UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 3148-2
Program	Step Therapy
Medications	Forteo (teriparatide)* *Forteo is excluded from coverage for the majority of our benefits
P&T Approval Date	9/2020, 1/2021
Effective Date	4/1/2021; Oxford only: 4/1/2021

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 is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, and for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture.

Teriparatide Injection (teriparatide) is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, and for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture.

Tymlos (abaloparatide) is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture.

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.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria [a]:

A. <u>Postmenopausal Osteoporosis</u>

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

a. Diagnosis of postmenopausal 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. Increase Bone Mass in Men with Primary or Hypogonadal Osteoporosis

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

a. Diagnosis of primary or hypogonadal osteoporosis

-AND-

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

Authorization will be issued for 24 months.

C. 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.

D. 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.

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]. Waltham, MA: Radius Health, Inc.; October 2020.
3. Teriparatide Injection [package insert]. Morristown, NJ: Alvogen, Inc.; November 2019.

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.