.** Natpara was not studied in this patient population.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Natpara® subcutaneous injection [prescribing information]. Lexington MA: Shire-NPS/Takeda; February 2023.
2. Takeda to discontinue manufacturing of Natpara®/Natpara® for patients with hypoparathyroidism at the end of 2024. Available at: https://www.takeda.com/en-us/newsroom/statements/2022/takeda-to-discontinue-manufacturing-of-natpar-natpara. Accessed on April 18, 2024.