Parathyroid hormone (Natpara®)

Place of Service

Office Administration
Outpatient Facility Administration
Infusion Center Administration
Home Infusion Administration
Self-Administration

HCPCS: J3490

NDCs:

- 2 cartridges of 25 mcg/dose strength (NDC 68875-0202-2)
- 2 cartridges of 50 mcg/dose strength (NDC 68875-0203-2)
- 2 cartridges of 75 mcg/dose strength (NDC 68875-0204-2)
- 2 cartridges of 100 mcg/dose strength (NDC 68875-0205-2)

Condition listed in policy (see criteria for details)

Hypocalcemia in patients with hypoparathyroidism

AHFS therapeutic class: Parathyroid Agents Mechanism of action: Parathyroid hormone

(1) Special Instructions and pertinent Information

This drug is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

For plans with self-injectables only covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)
All requests for Natpara® (parathyroid hormone) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Hypocalcemia in patients with hypoparathyroidism

- 1. Patient is 18 years or older, AND
- 2. Natpara will be used as an adjunct to calcium and Vitamin D, AND
- 3. Patient is unable to achieve target serum calcium level (8 to 9 mg/dL) with maximally tolerated doses of oral calcium and vitamin D analogs alone

Covered Doses

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Up to 100 mcg SC daily

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Coverage Period

Indefinitely

ICD-10:

E20

(3) The following condition(s) <u>DO NOT</u> require Prior Authorization/Preservice

All requests for Natpara® (parathyroid hormone) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are-met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- The medication cartridge contains a multiple-dose, dual-chamber glass cartridge containing a sterile lyophilized powder and a sterile diluent, within a plastic cartridge holder
- Each cartridge contains 14 doses
- Four available dosage strengths: 25 mcg/dose, 50 mcg/dose, 75 mcg/dose, 100 mcg/dose

The disposable Natpara medication cartridge is designed for use with a reusable mixing device for product reconstitution and a reusable Q-Cliq pen injector for drug delivery. The Q-Cliq pen is designed to deliver a fixed volumetric dose of 71.4 μ L. Using the Q-Cliq pen, each Natpara medication cartridge delivers 14 doses.

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(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Brandi ML, Bilezikian JP, Shoback D, et al. Management of Hypoparathyroidism: Summary Statement and Guidelines. J Clin Endocrinol Metab. 2016;101(6):2273-83.
- DrugDex®. Available by subscription at <u>http://www.micromedexsolutions.com/home/dispatch</u>
- Natpara® (parathyroid hormone) [Prescribing information]. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; 7/2020.

(7) Policy Update

Date of last review: 4Q2022 Date of next review: 4Q2023

Changes from previous policy version:

No clinical change to policy following routine annual review.

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