DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 04/30/2025; selected revision 06/25/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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:[1-3]
- **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.

In general, for all indications, patients at high risk for fracture are defined as those with a history of osteoporotic fractures, have multiple risk factors for fracture, or have failed or are intolerant to other osteoporosis therapy.[1-3]

Dosing

The recommended dose of teriparatide in osteoporosis is 20 mcg given subcutaneously (SC) once daily (QD).[1-3] 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.

Availability

Bonsity and Forteo (generic) are available as a 560 mcg/2.24 mL (250 mcg/mL) prefilled pens, containing 28 daily doses of 20 mcg each.[1,2] Teriparatide is available as a 620 mcg/2.48 mL (250 mcg/mL) prefilled pen, containing 28 daily doses of 20 mcg each.[3]

POLICY STATEMENT

This Drug Quantity Management program has been developed to manage potential premature dose escalation of the teriparatide products. 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
Bonsity® (teriparatide subcutaneous injection)	560 mcg/2.24 mL prefilled pen	2.24 mL (1 pen)	6.72 mL (3 pens)
Forteo® (teriparatide subcutaneous injection, generic)	560 mcg/2.24 mL prefilled pen (28 daily doses of 20 mcg)	2.24 mL (1 pen)	6.72 mL (3 pens)
Teriparatide subcutaneous injection	620 mcg/2.48 mL prefilled pen (28 daily doses of 20 mcg)	1 pen (2.48 mL)	3 pens (7.44 mL)

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Bonsity and Teriparatide (Forteo, generic) 560 mcg/2.24 mL pens
No override recommended.

Teriparatide 620 mcg/2.48 mL pen
No override recommended.

REFERENCES

1. Forteo® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; July 2024.
2. Bonsity® subcutaneous injection [prescribing information]. Morristown, NJ: Alvogen; January 2025.
3. Teriparatide subcutaneous injection [prescribing information]. Morristown, NJ: Alvogen; January 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
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
Annual Revision	No criteria changes.	05/15/2024
Annual Revision	**Teriparatide 560 mcg/2.24 mL pen (Forteo, generic):** The FDA updated this product from 600 mcg/2.4 mL pens to 560 mcg/2.24 mL pens. The quantity limit was updated to 2.24 mL (1 pen) per 28 days at retail and 6.72 mL (3 pens) per 84 days at home delivery for the new 560 mcg/2.24 mL pens. Previously, the quantity limits were 2.4 mL (1 pen) per 28 days at retail and 7.2 mL (3 pens) per 84 days at home delivery for the 600 mcg/2.4 mL pens. Override criteria were removed. No overrides apply to the updated quantity limits.	04/30/2025
Selected Revision	**Bonsity 560 mcg/2.24 mL pen:** New quantity limits were added to the policy of 2.24 mL (1 pen) per 28 days at retail and 6.72 mL (3 pens) per 84 days at home delivery. No overrides apply.	06/25/2025