Parathyroid hormone (Natpara®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO167

Description

Parathyroid hormone (Natpara) is subcutaneously administered, FDA-approved hormone replacement therapy for hypoparathyroidism. Parathyroid hormone acts to regulate the body's calcium levels.

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
Parathyroid hormone (Natpara)	25 mcg/dose cartridge	Adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism	2 cartridges/28 days
	50 mcg/dose cartridge		2 cartridges/28 days
	75 mcg/dose cartridge		2 cartridges/28 days
	100 mcg/dose cartridge		2 cartridges/28 days

Initial Evaluation

I. Parathyroid hormone (Natpara) may be considered medically necessary when the following criteria below are met:
   A. Member is being treated for hypocalcemia due to hypoparathyroidism; **AND**
   B. Member does not have following:
      1. Hypoparathyroidism due to calcium-sensing receptor mutations
      2. Acute post-surgical hypoparathyroidism; **AND**
   C. Member does not have a history of Page's disease of bone, open epiphyses, radiation therapy involving the skeleton, or hereditary disorders predisposing to osteosarcoma; **AND**
   D. Member has tried and failed treatment with calcium supplements and active forms of vitamin D (e.g. calcitriol); **AND**
   E. Member will be treated with this medication adjunct to calcium and vitamin D

II. Parathyroid hormone (Natpara) is considered investigational when used for all other conditions, including but not limited to:
   A. Hypoparathyroidism due to calcium-sensing receptor mutation
   B. Acute post-surgical hypoparathyroidism

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through the health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise; **AND**
III. Member has exhibited improvement or stability of disease symptoms

Supporting Evidence

I. Parathyroid hormone (Natpara) is FDA approved as adjunctive therapy with calcium + vitamin D to control hypocalcemia in patients with hypoparathyroidism.
II. Parathyroid hormone (Natpara) acts to regulate the body's calcium levels. Parathyroid hormone increases the rate of bone turnover by stimulating osteoclast and osteoblast activity, which leads to calcium resorption from bone. The net effects of parathyroid hormone are increases in serum calcium and magnesium concentration and decreased phosphate concentration.
III. Parathyroid hormone (Natpara) has not been studied in patients with hypoparathyroidism due to calcium sensing receptor mutation or patients with acute post-surgical hypoparathyroidism.
IV. Parathyroid hormone (Natpara) has a Black Box warning for use in patients with increased risk of osteosarcoma. Due to this potential risk, parathyroid hormone (Natpara) should be used only in patients who cannot be well-controlled on calcium and active forms of vitamin D.

Investigational Uses

I. Parathyroid hormone (Natpara) is not intended for use in members with hypoparathyroidism due to calcium-sensing receptor mutations, or acute post-surgical hypoparathyroidism.

References

1. Natpara [Prescribing Information]. Lexington, MA: Shire-NPS Pharmaceuticals, Inc., 2018.

Policy Implementation/Update:

Date Created	January 2015
Date Effective	January 2015
Last Updated	November 2019
Last Reviewed	11/2019

Action and Summary of Changes	Date
Criteria updated to new policy format.	11/2019