Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Natpara (parathyroid hormone)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***April 2015***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Natpara (parathyroid hormone).

Natpara (parathyroid hormone) is indicated for the treatment of hypocalcemia in patients with hypoparathyroidism.

DEFINITIONS

Vitamin D/Vitamin D Analogues Dosing

- Calcitriol: 0.5-1.0 mcg/day
- Ergocalciferol (D2): 25,000 to 100,000 IU/day
- Cholecalciferol (D3): 25,000 to 100,000 IU/day

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

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The drug, Natpara (parathyroid hormone), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. **Hypocalcemia in patients with hypoparathyroidism:**
   - Must be prescribed by or in consultation with an endocrinologist
   - Must be 18 years or older
   - Must not have Paget's disease of bone or unexplained elevations of alkaline phosphatase, hereditary disorders predisposing to osteosarcoma or prior external beam or implant radiation therapy involving the skeleton
   - Must not have hypoparathyroidism caused by calcium-sensing receptor mutations
   - Must not have acute (less than 6 months) post-surgical hypoparathyroidism
   - Must have a diagnosis of hypoparathyroidism confirmed by a recent parathyroid hormone level below the lower limit of normal (copy of laboratory reports required, must include reference range)
   - Must have a diagnosis of uncontrolled hypocalcemia while on concomitant calcium and vitamin D confirmed by the following:
     - A recent calcium level below the lower limit of normal (copy of laboratory reports required, must include reference range)
     - Chart documentation of concomitant use of calcium at a dose between 1250-3000 mg daily and oral active vitamin D at a calcitriol equivalent dose between 0.5-1 mcg daily for at least six months prior to the submitted calcium level unless there is a documented intolerance (e.g. calcifications in the kidney, brain or elsewhere, hypercalciuria, kidney stones, or reduced renal function) or contraindication

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial
Quantity Level Limit	
Natpara	2 cartridges (each containing 14 doses) per 28 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Natpara [prescribing information]. Bedminster, NJ: NPS Pharmaceuticals, Inc.; January 2015.
2. Mannstadt M, Clarke BL, Vokes T. Efficacy and safety of recombinant human parathyroid hormone (1-84) in hypoparathyroidism (REPLACE): a double-blind, placebo-controlled, randomized, phase III study. *Lancet Diabetes Endrocrinol.* 2013;1:278-83.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*