Clinical Policy: Teriparatide (Forteo)
Reference Number: ERX.SPA.63
Effective Date: 10.01.16
Last Review Date: 02.19

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Teriparatide (Forteo®) is a recombinant human parathyroid hormone (PTH) analog.

FDA Approved Indication(s)
Forteo is indicated:
• For the treatment of postmenopausal women with osteoporosis at high risk for fracture*. In postmenopausal women with osteoporosis, Forteo reduces the risk of vertebral and nonvertebral fractures
• To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture*
• 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*

*High risk of fracture is 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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Forteo is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Osteoporosis (must meet all):
      1. Diagnosis of osteoporosis;
      2. Age ≥ 18 years or documentation of closed epiphyses;
      3. Member meets one of the following (a or b):
         a. Prescribed by or in consultation with one of the following specialists: gynecologist, endocrinologist, rheumatologist, geriatrician, orthopaedist, or physiatrist;
         b. Failure of a 12-month trial of a bisphosphonate (alendronate is preferred) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
      4. Member has not received cumulative therapy on PTH analogs (e.g., Tymlos®, Forteo) that exceeds 2 years;
      5. Dose does not exceed 20 mcg per day (1 pen every 28 days).
      Approval duration: 6 months (limited to 2 years cumulative use of PTH analogs per lifetime)

   B. Other diagnoses/indications
      1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
   A. Osteoporosis (must meet all):
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1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member has not received cumulative therapy on PTH analogs (e.g., Tymlos, Forteo) that exceeds 2 years;
4. If request is for a dose increase, new dose does not exceed 20 mcg per day (1 pen every 28 days).

Approval duration: 12 months (limited to 2 years cumulative use of PTH analogs per lifetime)

B. Other diagnoses/indications (must meet 1 or 2):
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:
A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents

IV. Appendices/General Information
Appendix A: Abbreviation/Acronym Key
BMD: bone mineral density
FDA: Food and Drug Administration
PTH: parathyroid hormone

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>alendronate (Fosamax&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>Osteoporosis 10 mg PO QD or 70 mg PO q week</td>
<td>Osteoporosis 10 mg/day or 70 mg/week</td>
</tr>
<tr>
<td></td>
<td>Glucocorticoid-induced osteoporosis 5 mg PO QD or 10 mg PO QD (in postmenopausal women not receiving estrogen)</td>
<td>Glucocorticoid-induced osteoporosis 5 mg/day or 10 mg/day (in postmenopausal women not receiving estrogen)</td>
</tr>
<tr>
<td></td>
<td>Osteoporosis prophylaxis 5 mg PO QD or 35 mg PO q week</td>
<td>Osteoporosis prophylaxis 5 mg/day or 35 mg/week</td>
</tr>
<tr>
<td>Fosamax&lt;sup&gt;®&lt;/sup&gt; Plus D (alendronate/cholecalciferol)</td>
<td>Osteoporosis 70 mg alendronate/2,800 units cholecalciferol or 70 mg alendronate/5,600 units cholecalciferol PO q week</td>
<td>Osteoporosis 70 mg alendronate/5,600 units cholecalciferol/week</td>
</tr>
<tr>
<td>risedronate (Actonel&lt;sup&gt;®&lt;/sup&gt;, Atelvia&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>Osteoporosis (including prophylaxis) 5 mg PO QD or 35 mg PO q week or 75 mg PO QD for 2 consecutive days for 2 doses/month or 150 mg PO q month</td>
<td>Osteoporosis (including prophylaxis) 5 mg/day or 35 mg/week or 75 mg/day for 2 days per month or 150 mg/month</td>
</tr>
<tr>
<td></td>
<td>Glucocorticoid-induced osteoporosis 5 mg PO QD</td>
<td></td>
</tr>
</tbody>
</table>
### Clinical Policy

**Teriparatide**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
</table>
| zoledronic acid (Reclast<sup>®</sup>) | Postmenopausal osteoporosis, men with osteoporosis, glucocorticoid-induced osteoporosis 5 mg IV q year  
Postmenopausal osteoporosis prophylaxis 5 mg IV q 2 years | Postmenopausal osteoporosis, men with osteoporosis, glucocorticoid-induced osteoporosis 5 mg/year  
Postmenopausal osteoporosis prophylaxis 5 mg/2 years |
| ibandronate (Boniva<sup>®</sup>) | Postmenopausal osteoporosis 150 mg PO q month or 3 mg IV every 3 months  
Postmenopausal osteoporosis prophylaxis 150 mg PO q month | 150 mg/month or 3 mg/3 months |

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

**Appendix C: Contraindications/Boxed Warnings**
- Contraindication(s): hypersensitivity
- Boxed warning(s): risk of osteosarcoma

**Appendix D: General Information**
- The World Health Organization uses the following classifications for osteoporosis and osteopenia:

<table>
<thead>
<tr>
<th>Category</th>
<th>T-score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>-1.0 or above</td>
</tr>
<tr>
<td>Low bone mass (osteopenia)</td>
<td>Between -1.0 and -2.5</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>-2.5 or below</td>
</tr>
</tbody>
</table>
- Men with hypogonadal osteoporosis are defined as those who are receiving testosterone therapy but remain at high risk for fracture, or those who have a contraindication to testosterone therapy.

**V. Dosage and Administration**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoporosis</td>
<td>20 mcg SC QD</td>
<td>20 mcg/day for up to 2 years cumulative use of PTH analogs per lifetime</td>
</tr>
</tbody>
</table>

**VI. Product Availability**
- Multi-dose prefilled pen (2.4 mL): 28 daily doses of 20 mcg

**VII. References**

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy split from USS.CP.PHAR.20 Osteoporosis Injectable Therapy and converted to new template.</td>
<td>07.16</td>
<td>09.16</td>
</tr>
<tr>
<td>Safety criteria and requests for documentation removed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Criteria: For men with osteoporosis- criteria distinguished between primary osteoporosis and hypogonadal osteoporosis; testosterone requirement maintained for hypogonadal osteoporosis but year-long therapy prior to Forteo removed. Removed the expected 12-month duration criteria as anti-resorptive therapy is recommended at any glucocorticoid duration. Added “at femoral neck or spine” to T score. Removed requirement that age must be over 50 in cases where the osteoporosis diagnosis relies on history of an osteoporotic fracture. Added definition of bisphosphonate trial failure. Removed preferencing for Reclast as Forteo is PDL. Calcium/vitamin D requirement language edited to be less specific. Shortened approval durations to 6 months.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age requirement modified to apply to pediatric members with open epiphyses. Added “at total hip” to T score. Added that osteoporotic fracture should be confirmed by radiographic imaging. Removed requirement for administration of calcium/vitamin D. Added preferencing for injectable ibandronate/zoledronic acid since they are available as generics while Forteo is only available as a branded product. Added dose to continued therapy. Added requirement for positive response to therapy.</td>
<td>06.17</td>
<td>08.17</td>
</tr>
<tr>
<td>1Q18 annual review: Converted to new template. Removed requirements for evidence of diagnosis (T-score, history of fracture). Removed conditions of hypogonadal and glucocorticoid-induced osteoporosis from initial criteria. Modified criteria to add specialist requirement or trial and failure of a bisphosphate (alendronate is preferred). Removed definition of treatment failure. Removed requirements regarding admin of last doses of Reclast and injectable ibandronate. Changed approval duration for continuation treatment under other diagnoses/indications to 6 months for specialty drugs. Updated appendices, Therapeutic Alternatives, and Dosing and Administration.</td>
<td>11.08.17</td>
<td>02.18</td>
</tr>
<tr>
<td>1Q 2019 annual review: no significant changes; added geriatrician prescriber option; revised continued therapy approval duration to 12 months; references reviewed and updated.</td>
<td>10.31.18</td>
<td>02.19</td>
</tr>
</tbody>
</table>
Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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