DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Bone Modifiers – Teriparatide Drug Quantity Management Policy – Per Days
- Forteo® (teriparatide subcutaneous injection – Eli Lilly)
- Teriparatide subcutaneous injection (Alvogen)

REVIEW DATE: 05/03/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.[3-8] 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 600 mcg/2.4 mL (250 mcg/mL) prefilled pen, containing 28 daily doses of 20 mcg each.[1] Teriparatide is available as a 620 mcg/2.48 mL (250 mcg/mL) prefilled pen, containing 28 daily doses of 20 mcg each.[2]

POLICY STATEMENT

This Drug Quantity Management program has been developed to manage potential premature dose escalation of teriparatide. The quantity limit is specific to the specific chemical entity for all strengths combined. 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 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
Forteo® (teriparatide subcutaneous injection)	600 mcg/2.4 mL prefilled pen (28 daily doses of 20 mcg)	2.4 mL (1 pen)	7.2 mL (3 pens)
Teriparatide subcutaneous injection	620 mcg/2.48 mL prefilled pen (28 daily doses of 20 mcg)	2.48 mL (1 pen)	7.44 mL (3 pens)

Bone Modifiers – Teriparatide Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Forteo 600 mcg/2.4 mL pen

1. If the request is for the treatment of hypoparathyroidism, approve the requested quantity, not to exceed 12 mL (5 pens) per 28 days at retail or 36 mL (15 pens) per 84 days at home delivery.
   Note: This is a quantity sufficient to provide 100 mcg per day.

Teriparatide 620 mcg/2.48 mL pen

1. If the request is for the treatment of hypoparathyroidism, approve the requested quantity, not to exceed 12.4 mL (5 pens) per 28 days at retail or 37.2 mL (15 pens) per 84 days at home delivery.
   Note: This is a quantity sufficient to provide 100 mcg per day.

REFERENCES

1. Forteo® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; September 2021.
2. Teriparatide subcutaneous injection [prescribing information]. Morristown, NJ: Alvogen; October 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 March 23, 2023.
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.
7. Puliani G, Hasenmajer V, Simonelli I, et al. Safety and efficacy of PTH 1-34 and 1-84 therapy in chronic hypoparathyroidism: a meta-analysis of prospective trials. J Bone Min Res. 2022;37(7):1233-1250.
8. Khan AA, Guyatt G, Ali DS, et al. Management of hypoparathyroidism. J Bone Min Res. 2022;37(12):2663-2667.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Removed reference to Bonsity. Pfenex has granted Alvogen the exclusive rights to commercialize and manufacture teriparatide Injection (previously referred to as PF708 and Bonsity).	03/11/2021
Annual Revision	Forteo 600 mcg/2.4 ml pen or Teriparatide 620 mcg/2.48 ml pen. The table for weight-based dosing was removed. The override criteria were changed from a weight-based approach to allow an override for 5 pens in patients being treated for hypoparathyroidism to accommodate 100 mcg per day dosing. The duration of approval was changed from "2 years in the patients lifetime" to 2 years (patients could continue to receive in 2-year intervals).	04/27/2022
Annual Revision	Approval duration was changed from 2 years to 1 year. Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	05/03/2023