

## Pharmacy Policy Bulletin

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**Title:** Teriparatide (Forteo®)

**Policy #:** Rx.01.87

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

### ▾ Intent:

The intent of this policy is to communicate the medical necessity criteria for **teriparatide (Forteo®)** as provided under the member's pharmacy benefit.

### ▾ Description:

**Parathyroid hormone (PTH) and calcitriol are the two major hormones that regulate calcium and phosphate homeostasis. PTH maintains serum ionized calcium concentrations in a narrow range by stimulating renal tubular calcium reabsorption and bone resorption. Chronic exposure to high PTH results in bone resorption, however intermittent administration of recombinant human PTH stimulates bone formation to a greater extent than resorption, at least over the first 12 months of therapy. While PTH is an effective treatment for osteoporosis, it is generally not a first line drug due to route of administration (subcutaneous), long-term safety concerns, and availability of other agents.**

**Teriparatide** is recombinant human PTH.

**Teriparatide (Forteo®)** is indicated:

- A. For the treatment of postmenopausal women with osteoporosis who are at high risk for fracture. These include women with a history of osteoporotic fracture, or who have multiple risk factors for fracture, or who have failed or are intolerant of previous osteoporosis therapy, based upon physician assessment.
- B. To increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture. These include men with a history of osteoporotic fracture, or who have

multiple risk factors for fracture, or who have failed or are intolerant to previous osteoporosis therapy, based upon physician assessment.

- C. For treatment of osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture.

#### ▸ Policy:

##### **Initial Authorization:**

**Teriparatide (Forteo®)** is approved when ALL of the following inclusion criteria are met:

1. The member is 18 years of age or older
2. Diagnosis of ONE of the following:
  - a. Postmenopausal osteoporosis
  - b. Primary or hypogonadal osteoporosis in men
  - c. Glucocorticoid- induced osteoporosis in men or women (daily dose greater than or equal to 5mg prednisone or equivalent for at least 3 months)
3. Member is high risk for fracture defined by ONE of the following:
  - a. History of osteoporotic fractures
  - b. Multiple risk factors for a fracture
4. Documentation of inadequate response with at least one of the following osteoporosis therapies:
  - a. Bisphosphonates
  - b. Hormone replacement therapy
  - c. Selective-estrogen receptor modulators (SERM's)
  - d. Calcitonin-salmon (miacalcin)

**Continuation criteria:** Member does not exceed cumulative therapy of 2 years in their life time

**Duration of approval:** Initial and continuation authorization: 1 year

\* Osteoporosis defined as T score of the individual's bone mineral density (BMD) is at least -2.5 standard deviations below the young adult mean OR history of osteoporotic fracture (i.e. hip, spine, etc.)

#### ▸ Black Box Warning:

In male and female rats, teriparatide caused an increase in the incidence of osteosarcoma (a malignant bone tumor) that was dependent on dose and treatment duration. The effect was observed at systemic exposures to teriparatide ranging from 3 to 60 times the exposure in humans given a 20-mcg dose. Because of the uncertain relevance of the rat osteosarcoma finding to humans, prescribe teriparatide only for patients for whom the potential benefits are considered to outweigh the potential risk. Teriparatide should not be prescribed for patients who are at increased baseline risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton).

#### ▸ Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

## **BENEFIT APPLICATION**


Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**

Forteo (teriparatide) [package insert]. Indianapolis, IN. Lilly USA, LLC. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=aae667c5-381f-4f92-93df-2ed6158d07b0&type=display>. Accessed February 14, 2017.

Rosen CJ. Parathyroid hormone therapy for osteoporosis. UpToDate. July 2016. Available at: [https://www.uptodate.com/contents/parathyroid-hormone-therapy-for-osteoporosis?source=search\\_result&search=teriparatide&selectedTitle=4~150](https://www.uptodate.com/contents/parathyroid-hormone-therapy-for-osteoporosis?source=search_result&search=teriparatide&selectedTitle=4~150). Accessed February 14, 2017.

**Applicable Drugs:**

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Forteo	teriparatide

**Cross References:**

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<b>Policy Version Number:</b>	6.00
<b>P&amp;T Approval Date:</b>	January 12, 2017
<b>Policy Effective Date:</b>	March 01, 2017
<b>Next Required Review Date:</b>	January 12, 2018

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