UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1033-16
Program	Prior Authorization/Notification
Medication	Forteo® (teriparatide)*, Teriparatide Injection (teriparatide)
P&T Approval Date	8/2008, 8/2009, 7/2010, 7/2011, 8/2012, 11/2013, 10/2014, 10/2015, 9/2016, 7/2017, 11/2017, 11/2018, 11/2019, 9/2020, 1/2021, 1/2022, 1/2023, 2/2023, 10/2023, 10/2024
Effective Date	1/1/2025

1. Background:

Forteo (teriparatide)* and Teriparatide Injection (teriparatide) are recombinant human parathyroid hormone with three FDA approved indications[1-2]:

- **Treatment of postmenopausal patients with osteoporosis at high risk of fracture**
  Forteo and Teriparatide Injection are indicated for the treatment of postmenopausal patients 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 and Teriparatide Injection are indicated to increase bone mass in patients 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 patients with glucocorticoid-induced osteoporosis at high risk for fracture**
  Forteo and Teriparatide Injection are indicated for the treatment of patients 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.

Forteo* and Teriparatide Injection 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.[1-2]

The American Association of Clinical Endocrinologists/American College of Endocrinology AACE/ACE) recommend the use of teriparatide be considered for patients unable to use oral therapy and as initial therapy for patients at very high fracture risk defined as the following: patients with a recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than −3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%) or other validated fracture risk algorithm to be at very high fracture risk.[3] Additionally, the AACE/ACE and Endocrine Society both recommend to limit treatment with teriparatide to 2 years.[3-4]

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

2. Coverage Criteria[a]:

A. Osteoporosis

1. **Forteo* and Teriparatide Injection** will be approved based on **all** of the following criteria:

   a. **One** of the following:

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

         (a) Patient is female

         -AND-

         (b) Diagnosis of postmenopausal osteoporosis

      -OR-

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

         (a) Patient is male

         -AND-

         (b) Diagnosis of osteoporosis

      -AND-

   b. **One** of the following:

      (1) Patient is at high risk of fracture [e.g., recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than −3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%)]

      -OR-

      (2) Patient has a history of failure, intolerance or contraindication to other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate)

      -AND-

   c. **One** of the following:

      (1) Treatment duration has not exceeded a total of 24 months of cumulative use of

parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos)

-OR-

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

(a) Patient is currently or has previously been treated with parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos)

-AND-

(b) The prescriber attests that the patient remains at or has returned to having a high risk for fracture

Authorization will be issued for 24 months.

2. **Reauthorization**

a. **Forteo and Teriparatide Injection** will be approved based on **both** of the following criteria:

(1) The prescriber attests that the patient remains at or has returned to having a high risk for fracture despite 24 months of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos)

-AND-

(2) The prescriber attests that the risk versus benefit of use greater than 24 months of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos) has been reviewed with the patient

Authorization will be issued for 12 months.

B. Osteoporosis Associated with Sustained Systemic Glucocorticoid Therapy

1. **Forteo and Teriparatide Injection** 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

-AND-

c. **One** of the following:

(1) Patient is at high risk of fracture [e.g., recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than −3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%)]

-OR-

(2) Patient has a history of failure, intolerance or contraindication to other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate)

-AND-

d. **One** of the following:

(1) Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos)

-OR-

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

(a) Patient is currently or has previously been treated with parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos)

-AND-

(b) The prescriber attests that the patient remains at or has returned to having a high risk for fracture

Authorization will be issued for 24 months.

2. **Reauthorization**

a. **Forteo and Teriparatide Injection** will be approved based on **both** of the following criteria:

(1) The prescriber attests that the patient remains at or has returned to having a high risk for fracture despite 24 months of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos)

-AND-

(2) The prescriber attests that the risk versus benefit of use greater than 24 months of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos) has been reviewed with the patient

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*Forteo is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Exclusion: Forteo is excluded from coverage for the majority of our benefits
- Medical Necessity, Supply Limits and/or Step Therapy may be in place.

4. References:

1. Forteo [package insert]. Indianapolis, IN: Eli Lilly, Inc.; July 2024.
2. Teriparatide Injection [package insert]. Morristown, NJ: Alvogen, Inc.; November 2023.
3. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis – 2020 Update. Endocr Pract. 2020;26(Supp1): 1-46.
4. Shoback D, Rosen CJ, Black DM, Cheung AM, Murad MH, Eastell R. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update. J Clin Endocrinol Metab. 2020 Mar 1;105(3):dgaa048.

Program	Prior Authorization/Notification - Forteo (teriparatide)
Change Control	
11/2013	Annual review. Added diagnosis criteria for osteoporosis and glucocorticoid-induced osteoporosis. Added criteria to allow coverage when both of the following are met: 'history of vertebral compression fracture, fracture of the hip or fracture of the distal radius resulting from minimal trauma' and 'history of failure, contraindication, or intolerance to one conventional osteoporosis therapy.' Added 'history of failure, contraindication, or intolerance to one conventional osteoporosis therapy' as one of the criteria required in addition to 'BMD T-score between -1.0 and -2.0.'
9/2014	Administrative change – Tried/Failed exemption for State of New Jersey removed.
10/2014	Annual review with no change to clinical criteria.
10/2015	Annual review with no change to clinical criteria.
9/2016	Annual review. No change to clinical criteria. Updated references.
7/2017	Annual Review. Updated language to remove gender references, updated references, updated diagnosis criteria for osteoporosis to include history of fragility fractures, and FRAX assessment tool, added fractures of proximal humerus and pelvis as examples of fragility fractures. Updated approval to include cumulative use of parathyroid hormone analogs.
11/2017	Added requirement for BMD T-score submission and previous medication trial documentation. Added physician attestation criterion.

11/2018	Annual review with no change to clinical criteria. Updated references.
11/2019	Annual review with no change to clinical criteria. Updated references.
9/2020	Added Teriparatide Injection to the program. Updated criteria to reflect change in preferred product and Forteo exclusion for 1/1/2021. Renamed section headers to match step therapy program. Updated background and references.
1/2021	Updated criteria based on changes to prescribing information on use beyond 2 years. References updated.
1/2022	Annual review with no change to clinical criteria. Updated background and references.
1/2023	Annual review with no change to clinical criteria. Updated exclusion statement, added state mandate footnote and updated references.
2/2023	Updated coverage criteria confirming osteoporosis diagnosis and high fracture risk to align with current treatment guidelines. Updated background and references.
10/2023	Annual review. Updated background and coverage criteria to align with the label and treatment guidelines. Removed “routine audit” language from criteria. Updated references.
10/2024	Annual review with no change to coverage criteria. Updated background and references.