Reference number(s)
2306-A

SPECIALTY GUIDELINE MANAGEMENT

NATPARA (parathyroid hormone)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Natpara is indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

Limitations 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.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
   1. Lab results confirming serum parathyroid hormone concentrations below the lower limit of normal for the laboratory reference range on 2 separate days (at least 21 days apart) within the last 12 months.
   2. Lab results confirming magnesium levels within normal laboratory limits.
   3. Lab results confirming 25-hydroxyvitamin D concentration above the lower limit of normal laboratory range.
   4. Lab results confirming serum calcium is above 7.5 mg/dL prior to initiating therapy with the requested medication.

B. Continuation of therapy requests: Lab results confirming maintenance or normalization of calcium levels compared to baseline.

III. EXCLUSIONS

Coverage will not be provided for members with the following exclusion:
Acute postsurgical hypoparathyroidism (within 6 months of surgery) and expected recovery from the hypoparathyroidism.

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2306-A

IV. CRITERIA FOR INITIAL APPROVAL

Hypocalcemia - Hypoparathyroidism
Authorization of 12 months may be granted for treatment of hypocalcemia associated with hypoparathyroidism when all of the following criteria are met:

A. Member has hypocalcemia and concomitant serum parathyroid hormone concentrations below the lower limit of normal for the laboratory reference range on at least 2 separate dates at least 21 days apart within the last 12 months.
B. Member is receiving vitamin D metabolite/analog therapy with calcitriol greater than or equal to 0.25 mcg per day or alphacalcidol greater than or equal to 0.5 mcg/day (or equivalent).
C. Member is receiving supplemental calcium treatment greater than or equal to 1000 mg/day over and above normal dietary calcium intake.
D. Serum magnesium levels are within normal laboratory limits.
E. Serum 25-hydroxyvitamin D concentration is above the lower limit of normal laboratory range.
F. Serum calcium level is greater than 7.5 mg/dL prior to initiating therapy with the requested medication.

V. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section IV who are experiencing benefit from therapy as evidenced by maintenance or normalization of calcium levels compared to baseline.

VI. REFERENCES

1. Natpara [package insert]. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; July 2020.
2. Khan MI, Waguespack SG, Hu MI. Medical management of postsurgical hypoparathyroidism. *Endocr Pract*. 2011;17(Suppl 1): 18-25.