UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Forteo

Program	Prior Authorization
Medication	Forteo™ (teriparatide), Teriparatide Injection (teriparatide)
Markets in Scope	California, Colorado, Hawaii, Maryland, Nevada, New York, New York EPP, Rhode Island, New Jersey, Pennsylvania- CHIP, South Carolina
Issue Date	12/2009
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

1. Background:

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

- **Treatment of postmenopausal patients with osteoporosis at high risk of fracture**

  Forteo and Teriparatide Injection (teriparatide) 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 patients with primary or hypogonadal osteoporosis at high risk for fracture**

  Forteo and Teriparatide Injection (teriparatide) 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 (teriparatide) 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)

The safety and efficacy of Forteo and Teriparatide Injection (teriparatide) have not been evaluated beyond 2 years of treatment. Consequently, use of the drug for more than 2 years during a patient's lifetime is contraindicated.[1] Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is not recommended.[12]

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. **Forteo** and Teriparatide Injection (teriparatide) will be approved based on **<u>all</u>** of the following criteria:

   a. **One** of the following diagnoses:

      (1) Postmenopausal osteoporosis

OR

(2) Primary or hypogonadal osteoporosis

-AND-

b. **One** of the following:

(1) BMD T-score ≤ -3.5 based on BMD measurements from lumber 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 lumber 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) **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 lumber 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. **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. Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos) during the patient's lifetime

-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

-AND-

e. If the request is for a post-menopausal patient, history of failure, contraindication, or intolerance to Tymlos

Authorization will be issued for 24 months. Duration of coverage will be limited to 24 months of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, **Forteo, Tymlos) in the member's lifetime.**

B. Osteoporosis Associated with Sustained Systemic Glucocorticoid Therapy

1. **Forteo** and Teriparatide Injection (teriparatide) 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 lumber 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 lumber 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. Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos) during the patient's lifetime

-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 for 24 months. Duration of coverage will be limited to 24 months of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, **Forteo, Tymlos) in the member's lifetime.**

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.
- Supply limits may be in place**.**

4. References:

1. Forteo [package insert]. Indianapolis, IN: Eli Lilly, Inc.; April 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 p. (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 2018.
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 -Forteo™ (teriparatide)
Change Control	
Date	Change
12/2009	New drug policy.
12/2010	Annual Review
12/2011	Annual Review. Revisions made to high-risk for fracture criteria based on currently available literature. Created glucocorticoid-induced osteoporosis criteria.
12/2012	Annual Review. Revisions made to Postmenopausal women with osteoporosis or men with primary or hypogonadal osteoporosis at high risk for fracture and glucocorticoid-induced osteoporosis at high risk for fracture criteria based on currently available literature. Added background section for National Guidelines. Updated References.
3/2015	Template updated to UHC standard. Background revisions and removal of prescriber's notes. No change to clinical criteria
9/2015	Added requirement for trial and failure of Prolia (denosumab) in addition to a bisphosphonate for postmenopausal women with

	osteoporosis or men with primary or hypogonadal osteoporosis at high risk for fracture, except for patients with a T score of -3.5 or less.
9/2016	Updated policy template
7/2017	Updated language to remove gender 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.
8/2017	Updated trial/fail products in Section A, including adding a trial of Tymlos if the patient is post-menopausal.
11/2017	Added requirement for BMD T-score submission and previous medication trial documentation. Added physician attestation criterion.
2/2018	Modified osteoporosis at high risk of fracture section to require a trial of Tymlos regardless of patient's BMD score or history of fracture.
11/2018	Annual review. No changes to clinical criteria. Updated references.
11/2019	Annual review with no change to clinical criteria. Updated references.
11/2020	Annual review. Added Teriparatide Injection to the program. Renamed section headers. Updated background and references.