Clinical Pharmacy Program Guidelines for Forteo™

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<tr>
<th>Program</th>
<th>Prior Authorization</th>
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<tbody>
<tr>
<td>Medication</td>
<td>Forteo™ (teriparatide)</td>
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<tr>
<td>Pharmacy and Therapeutics</td>
<td></td>
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<tr>
<td>Approval Date</td>
<td>9/2016</td>
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<tr>
<td>Effective Date</td>
<td>11/2016</td>
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1. **Background:**

   Forteo (teriparatide) is a recombinant human parathyroid hormone, which has three FDA approved indications:¹

   - **Treatment of postmenopausal women with osteoporosis at high risk of fracture**

     Forteo is indicated for the treatment of postmenopausal women with osteoporosis who are at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

   - **Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture**

     Forteo is indicated to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

   - **Treatment of men and women with glucocorticoid-induced osteoporosis at high risk for fracture**

     Forteo is indicated for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

     Available literature defines high risk for fracture as bone mineral density (BMD) T-scores of -3.5 or less, while it defines severe osteoporosis as T-scores of -2.5 or less with at least one fragility fracture.²⁻⁹ The leading study of Forteo for treatment of glucocorticoid-induced osteoporosis allowed high-risk patients using the following
inclusion criteria: a history of prednisone or its equivalent at a dose ≥ 5 mg/day for ≥ 3 months, and a T-score ≤ -2.0 or a T-score ≤ -1.0 with a history of fragility fracture.¹

Potential candidates for parathyroid therapy include:⁵⁻⁶,⁹

- Men or postmenopausal women with severe osteoporosis (T-score of -3.5 or below even in the absence of fractures; T-score of -2.5 or below plus a fragility fracture)
- Patients with osteoporosis who are unable to tolerate bisphosphonates or who have relative contraindications to bisphosphonates (achalasia, scleroderma esophagus, esophageal strictures)
- Patients who fail other osteoporosis therapies (fracture with loss of bone mineral density [BMD] in spite of compliance with therapy)

The safety and efficacy of Forteo have not been evaluated beyond 2 years of treatment. Consequently, use of the drug for more than 2 years during a patient’s lifetime is contraindicated.¹

Coverage will be provided for members who meet the following criteria.

2. **Coverage Criteria:**

<table>
<thead>
<tr>
<th>A. Postmenopausal women with osteoporosis or men with primary or hypogonadal osteoporosis at high risk for fracture</th>
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<tbody>
<tr>
<td>1. <strong>Forteo</strong> will be approved based on <strong>all</strong> of the following criteria:</td>
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ii. **One** of the following:

   a. History of **one** of the following resulting from minimal trauma:
      - Vertebral compression fracture
      - Fracture of the hip
      - Fracture of the distal radius

   -OR-

   b. History of failure, contraindication, or intolerance to **both** of the following:
      - A bisphosphonate [e.g., Fosamax (alendronate)]
      - Prolia (denosumab)

   -OR-

   (b) **Both** of the following:

   i. History of **one** of the following resulting from minimal trauma:
      - Vertebral compression fracture
      - Fracture of the hip
      - Fracture of the distal radius

   -AND-

   ii. History of failure, contraindication, or intolerance to **both** of the following:
      - A bisphosphonate [e.g., Fosamax (alendronate)]
      - Prolia (denosumab)

   -AND-

   c. Treatment duration has not exceeded a total of 24 months during the patient’s lifetime

Authorization will be issued for 24 months. (Duration of coverage will be limited to 24 months of teriparatide therapy in the member’s lifetime.)

B. **Glucocorticoid-induced osteoporosis at high risk for fracture**

1. **Forteo** will be approved based on **all** of the following criteria:
a. Diagnosis of glucocorticoid-induced osteoporosis

-AND-

b. History of prednisone or its equivalent at a dose ≥ 5 mg/day for ≥ 3 months

-AND-

c. **One** of the following:

   (1) BMD T-score ≤ -2.0 based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site).

   -OR-

   (2) **Both** of the following:

      (a) BMD T-score between -1.0 and -2.0 (-2.0 > BMD T-score ≤ -1.0) based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site).

      -AND-

      (b) **One** of the following:

         i. History of **one** of the following resulting from minimal trauma:

            • Vertebral compression fracture
            • Fracture of the hip
            • Fracture of the distal radius

         -OR-

         ii. History of failure, contraindication, or intolerance to **one** conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)]

         -OR-

   (3) **Both** of the following:

      (a) History of **one** of the following resulting from minimal trauma:

         i. Vertebral compression fracture
         ii. Fracture of the hip
         iii. Fracture of the distal radius
(b) History of failure, contraindication, or intolerance to one conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)]

AND

d. Treatment duration has not exceeded a total of 24 months during the patient's lifetime

Authorization will be issued for 24 months. (Duration of coverage will be limited to 24 months of teriparatide therapy in the member’s lifetime.)

3. References:


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<tr>
<th>Program</th>
<th>Prior Authorization -Forteo™ (teriparatide)</th>
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<tbody>
<tr>
<td><strong>Change Control</strong></td>
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<tr>
<td>Date</td>
<td>Change</td>
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<tr>
<td>12/2010</td>
<td>Annual Review</td>
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<tr>
<td>12/2012</td>
<td>Annual Review. Revisions made to Postmenopausal women with osteoporosis or men with primary or hypogonadal osteoporosis at high risk for fracture and glucocorticoid-induced osteoporosis at high risk for fracture criteria based on currently available literature. Added background section for National Guidelines. Updated References.</td>
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<tr>
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<td>Background revisions and removal of prescriber’s notes. No change to clinical criteria</td>
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<tr>
<td>9/2015</td>
<td>Added requirement for trial and failure of Prolia (denosumab) in addition to a bisphosphonate for postmenopausal women with osteoporosis or men with primary or hypogonadal osteoporosis at high risk for fracture, except for patients with a T score of -3.5 or less.</td>
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<tr>
<td>9/2016</td>
<td>Updated policy template</td>
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