BlueCross BlueShield Federal Employee Program

NATPARA
(parathyroid hormone)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Natpara (parathyroid hormone) is a hormonal injection administered once daily that helps to regulate the body's calcium levels. Natpara is used as add-on therapy to manage hypocalcemia of hypoparathyroidism in patients who do not respond to calcium and vitamin D alone. It works by raising serum calcium through increased tubular reabsorption, increased intestinal absorption and increased bone turnover. Hypoparathyroidism is caused by loss of function of the parathyroid glands and occurs most commonly as a result of surgical removal of the parathyroid glands and more rarely as a result of autoimmune or congenital diseases (1).

Regulatory Status

FDA-approved indication: Natpara is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism (1).

Limitations of Use: (1)

1. Natpara is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone due potential risk of osteosarcoma.
2. Natpara was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations.
3. Natpara was not studied in patients with acute post-surgical hypoparathyroidism.

Natpara has a boxed warning for risk of osteosarcoma (malignant bone tumor) that is dose and duration dependent. Patients at increased baseline risk (such as those with Paget's disease or with certain hereditary disorders) should avoid use of Natpara. Due to the unusual risk of osteosarcoma associated with Natpara, the drug is only available through a Risk Evaluation and Mitigation Strategy (REMS) program (1).

Serum calcium levels should be closely monitored when adjusting therapy due to the risk for hypercalcemia and hypocalcemia. Adjustments to calcium and vitamin D supplementation should be made accordingly. In patients who are concomitantly taking digoxin, calcium levels should be monitored more frequently due to the risk for digoxin toxicity that is associated with hypercalcemia (1).

Safety and efficacy of Natpara have not been established in pediatric patients (1).

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Summary

Natpara is recombinant parathyroid hormone used in the management of hypocalcemia secondary to hypoparathyroidism. Natpara is associated with an increased risk of osteosarcoma and is only available through a REMS program. During therapy, serum calcium levels should be monitored to assess for hypocalcemia and hypercalcemia. The safety and efficacy of Natpara in patients less than 18 years of age has not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Natpara while maintaining optimal therapeutic outcomes.

References

1. Natpara [package insert]. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; February 2023.