

## Policies Repository



**Policy Title** Teriparatide (Forteo™) (rDNA origin) Injection

**Policy Number** FS.CLIN.38

*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 edits. 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. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. 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.*

**Policy**

**Teriparatide (Forteo®)** is indicated 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. Forteo is also indicated 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. Forteo is also indicated for treatment of osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture.

The use of teriparatide (Forteo®) requires prior authorization (ie, clinical pharmacy and/or Medical director review).

**Policy Description**

**Teriparatide (Forteo)** contains recombinant human parathyroid hormone (PTH). PTH is the primary regulator of calcium and phosphate metabolism in the bone and kidneys. It regulates bone metabolism, renal tubular reabsorption of calcium and phosphate, and intestinal absorption of calcium. The biological actions of PTH and teriparatide (Forteo) are mediated through binding to specific high-affinity cell-surface receptors. Teriparatide (Forteo) and the amino acids of PTH bind to these receptors with the same affinity and have the same physiological effects on the bones and kidneys. Daily usage has been shown to stimulate new bone formation on trabecular and cortical bone surfaces by preferentially stimulating osteoblastic activity over osteoclastic activity. The anabolic effect (promoting growth) seen in humans includes increased skeletal mass and increased markers of bone formation and resorption, as well as increased bone strength. Forteo has been associated with an increased incidence of osteosarcoma in rats. There is an uncertain relevance of the rat osteosarcoma to humans.

**Policy Guideline Inclusion**

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

- Documentation that the patient is 18 years of age or older
- Documented diagnosis of **one** of the following:
  - Primary (postmenopausal) or hypogonadal osteoporosis
  - Osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture
- Documentation of failure or intolerance with at least **one** of the following osteoporosis therapies
  - Bisphosphonates
  - Hormone replacement therapy
  - Selective-estrogen receptor modulators (SERM's)
  - Calcitonin-salmon (miacalcin)
- No documentation of a contraindication to Forteo
- Documentation of **one** of the following:
  - Osteoporotic fractures
  - History of osteoporotic fractures
  - Multiple risk factors for a fracture

**Policy Guideline Exclusion**

**Teriparatide (Forteo®)** is denied when **any** of the following exclusion criteria is present:

- No documentation that the patient is 18 years of age or older
- No documented diagnosis of **one** of the following:
  - Primary (postmenopausal) or hypogonadal osteoporosis
  - Osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture
- No documentation of failure or intolerance with at least **one** of the following
  - Bisphosphonates
  - Hormone replacement therapy
  - Selective-estrogen receptor modulators (SERM'S)
  - Calcitonin-salmon (miacalcin)
- Documentation of a contraindication to Forteo
- No Documentation of **one** of the following:
  - Osteoporotic fractures
  - History of osteoporotic fractures
  - Multiple risk factors for a fracture

**Policy List of Applicable Drugs**

Brand Name	Generic Name
Forteo	teriparatide

**Dosing and Administration**

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

**Policy References**

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Highmark Medicare Services. Drugs & Biologicals: Self-Administered Drug Exclusions. [Highmark Medicare Services Web site]. Available at: <http://www.highmarkmedicareservices.com/drug-bio/drug-self.html>.

Accessed October 15, 2008.

Micromedex® Healthcare Series [online through STAT! Ref]. Greenwood Village, CO: Thomson Micromedex. Teriparatide. Available at: <http://www.thomsonhc.com>. Accessed June 17, 2010.

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World Health Organization (WHO). Assessment of fracture risk and its application to screening for postmenopausal osteoporosis: Report of a WHO study group. WHO Technical Report Series 843. Geneva, Switzerland: WHO; 1994. Available at: [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_843.pdf](http://whqlibdoc.who.int/trs/WHO_TRS_843.pdf). Accessed October 15, 2008.

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## Policy Link to Related Policies

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