

DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Bone Modifiers – Teriperatide Drug Quantity Management Policy – Per Days

- Forteo® (teriparatide subcutaneous injection – Eli Lilly)
- Teriparatide subcutaneous injection – Alvogen

REVIEW DATE: 04/27/2022

OVERVIEW

Teriparatide products, which are parathyroid hormone analogs (PTH 1-34), are indicated for the following uses:^{1,2}

- **Glucocorticoid-induced osteoporosis (treatment)**, in men and women at high risk for fracture associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone).
- **Osteoporosis, treatment of postmenopausal women** at high risk for fracture.
- **Osteoporosis, to increase bone mass in men with primary or hypogonadal osteoporosis** at high risk for fracture.

Teriparatide has been used for patients with hypoparathyroidism.³⁻⁶ Natpara® (parathyroid hormone subcutaneous injection) is indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism. However, there is a recall of Natpara and teriparatide is one of two main alternatives recommended in a joint guidance statement from the American Society for Bone and Mineral Research and Endocrine Society for patients with hypoparathyroidism transitioning from Natpara.³

Dosing

The recommended dose of teriparatide in osteoporosis is 20 mcg given subcutaneously (SC) once daily (QD).^{1,2} The use of teriparatide for > 2 years during a patient's lifetime for the FDA-approved indications should only be considered if a patient remains at or has returned to having a high risk for fracture.

For hypoparathyroidism, teriparatide has been studied at a dose of 20 mcg twice daily (BID), but higher doses (up to 100 mcg given daily or every other day) have also been used.⁴⁻⁶

Availability

Forteo is available as a prefilled pen in the following strength: 600 mcg/2.4 mL (250 mcg/mL) [containing 28 daily doses of 20 mcg].¹ Teriparatide is available as a prefilled pen in the following strength: 620 mcg/2.48 mL (250 mcg/mL) [containing 28 daily doses of 20 mcg].²

POLICY STATEMENT

This Drug Quantity Management program has been developed to manage potential premature dose escalation of teriparatide. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 2 years in duration.

Automation: None.

Drug Quantity Limits

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The quantity limit is specific to the specific chemical entity for all strengths combined. Exceptions are allowed for patients using teriparatide for the treatment of hypoparathyroidism.

Product	Strength and Form	Maximum Quantity per 28 Days
Forteo® (teriparatide subcutaneous injection)	600 mcg/2.4 mL prefilled pen (28 daily doses of 20 mcg)	1 pen
Teriparatide subcutaneous injection	620 mcg/2.48 mL prefilled pen (28 daily doses of 20 mcg)	1 pen

CRITERIA

Forteo 600 mcg/2.4 ml pen or Teriparatide 620 mcg/2.48 ml pen

1. If the request is for the treatment of hypoparathyroidism, approve up to 5 pens per 28 days.

Note: This is a quantity sufficient to provide 100 mcg per day for 28 days.

REFERENCES

1. Forteo® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; September 2021.
2. Teriparatide subcutaneous injection [prescribing information]. Morristown, NJ: Alvogen; November 2019.
3. Joint American Society for Bone and Mineral Research (ASBMR) and Endocrine Society guidance on transitioning hypoparathyroidism patients from Natpara. Available at: [Joint American Society for Bone and Mineral Research \(ASBMR\) – Endocrine Society Guidance on Transitioning Hypoparathyroidism Patients from NATPARA® - American Society for Bone and Mineral Research](#). Accessed on April 19, 2022.
4. Marucci G, Masi L, Cianferotti L, et al. Chronic hypoparathyroidism and treatment with teriparatide. *Endocrine*. 2021;72:249-259.
5. Bernardor J, Flammier S, Cabet S, et al. Intermittent bi-daily sub-cutaneous teriparatide administration in children with hypoparathyroidism: a single-center experience. *Experience Front Pediatr*. 2021;9:764040.
6. Winer KK. Advances in the treatment of hypoparathyroidism with PTH 1-34. *Bone*. 2019;120:535-541.