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. There are several limitations to Natpara use: it is only recommended for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone; it was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations; and it was not studied in patients with acute post-surgical hypoparathyroidism. Natpara was studied in one randomized, double-blind, placebo-controlled pivotal study. The primary endpoint was the proportion of patients who achieved all three criteria for the composite endpoint at Week 24: ≥ 50% reduction in the oral calcium dose (from baseline), ≥ 50% reduction in the oral active vitamin D dose (from baseline), and maintenance of a stable albumin-corrected total serum calcium concentration ≥ baseline concentration and ≤ the upper limit of normal, but ideally within the target range of 2.0 to 2.25 mmol/L (8 mg/dL to 9 mg/dL). At Week 24, significantly more patients in the Natpara group achieved the primary endpoint compared with placebo: 53% vs. 2%, respectively (P < 0.0001).

REMS Program
Because of the potential risk of osteosarcoma associated with NATPARA therapy, NATPARA is available only through a restricted REMS program called the NATPARA REMS Program. Under the NATPARA REMS Program, only certified healthcare providers can prescribe and only certified pharmacies can dispense NATPARA. Further information is available at www.NATPARAREMS.com or by telephone at 1-855-NATPARA.

Policy Statement
Prior authorization is recommended for prescription benefit coverage of Natpara. All approvals are provided for 12 months in duration unless otherwise noted below.

Automation: None.

Recommended Authorization Criteria
Coverage of Natpara is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

   A) Not well-controlled on calcium supplements and active forms of vitamin D alone; AND
   B) 25-hydroxyvitamin D stores are sufficient (before initiating Natpara therapy) per the prescribing physician; AND
   C) Serum calcium concentration is > 7.5 mg/dL before initiating Natpara therapy; AND
   D) Creatinine clearance > 30 mL/min on two separate measurements OR creatinine clearance > 60 mL/min AND serum creatinine < 1.5 mg/dL; AND
E) Age >18 years; AND
F) History of hypoparathyroidism for >18 months; AND
G) Prescribed by or in consultation with an endocrinologist; AND
H) Prescribed by or in consultation with a prescriber that has fulfilled the Natpara REMS requirements for certification; AND
I) No history of Paget’s disease of bone or unexplained elevations of alkaline phosphatase; AND
J) No open epiphyses; AND
K) No hereditary disorders predisposed to osteosarcoma; AND
L) No prior history of external beam or implant radiation involving the skeleton

2. **Patient is Currently Receiving Natpara.** Approve if the patient meets ALL of the following criteria (A and B):
A) Serum calcium and 25-hydroxyvitamin D stores are sufficient (during Natpara therapy) per the prescribing physician; AND
B) The patient is responding to Natpara therapy (e.g., 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), as determined by the prescriber.

**CONDITIONS NOT RECOMMENDED FOR APPROVAL**
Natpara has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Patients with acute post-surgical hypoparathyroidism.** Natpara was only studied in patients with chronic hypoparathyroidism.

2. **Patients with 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**