UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1033-11
Program	Prior Authorization/Notification
Medication	Forteo™ (teriparatide)*, Teriparatide Injection (teriparatide) *Forteo is excluded from coverage for the majority of our benefits
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
Effective Date	4/1/2021; Oxford only: 4/1/2021

1. Background:

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

- **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.

  Current guidelines define osteoporosis as a bone mineral density (BMD) T-score of -2.5 or below, and osteopenia as a T-score between -1 and -2.5. Additionally, guidelines state that osteoporosis can also be diagnosed by the history of a low-trauma spine or hip fracture regardless of BMD, a history of a fragility fracture in osteopenic patients, or in

osteopenic patients with an elevated fracture risk as defined by the FRAX® fracture assessment tool.[2] Available literature defines high risk for fracture as bone mineral density (BMD) T-scores of -3.5 or less, while it defines severe osteoporosis as T-scores of -2.5 or less with at least one fragility fracture.[2] The FRAX tool is designed to assist clinicians in predicting the ten-year probability of fracture with or without the addition of femoral neck bone mineral density (BMD).[13]

The leading study of Forteo for treatment of glucocorticoid-induced osteoporosis allowed high-risk patients using the following inclusion criteria: a history of prednisone or its equivalent at a dose ≥ 5 mg/day for ≥ 3 months, and a T-score ≤ -2.0 or a T-score ≤ -1.0 with a history of fragility fracture.[7]

Potential candidates for parathyroid therapy include:[5-6,9]

- Patients with severe osteoporosis (T-score of -3.5 or below even in the absence of fractures; T-score of -2.5 or below plus a fragility fracture)
- Patients with osteoporosis who are unable to tolerate bisphosphonates or who have relative contraindications to bisphosphonates (achalasia, scleroderma esophagus, esophageal strictures)
- Patients who fail other osteoporosis therapies (fracture with loss of bone mineral density [BMD] in spite of compliance with therapy)

Use of Forteo 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.

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

2. Coverage Criteria:

A. <u>Postmenopausal Osteoporosis or Increase Bone Mass in Men with Primary or Hypogonadal Osteoporosis</u>

1. Teriparatide Injection will be approved based on **<u>all</u>** of the following criteria:

a. **<u>One</u>** of the following diagnoses:

(1) Postmenopausal osteoporosis

-OR-

(2) Primary or hypogonadal osteoporosis

-AND-

b. **<u>One</u>** of the following:

(1) BMD T-score ≤ -3.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius

site) [Provider must submit patient specific BMD T-score]

-OR-

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

(a) BMD T-score between -2.5 and -3.5 (BMD T-score greater than -3.5 and less than or equal to -2.5) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-score]

-AND-

(b) **One** of the following:

i. History of **one** of the following resulting from minimal trauma:

1. Vertebral compression fracture
2. Fracture of the hip
3. Fracture of the distal radius
4. Fracture of the pelvis
5. Fracture of the proximal humerus

-OR-

ii. History of failure, contraindication, or intolerance to **one** conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)] (Document drug, date, and duration of trial)

-OR-

(3) **All** of the following:

(a) BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-score]

-AND-

(b) **One** of the following:

i. History of **one** of the following resulting from minimal trauma:

1. Vertebral compression fracture
2. Fracture of the hip
3. Fracture of the distal radius
4. Fracture of the pelvis

5. Fracture of the proximal humerus

-OR-

ii. **One** of the following FRAX 10-year probabilities:

1. Major osteoporotic fracture at 20% or more
2. Hip fracture at 3% or more

-AND-

(c) History of failure, contraindication, or intolerance to one conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)] (Document drug, date, and duration of trial)

-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)

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

-AND-

d. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

Authorization will be issued for 24 months.

2. Reauthorization

a. **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. **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 for ≥ 3 months

   -AND-

   c. **One** of the following:

      (1) BMD T-score ≤ -2.0 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-score]

      -OR-

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

         (a) BMD T-score between -1.0 and -2.0 (BMD T-score greater than -2.0 and less than or equal to -1.0) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-score]

         -AND-

         (b) **One** of the following:

            i. History of **one** of the following resulting from minimal trauma:

               - Vertebral compression fracture
               - Fracture of the hip
               - Fracture of the distal radius
               - Fracture of the pelvis
               - Fracture of the proximal humerus

-OR-

ii. History of failure, contraindication, or intolerance to **one** conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)] (Document drug, date, and duration of trial)

-OR-

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

(a) History of **one** of the following resulting from minimal trauma:

i. Vertebral compression fracture
ii. Fracture of the hip
iii. Fracture of the distal radius
iv. Fracture of the pelvis
v. Fracture of the proximal humerus

-AND-

(b) History of failure, contraindication, or intolerance to **one** conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)] (Document drug, date, and duration of trial)

-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)

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

-AND-

e. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy

of the information provided

Authorization will be issued for24 months.

2. Reauthorization

a. **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.

.

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.; November 2020.
2. 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.
3. North American Menopause Society (NAMS). Management of osteoporosis in postmenopausal women: 2010 position statement of The North American Menopause Society. Menopause 2010;17(1):25-54.
4. Cosman F, de Beur SJ, LeBoff MS, et al. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014. Osteoporos Int. 2014 Oct;25(10):2359-81. Epub 2014 Aug. 15.
5. Hodsman AB, Bauer DC, Dempster DW, et al. Parathyroid hormone and teriparatide for the treatment of osteoporosis: a review of the evidence and suggested guidelines for its use. Endocr Rev. 2005(5):688-703.
6. Hodsman A, Papaioannou A, Cranney A. Clinical practice guidelines for the use of parathyroid hormone in the treatment of osteoporosis. CMAJ. 2006;175(1):48.
7. Saag KG, Zanchetta JR, Devogelaer JP, et al. Effects of teriparatide versus alendronate for treating glucocorticoid-induced osteoporosis: thirty-six-month results of a randomized, double-blind, controlled trial. Arthritis Rheum. 2009;60(11):3346-55.
8. American College of Obstetricians and Gynecologists (ACOG). Osteoporosis. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2012 Sep. 17, reaffirmed 2019. (ACOG practice bulletin; no. 129).
9. Florence R, Allen S, Benedict L, Compo R, Jensen A, Kalogeropoulou D, Kearns A, Larson S, Mallen E, O'Day K, Peltier A, Webb B. Diagnosis and treatment of osteoporosis. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2017 Jul. 62 p.
10. Cranney A, Papaioannou A, Zytaruk N, et al. Parathyroid hormone for the treatment of osteoporosis: a systematic review. CMAJ. 2006;175(1):52.
11. Watts NB, Adler RA, Bilezikian JP, Drake MT, Eastell R, Orwoll ES, Finkelstein JS. Osteoporosis in men: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2012 Jun;97(6):1802-22.
12. Tymlos [package insert]. Waltham, MA: Radius Health, Inc.; October 2020.
13. WHO FRAX tool: shef.ac.uk/FRAX Accessed 9/12/2018.
14. Eastell R, Rosen CJ, Black DM, Cheung AM, Murad MH, Shoback D. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab, May 2019, 104(5):1595–1622.
15. Teriparatide Injection [package insert]. Morristown, NJ: Alvogen, Inc.; November 2019.

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.