UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3148-6
Program	Step Therapy
Medications	Forteo® (teriparatide)*
P&T Approval Date	9/2020, 1/2021, 1/2022, 1/2023, 2/2023, 2/2024
Effective Date	5/1/2024

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try preferred products before providing coverage for Forteo.

Forteo and Teriparatide Injection are recombinant human parathyroid hormone analogs with three FDA approved indications:

- **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.

Tymlos (abaloparatide) is a parathyroid hormone analog with two FDA approved indications:

- **Treatment of postmenopausal patients with osteoporosis at high risk of fracture**
  Tymlos is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

- **Increase of bone mass in men with osteoporosis at high risk for fracture**
  Tymlos is indicated to increase bone density in men with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

Cumulative use of 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.[1,3]

The safety and efficacy of Tymlos have not been evaluated beyond 2 years of treatment. Cumulative use of Tymlos for more than 2 years during a patient's lifetime is not recommended.[2]

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Osteoporosis

1. **Forteo** will be approved based on **all** of the following:

   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. History of failure, contraindication, or intolerance to Teriparatide Injection (teriparatide)

      -AND-

   c. History of failure, contraindication, or intolerance to Tymlos (abaloparatide)

   Authorization will be issued for 24 months.

B. Osteoporosis Associated with Sustained Systemic Glucocorticoid Therapy

1. **Forteo** will be approved based on **both** of the following:

   a. Diagnosis of glucocorticoid-induced osteoporosis

      -AND-

   b. History of failure, contraindication, or intolerance to Teriparatide Injection (teriparatide)

Authorization will be issued for 24 months.

C. Other Diagnoses

1. **Forteo** will be approved based on the following:

   a. History of failure, contraindication, or intolerance to Teriparatide Injection (teriparatide)

Authorization will be issued for 24 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 Notification may be in place.

4. References:

1. Forteo [package insert]. Indianapolis, IN: Eli Lilly, Inc.; November 2020.
2. Tymlos [package insert]. Boston, MA: Radius Health, Inc.; December 2022.
3. Teriparatide Injection [package insert]. Morristown, NJ: Alvogen, Inc.; November 2023.

Program	Step Therapy – Forteo (teriparatide)
Change Control	
9/2020	New program.
1/2021	Updated criteria based on changes to prescribing information on use beyond 2 years. Added diagnosis to criteria. References updated.
1/2022	Annual review with no change to step criteria. Updated background and references.
1/2023	Annual review with no change to step criteria. Updated exclusion statement and references.
2/2023	Added step through Tymlos for osteoporosis in men. Updated background and references.
2/2024	Annual review with no changes to step criteria. Updated background and references.