PRIOR AUTHORIZATION POLICY

POLICY: Bone Modifiers – Teriparatide Products Prior Authorization Policy
- Forteo® (teriparatide injection for subcutaneous injection – Eli Lilly)
- Teriparatide injection for subcutaneous use – Alvogen

REVIEW DATE: 07/29/2020; selected revision 02/24/2021

OVERVIEW

Teriparatide products, recombinant human parathyroid hormone (PTH) [1-34], are indicated for the following uses:[1-3]

- **Glucocorticoid-induced osteoporosis (treatment)**, in men and women at high risk for fracture associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone).
- **Osteoporosis, treatment of postmenopausal women** at high risk for fracture.
- **Osteoporosis, to increase bone mass in men with primary or hypogonadal osteoporosis** at high risk for fracture.

In general, for all indications, patients at high risk for fracture are defined as those with a history of osteoporotic fractures, have multiple risk factors for fracture, or have failed or are intolerant to other osteoporosis therapy.[1-3]

Teriparatide has been used for patients with hypoparathyroidism.[4-11] Natpara® (parathyroid hormone injection for subcutaneous use) is indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.[12] However, there is a recall of Natpara and teriparatide is one of two main alternatives recommended in a joint guidance statement from the American Society for Bone and Mineral Research and Endocrine Society for patients with hypoparathyroidism transitioning from Natpara.[13] It is notable that if teriparatide therapy is used in this clinical scenario, twice daily or even three times daily injections are usually needed.

Guidelines

Teriparatide is addressed in various clinical guidelines.[14-16]

- **Glucocorticoid-Induced Osteoporosis (GIO):** The American College of Rheumatology updated guidelines for the prevention and treatment of GIO (2017).[16] In various clinical scenarios, teriparatide is recommended after trial of other agents (e.g., oral bisphosphonates, intravenous bisphosphonates).
- **Postmenopausal Osteoporosis:** Teriparatide products are mentioned in guidelines for postmenopausal osteoporosis by the Endocrine Society (2019)[14] and the American Association of Clinical Endocrinologists and the American College of Endocrinology (2020)[15]. Teriparatide is one of among several agents cited as an alternative for patients at very high risk for fractures or among those who cannot tolerate oral therapy.

Safety

An increased incidence of osteosarcoma was noted in male and females rates who received teriparatide.[1] Osteosarcoma has been reported in patients treated with teriparatide in the postmarketing setting, however, an increased risk of osteosarcoma has not been observed in observational studies involving humans. There are limited data evaluating the risk of osteosarcoma beyond 2 years of teriparatide use. Avoid use of teriparatide in patients with a baseline risk of osteosarcoma.

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of teriparatide products. All approval(s) are provided for 2 years in duration unless otherwise noted below. For the indication of hypoparathyroidism, because of the specialized skills required for evaluation and diagnosis of patients treated with teriparatide as well as monitoring for adverse events and long-term efficacy, approval requires teriparatide to be prescribed by or in consultation with a physician who specialized in the condition being treated. In the approval indication, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: men are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression.

Automation: Smart Coverage Review uses patient claim history to answer Prior Authorization questions regarding medication history of Boniva® (ibandronate injection for intravenous use) or Reclast® (zoledronic acid injection for intravenous use). A 2-year look back period will be used to check claim history and automate for use of either agent (Boniva intravenous or Reclast). If not in claims, medication history can be obtained through Prior Authorization criteria. For all reviews, other Prior Authorization criteria listed below will also be applied.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of teriparatide products is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Glucocorticoid-Induced Osteoporosis – Treatment.** Approve for 2 years if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is either initiating or continuing systemic glucocorticoids; AND
     Note: An example of a systemic glucocorticoid is prednisone.
   - **B)** Patient meets ONE of the following (i, ii, iii, or iv):
     - **i.** Patient has tried zoledronic acid injection (Reclast); OR
     - **ii.** Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a, b, or c):
       Note: Examples of oral bisphosphonate products include Fosamax® (alendronate tablets and oral solution), Fosamax® Plus D (alendronate/cholecalciferol tablets), Actonel® (risedronate tablets), Atelvia® (risedronate delayed-release tablets), and Boniva® (ibandronate tablets).
       - **a)** Patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber; OR
         Note: An example of an inadequate efficacy is ongoing and significant loss of bone mineral density (BMD) or a lack of a BMD increase.
       - **b)** Patient has had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy; OR
       - **c)** Patient has experienced significant intolerance to an oral bisphosphonate; OR
         Note: Examples of significant intolerance include severe gastrointestinal related adverse events, severe musculoskeletal related adverse events, or a femoral fracture.
     - **iii.** Patient cannot take an oral bisphosphonate due to one of the following circumstances (a, b, or c):
       - **a)** Patient cannot swallow or has difficulty swallowing; OR
       - **b)** Patient cannot remain in an upright position post oral bisphosphonate administration; OR

c) Patient has a pre-existing gastrointestinal (GI) medical condition; OR
Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).

iv. Patient meets one of the following conditions (a, b, or c):
a) Severe renal impairment; OR
Note: An example of severe renal impairment is a creatinine clearance < 35 mL/min.
b) Chronic kidney disease (CKD); OR
c) Patient has had an osteoporotic fracture or a fragility fracture; AND

C) Use of teriparatide exceeding 2 years during a patient's lifetime, approve if the patient is at high risk for fracture as determined by the prescriber.
Note: Examples of high risk for fracture include a previous osteoporotic fracture or fragility fracture, receipt of medications that increase the risk of osteoporosis, advanced age, and very low bone mineral density.

2. Osteoporosis – Treatment for a Postmenopausal Patient. Approve for 2 years if the patient meets the following criteria (A, B, and C):

A) Patient meets ONE of the following conditions (i, ii, or iii):
i. Patient has had a T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius (wrist); OR
ii. Patient has had an osteoporotic fracture or a fragility fracture; OR
iii. Patient meets both of the following (a and b):
a) Patient has low bone mass; AND
Note: An example of low bone mass includes a T-score (current or at any time in the past) between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist).
b) Prescriber determines the patient is at high risk for fracture; AND

B) Patient meets ONE of the following (i, ii, iii, or iv):
i. Patient has tried ibandronate injection (Boniva) or zoledronic acid injection (Reclast); OR
ii. Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a, b, or c):
Note: Examples of oral bisphosphonate products include Fosamax® (alendronate tablets and oral solution), Fosamax® Plus D (alendronate/cholecalciferol tablets), Actonel® (risedronate tablets), Atelvia® (risedronate delayed-release tablets), and Boniva® (ibandronate tablets).
a) Patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber; OR
Note: An example of an inadequate efficacy is ongoing and significant loss of bone mineral density (BMD) or a lack of a BMD increase.
b) Patient has had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy; OR
c) Patient has experienced significant intolerance to an oral bisphosphonate; OR
Note: Examples of significant intolerance include severe gastrointestinal related adverse events, severe musculoskeletal related adverse events, or a femoral fracture.
iii. Patient cannot take an oral bisphosphonate due to one of the following circumstances (a, b, or c):
a) Patient cannot swallow or has difficulty swallowing; OR
b) Patient cannot remain in an upright position post oral bisphosphonate administration; OR
c) Patient has a pre-existing gastrointestinal (GI) medical condition; OR

Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).

iv. Patient meets one of the following conditions (a, b, or c):
- **a)** Severe renal impairment; OR
  Note: An example of severe renal impairment is a creatinine clearance < 35 mL/min.
- **b)** Chronic kidney disease (CKD); OR
- **c)** Patient has had an osteoporotic fracture or a fragility fracture; AND

C) Use of teriparatide exceeding 2 years during a patient's lifetime, approve if the patient is at high risk for fracture as determined by the prescriber.
Note: Examples of high risk for fracture include a previous osteoporotic fracture or fragility fracture, receipt of medications that increase the risk of osteoporosis, advanced age, and very low bone mineral density.

3. Osteoporosis – (to Increase Bone Mass) in Men* with Primary or Hypogonadal Osteoporosis.
Approve for 2 years if the patient meets the following criteria (A, B and C):

A) Patient meets ONE of the following conditions (i, ii, or iii):
- **i.** Patient has had a T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist); OR
- **ii.** Patient has had an osteoporotic fracture or a fragility fracture; OR
- **iii.** Patient meets both of the following (a and b):
  - **a)** Patient has low bone mass; AND
    Note: An example of low bone mass includes a T-score (current or at any time in the past) between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist).
  - **b)** Prescriber determines the patient is at high risk for fracture; AND

B) Patient meets one of the following (i, ii, iii, or iv):
- **i.** Patient has tried zoledronic acid injection (Reclast); OR
- **ii.** Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a, b, or c):
  Note: Examples of oral bisphosphonate products include Fosamax® (alendronate tablets and oral solution), Fosamax® Plus D (alendronate/cholecalciferol tablets), Actonel® (risedronate tablets), Atelvia® (risedronate delayed-release tablets), and Boniva® (ibandronate tablets).
  - **a)** Patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber; OR
    Note: An example of an inadequate efficacy is ongoing and significant loss of bone mineral density (BMD) or a lack of a BMD increase.
  - **b)** Patient has had an osteoporotic fracture or a fragility fracture while receiving oral bisphosphonate therapy; OR
  - **c)** Patient has experienced significant intolerance to an oral bisphosphonate; OR
    Note: Examples of significant intolerance include severe gastrointestinal related adverse events, severe musculoskeletal related adverse events, or a femoral fracture.
- **iii.** Patient cannot take an oral bisphosphonate due to one of the following circumstances (a, b, or c):
  - **a)** Patient cannot swallow or has difficulty swallowing; OR
  - **b)** Patient cannot remain in an upright position post oral bisphosphonate administration; OR
  - **c)** Patient has a pre-existing gastrointestinal medical condition; OR

Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying (e.g., stricture, achalasia).

iv. Patient meets one of the following conditions (a, b, or c):
- **a)** Severe renal impairment; OR
  Note: An example of severe renal impairment is a creatinine clearance < 35 mL/min.
- **b)** Chronic kidney disease (CKD); OR
- **c)** Patient has had an osteoporotic fracture or a fragility fracture; AND

C) Use of teriparatide exceeding 2 years during a patient's lifetime, approve if the patient is at high risk for fracture as determined by the prescriber.
Note: Examples of high risk for fracture include a previous osteoporotic fracture or fragility fracture, receipt of medications that increase the risk of osteoporosis, advanced age, and very low bone mineral density.

***** Refer to the Policy Statement.

Other Uses with Supportive Evidence

4. Hypoparathyroidism. Approve for 2 years if the patient meets the following criteria (A and B):
- **A)** Patient meets one of the following (i or ii):
  - **i.** Patient has tried Natpara (parathyroid hormone injection); OR
  - **ii.** Natpara is not available; AND

  Note: Approval for this use is a unique circumstance and the other criterion regarding the other indications do not apply.
- **B)** Medication is prescribed by or in consultation with an endocrinologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of teriparatide is not recommended in the following situations:

1. Concurrent Use with Other Medications for Osteoporosis.
Note: Examples include Prolia® (denosumab injection for subcutaneous use), oral bisphosphonates (e.g., alendronate, risedronate, ibandronate), intravenous bisphosphonates (zoledronic acid injection [Reclast], intravenous ibandronate), calcitonin nasal spray (Miacalcin®/Fortical®), Tymlos® (abaloparatide injection for subcutaneous use) and Evenity® (romosozumab-aqqg injection for subcutaneous use).

2. Osteoporosis Prevention. Teriparatide products have not been studied in this patient population. The benefits and risks of building bone with teriparatide products in a condition in which substantial bone loss has not occurred have not been investigated.[1]

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated, as new published data are available.

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