



## Drug Quantity Management – Per Days

### Teriparatide injection (Forteo<sup>®</sup>, Bonsity<sup>™</sup>, Teriparatide [branded generic])

### Duration Limit

#### Table of Contents

National Formulary Medical Necessity .....	1
Conditions Not Covered.....	2
Background.....	2
References .....	2
Revision History .....	2

#### Product Identifier(s)

79965

#### 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.

#### National Formulary Medical Necessity

##### Forteo 600 mcg/2.4 ml pen

Maximum quantity per 28 days = 1 pen

##### Bonsity/Teriparatide 620 mcg/2.48 ml pen

Maximum quantity per 28 days = 1 pen

A quantity of one Forteo 600 mcg/2.4 ml pen or one Bonsity/Teriparatide 620 mcg/2.48 ml pen every 28 days will be allowed without coverage review. This is enough drug for a 28-day supply of 20 mcg/day for 28 days. The quantity limit is specific to the specific chemical entity for all strengths combined. Exceptions are allowed for individuals using teriparatide for the treatment of hypoparathyroidism.

The objective of this program is to manage potential premature dose escalation of Forteo or Bonsity/Teriparatide in the treatment of postmenopausal women with osteoporosis at high risk for fracture, to increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, or treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture.

## Criteria

**Cigna covers quantities as medically necessary when the following criteria are met:**

All approvals are provided for 2 years in duration.

### **Forteo 600 mcg/2.4 ml pen or Bonsity/Teriparatide 620 mcg/2.48 ml pen**

- For individuals using Forteo or Bonsity/Teriparatide for the treatment of hypoparathyroidism, the following quantities in the table below may be approved per 28 days based on weight for up to two years.

Weight	Override Quantity per 28 Days of either Forteo or Bonsity/Teriparatide
Up to 28.5 kg	No override recommended
>28.5 kg to 57 kg	2 pens (Forteo – 4.8 ml or Bonsity – 4.96 ml)
>57 kg to 85.7 kg	3 pens (Forteo – 7.2 ml or Bonsity – 7.44 ml)
>85.7 kg to 114.3 kg	4 pens (Forteo – 9.6 ml or Bonsity – 9.92 ml)
>114.3 kg to 142.8 kg	5 pens (Forteo – 12 ml or Bonsity – 12.4 ml)
>142.8 kg to 183.6 kg	6 pens (Forteo – 14.4 ml or Bonsity – 14.88 ml)

## Conditions Not Covered

Any other exception is considered not medically necessary.

## Background

### Overview

Forteo, Bonsity/Teriparatide are parathyroid analogs that are indicated for:<sup>1,2,3</sup>

- Treatment of postmenopausal women with osteoporosis at high risk for fracture.
- Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture.
- Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture.

Teriparatide (Forteo, Bonsity/Teriparatide) have been studied in the treatment of hypoparathyroidism at a dose of 0.7 mcg/kg/day either as a single daily dose or twice daily administration.<sup>3</sup>

### Dosing

Forteo and Bonsity/Teriparatide are administered by subcutaneous injection into the thigh or abdominal wall. The safety and efficacy of Forteo and Bonsity/Teriparatide have not been evaluated beyond 2 years of treatment. Consequently, use of teriparatide for more than 2 years during an individual's lifetime is not recommended.

## References

- Forteo® [prescribing information]. Indianapolis, IN: Eli Lilly and Company; October 2019.
- Bonsity™ [prescribing information]. San Diego, CA: Pfenex, Inc.; October 2019.
- Teriparatide [prescribing information]. Morristown, NJ: Alvogen, Inc.; November 2019.
- Winer K, Yanovski JA, Sarani B, et al., A Randomized, Cross-Over Trial of Once-Daily Versus Twice-Daily Parathyroid Hormone 1–34 in Treatment of Hypoparathyroidism. *J Clin Endocrinol Metab.* 1998;83:3480-3486.

## Revision History

Type of Revision	Summary of Changes	Date
Selected Revision	Add branded generic teriparatide.	08/28/2020

---

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Cigna Behavioral Health, Inc., Cigna Health Management, Inc., QualCare, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2021 Cigna.