

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## Forteo (teriparatide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	2 years

Medications	Quantity Limit
Forteo (teriparatide) Injection pen	May be subject to quantity limit

### APPROVAL CRITERIA

Requests for Forteo (teriparatide) may be approved for the following:

- I. Individual has one of the following:
  - A. Individual is a postmenopausal female with a diagnosis of osteoporosis [defined as bone mineral density (BMD) T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture)]at high risk for fracture<sup>1</sup>; **OR**
  - B. Individual is a male diagnosed with primary or hypogonadal osteoporosis [defined as BMD T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young-adult reference population OR a clinical diagnosis based on a history of a low trauma fracture (fragility fracture)]at high risk for fracture<sup>1</sup> using to increase bone mass; **OR**
  - C. Individual has a diagnosis of osteoporosis [defined as BMD T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young-adult reference population OR a clinical diagnosis based on history of low trauma fracture (fragility fracture)] associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone for at least 3 months) at high risk for fracture<sup>1</sup>.

### **AND**

- II. Individual meets one of the following:
  - A. Has been refractory to a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of a preferred oral bisphosphonate; **OR**

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Preferred agents: Alendronate tablet (generic Fosamax), alendronate oral solution (generic Fosamax oral solution)

- B. Is intolerant to or has a contraindication to oral bisphosphonate as defined by:
1. Hypersensitivity to TWO oral bisphosphonates (one of which must be alendronate); **OR**
  2. Inability to stand or sit upright for at least 30 minutes; **OR**
  3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, atrophic gastritis, etc.); **OR**
  4. Uncorrected hypocalcemia; **OR**
  5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents or creatinine clearance less than 30 mL/min for risedronate and ibandronate;

**AND**

- III. Individual is not using Forteo (teriparatide) in combination with any of the following:
- A. Prolia (denosumab);
  - B. Bisphosphonates;
  - C. Evista (raloxifene);
  - D. Miacalcin/Fortical (calcitonin nasal spray);
  - E. Reclast (zoledronic acid);
  - F. Tymlos (abaloparatide);

**AND**

- IV. Individual has utilized Forteo (teriparatide) and Tymlos (abaloparatide) for a combined total duration of less than 24 months in their lifetime.

**Notes:**

1. High risk for fracture is defined as the following:
  - A. History of osteoporotic fracture; or
  - B. Multiple risk factors for fractures including but not limited to: Prior low-trauma fracture as an adult, advanced age, gender, ethnicity, low bone mineral density, low body weight, family history of osteoporosis, use of glucocorticoids (daily dosage equivalent to 5mg per day or greater prednisone for at least 3 months), cigarette smoking, excessive alcohol consumption (3 or more drinks/day), secondary osteoporosis (such as,

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rheumatoid arthritis), early menopause, height loss or kyphosis, fall risk and low calcium intake; ; or

C. Failure or intolerance to other osteoporosis therapies.

2. In the absence of fragility fracture, BMD T-Scores > -2.5 (closer to 0 or positive) are NOT considered osteoporotic.
3. Requests to continue therapy beyond 24 months (2 years) should NOT be approved. [The safety and efficacy of Forteo have not been evaluated beyond 2 years of treatment. The use of the drug for more than 2 years during a patient’s lifetime is NOT recommended [Forteo Product Information, 2013].
4. Forteo (teriparatide) has a black box warning for potential risk of osteosarcoma. In rates, an increase in the incidence of osteosarcoma (malignant bone tumor dependent on dose and treatment duration has been identified with uncertain relevance to humans. Forteo should not be prescribed for individuals 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 adults with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton).

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis – 2016. *Endocrine Practice*. 2016;22(4):1-42.

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: December 29, 2017.

DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2017. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.