PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 10/23/2024; selected revision 10/30/2024, 04/30/2025, and 07/02/2025

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Teriparatide products, which are parathyroid hormone (PTH 1-34) analogs, are indicated for the following uses:[1-5]
- **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.[1-5]

Guidelines
Teriparatide is addressed in various clinical guidelines.[6-9]

- **Glucocorticoid-Induced Osteoporosis:** The American College of Rheumatology has guidelines for the prevention and treatment of glucocorticoid-induced osteoporosis (2022).[6] 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)[7] and the American Association of Clinical Endocrinologists and the American College of Endocrinology (2020)[8]. 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.[9]

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.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Glucocorticoid-Induced Osteoporosis – Treatment.** Approve for the duration noted below if the patient meets ALL of 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 (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 (a or b):
a) According to the prescriber, the patient has severe renal impairment or chronic kidney disease; OR
Note: An example of severe renal impairment is a creatinine clearance < 35 mL/minute.
b) Patient has had an osteoporotic fracture or a fragility fracture; AND

C) Patient meets 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 a 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 a patient has already received ≥ 1 year of therapy with a teriparatide product, approve for 1 year; OR
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 ALL of the following (A, B, and C):
   A) Patient meets ONE of the following (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 (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 (a or b):
         a) According to the prescriber, the patient has severe renal impairment or chronic kidney disease; OR
            Note: An example of severe renal impairment is a creatinine clearance < 35 mL/minute.
         b) Patient has had an osteoporotic fracture or a fragility fracture; AND
   C) Patient meets 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 a 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 a patient has already received ≥ 1 year of therapy with a teriparatide product, approve for 1 year; OR
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 ALL of the following (A, B, and C):

A) Patient meets ONE of the following (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 (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 (a or b):

a) According to the prescriber, the patient has severe renal impairment or chronic kidney disease; OR
Note: An example of severe renal impairment is a creatinine clearance < 35 mL/minute.

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

C) Patient meets 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 a 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 a patient has already received ≥ 1 year of therapy with a teriparatide product, approve for 1 year; OR
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.

CONDITIONS NOT COVERED

- **Bonsity® (teriparatide subcutaneous injection – Alvogen)**
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is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as newly published data are available):

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 the 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]

REFERENCES

1. Forteo® subcutaneous injection [prescribing information]. Mason, OH and Indianapolis, IN: Prasco and Eli Lilly; July 2024.
2. Teriparatide subcutaneous injection [prescribing information]. Morristown, NJ: Alvogen; November 2023.
3. Teriparatide subcutaneous injection [prescribing information]. Weston, FL: Apotex; January 2023.
4. Teriparatide subcutaneous injection [prescribing information]. Parsippany, NJ: Teva; November 2021.
5. Bonsity® subcutaneous injection [prescribing information]. Morristown, NJ: Alvogen; December 2024.
6. Humphrey MB, Russell L, Danila MI, et al. 2022 American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis. *Arthritis Rheumatol*. 2023;75(12):2088-2102.
7. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2019;104(5):1595-1622. Available at: https://www.endocrine.org/guidelines-and-clinical-practice/clinical-practice-guidelines/osteoporosis-in-postmenopausal-women. Accessed on September 3, 2024.
8. 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-2020 update. *Endocrin Pract*. 2020;26(Suppl 1):1-46.
9. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. *Osteoporosis Int*. 2022;33(10):2049-2102.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	To comply with standard wording, the phrase "as determined by the prescriber" was replaced with "according to the prescriber". In addition, the following changes were made: **Glucocorticoid-Induced Osteoporosis –Treatment:** The exception that the patient has had an osteoporotic fracture or a fragility fracture while receiving oral bisphosphonate therapy was removed. Instead, this exception was incorporated into a Note that lists osteoporotic fracture or a fragility fracture as an example of inadequate efficacy or significant intolerance to a trial of an oral bisphosphonate or an oral bisphosphonate-containing product. Femoral fracture was removed as an example of significant intolerance to an oral bisphosphonate. **Osteoporosis Treatment (to Increase Bone Mass) for Men with Primary or Hypogonadal Osteoporosis:** The indication was revised to as stated to follow standard formatting. The exception that the patient has had an osteoporotic fracture or a fragility fracture while receiving oral bisphosphonate therapy was removed. Instead, this exception was incorporated into a Note that lists osteoporotic fracture or a fragility fracture as an example of inadequate efficacy or significant intolerance to a trial of an oral bisphosphonate or an oral bisphosphonate-containing	09/27/2023

	product. Femoral fracture was removed as an example of significant intolerance to an oral bisphosphonate. **Osteoporosis Treatment for a Postmenopausal Patient:** The exception that the patient has had an osteoporotic fracture or a fragility fracture while receiving oral bisphosphonate therapy was removed. Instead, this exception was incorporated into a Note that lists osteoporotic fracture or a fragility fracture as an example of inadequate efficacy or significant intolerance to a trial of an oral bisphosphonate or an oral bisphosphonate-containing product. Femoral fracture was removed as an example of significant intolerance to an oral bisphosphonate.	
Update	11/27/2023: No criteria changes. It was added that multiple generics for Forteo are available.	NA
Annual Revision	Glucocorticoid-Induced Osteoporosis – Treatment: The exception to the requirement for a trial of a bisphosphonate due to severe renal impairment or chronic kidney disease were revised. The criteria are now combined and the phrase "according to the prescriber" was added. **Osteoporosis Treatment (to Increase Bone Mass) for Men with Primary or Hypogonadal Osteoporosis:** The exception to the requirement for a trial of a bisphosphonate due to severe renal impairment or chronic kidney disease were revised. The criteria are now combined and the phrase "according to the prescriber" was added. **Osteoporosis Treatment for a Postmenopausal Patient:** The exception to the requirement for a trial of a bisphosphonate due to severe renal impairment or chronic kidney disease were revised. The criteria are now combined and the phrase "according to the prescriber" was added. **Hypoparathyroidism:** The exception provided that Natpara is not available was removed. An exception was added if the patient has tried Yorvipath (palopegteriparatide subcutaneous injection).	10/23/2024
Selected Revision	**Chronic Hypoparathyroidism:** The indication was revised from "Hypoparathyroidism" to as stated. A nephrologist was added as a physician type that counts toward the specialist requirement.	10/30/2024
Selected Revision	**Chronic Hypoparathyroidism:** This condition of approval was removed.	4/30/2025
Selected Revision	Bonsity was added to the policy with the same criteria as existing teriparatide products.	07/02/2025