PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/27/2023

OVERVIEW

Teriparatide products, which are parathyroid hormone analogs (PTH 1-34), are indicated for the following uses:[1,2,13,14]

- **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.[1,2]

Teriparatide has been used for patients with hypoparathyroidism.[3-6] Natpara® (parathyroid hormone subcutaneous injection) is indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.[7] 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.[8] 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.[9-11]

- **Glucocorticoid-Induced Osteoporosis:** The American College of Rheumatology updated guidelines for the prevention and treatment of glucocorticoid-induced osteoporosis (2017).[9] 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)[10] and the American Association of Clinical Endocrinologists and the American College of Endocrinology (2020)[11]. Teriparatide is one of several agents cited as an alternative for patients at very high risk for fractures or among those who cannot tolerate oral therapy. The Bone Health and Osteoporosis Foundation clinician guide for the prevention and treatment of osteoporosis (2022) cite robust reductions in vertebral and non-vertebral fractures with teriparatide.[12]

Safety

An increased incidence of osteosarcoma was noted in male and female rats who received teriparatide.[1] Osteosarcoma has been reported in patients treated with teriparatide in the post-marketing 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. Use of teriparatide for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of teriparatide products. All approvals are provided for the duration 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 specializes 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 intravenous injection) or Reclast® (zoledronic acid intravenous infusion). 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 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 one of the following criteria:

FDA-Approved Indications

1. **Glucocorticoid-Induced Osteoporosis – Treatment.** Approve for the duration noted below if the patient meets the following (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 intravenous infusion (Reclast); OR
     - **ii.** Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a or b):
       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)** According to the prescriber, patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months; OR
         Note: Examples of inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack of a BMD increase, and/or an osteoporotic fracture or a fragility fracture.
       - **b)** Patient has experienced significant intolerance to an oral bisphosphonate; OR

Note: Examples of significant intolerance include severe gastrointestinal-related adverse events and/or severe musculoskeletal related-adverse events.

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 preexisting gastrointestinal medical condition; OR
  Note: Examples of preexisting 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; OR
- **c)** Patient has had an osteoporotic fracture or a fragility fracture; AND

C) Approve for one of the following (i or ii):

i. According to the prescriber, if the patient is at high risk for fracture, approve for one of the following (a or b):
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.
- **a)** If patient is initiating therapy or has received a teriparatide product for < 1 year, approve for up to 2 years; OR
  Note: For example, a patient who has already received 3 months of treatment with teriparatide should be approved for a duration of 21 months. This allows for completion of 2 years of therapy. Use of a teriparatide product beyond 2 years is evaluated annually for continued high risk of fracture.
- **b)** If patient has already received ≥ 1 year of therapy with a teriparatide product, approve for 1 year.
  Note: Use of a teriparatide product beyond 2 years is evaluated annually for continued high risk of fracture.

ii. According to the prescriber, if the patient is not at high risk for fracture, approve for the duration necessary to complete a maximum of 2 years of therapy (total) during a patient's lifetime.
Note: For example, a patient who has already received 3 months of treatment with teriparatide should be approved for a duration of 21 months. This allows for completion of a maximum of 2 years of therapy.

2. Osteoporosis Treatment for a Postmenopausal Patient. Approve for the duration noted below if the patient meets the following (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)** According to the prescriber, 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 intravenous injection (Boniva) or zoledronic acid intravenous infusion (Reclast); OR

ii. Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a or b):
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) According to the prescriber, patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months; OR
Note: Examples of inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack of a BMD increase, and/or an osteoporotic fracture or a fragility fracture.
b) Patient has experienced significant intolerance to an oral bisphosphonate; OR
Note: Examples of significant intolerance include severe gastrointestinal-related adverse events and/or severe musculoskeletal-related adverse events.

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 preexisting gastrointestinal medical condition; OR
Note: Examples of preexisting 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; OR
c) Patient has had an osteoporotic fracture or a fragility fracture; AND

C) Approve for one of the following (i or ii):

i. According to the prescriber if the patient is at high risk for fracture, approve for one of the following (a or b):
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.
a) If patient is initiating therapy or has received a teriparatide product for < 1 year, approve for up to 2 years; OR
Note: For example, a patient who has already received 3 months of treatment with teriparatide should be approved for a duration of 21 months. This allows for completion of 2 years of therapy. Use of a teriparatide product beyond 2 years is evaluated annually for continued high risk of fracture.
b) If patient has already received ≥ 1 year of therapy with a teriparatide product, approve for 1 year.
Note: Use of a teriparatide product beyond 2 years is evaluated annually for continued high risk of fracture.

ii. According to the prescriber if the patient is not at high risk for fracture, approve for the duration necessary to complete a maximum of 2 years of therapy (total) during a patient's lifetime.
Note: For example, a patient who has already received 3 months of treatment with teriparatide should be approved for a duration of 21 months. This allows for completion of a maximum of 2 years of therapy.

3. Osteoporosis Treatment (to Increase Bone Mass) for Men* with Primary or Hypogonadal Osteoporosis. Approve for the duration noted below if the patient meets the following (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) According to the prescriber, 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 intravenous infusion (Reclast); OR

ii. Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a or b):

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) According to the prescriber, patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months; OR

Note: Examples of inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack of a BMD increase, and/or an osteoporotic fracture or a fragility fracture.

b) Patient has experienced significant intolerance to an oral bisphosphonate; OR

Note: Examples of significant intolerance include severe gastrointestinal-related adverse events and/or severe musculoskeletal-related adverse events.

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 preexisting gastrointestinal medical condition; OR

Note: Examples of preexisting 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; OR

c) Patient has had an osteoporotic fracture or a fragility fracture; AND

C) Approve for one of the following (i or ii):

i. According to the prescriber if the patient is at high risk for fracture, approve for one of the following (a or b):

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.

a) If patient is initiating therapy or has received a teriparatide product for < 1 year, approve for up to 2 years; OR

Note: For example, a patient who has already received 3 months of treatment with teriparatide should be approved for a duration of 21 months. This allows for completion

of 2 years of therapy. Use of a teriparatide product beyond 2 years is evaluated annually for continued high risk of fracture.

b) If patient has already received ≥ 1 year of therapy with a teriparatide product, approve for 1 year.
Note: Use of a teriparatide product beyond 2 years is evaluated annually for continued high risk of fracture.

ii. According to the prescriber if the patient is not at high risk for fracture, approve for the duration necessary to complete a maximum of 2 years of therapy (total) during a patient's lifetime.
Note: For example, a patient who has already received 3 months of treatment with teriparatide should be approved for a duration of 21 months. This allows for completion of a maximum of 2 years of therapy.

***** Refer to the Policy Statement.

Other Uses with Supportive Evidence

4. Hypoparathyroidism. Approve for 1 year if the patient meets the following (A and B):
A) Patient meets one of the following (i or ii):
i. Patient has tried Natpara (parathyroid hormone subcutaneous 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 of medications for osteoporosis that teriparatide should not be given with include Prolia (denosumab subcutaneous injection), oral bisphosphonates (e.g., alendronate, risedronate, ibandronate), intravenous bisphosphonates (zoledronic acid intravenous infusion [Reclast], intravenous ibandronate), calcitonin nasal spray (Miacalcin/Fortical), Tymlos (abaloparatide subcutaneous injection), and Evenity (romosozumab-aqqg subcutaneous injection). However, this does NOT exclude use of calcium and/or vitamin D supplements in combination with teriparatide.

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.

REFERENCES

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14. Teriparatide subcutaneous injection [prescribing information]. Parsippany, NJ: Teva; November 2021.