Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	August 13, 2010 February 4, 2011, May 1, 2012, November 17, 2015, August 16, 2017, April 2, 2018, September 2, 2020; January 24, 2024

Forteo® (teriparatide) Injection

LENGTH OF AUTHORIZATION: UP TO ONE YEAR

REVIEW CRITERIA:
For the treatment of postmenopausal women with osteoporosis at high risk for fracture; or increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture; or treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture:

INITIATION OF THERAPY

- Prescribed by or in consultation with a specialist (endocrinologist, rheumatologist, or obstetrician/gynecologist); **AND**
- The patient is taking calcium and vitamin D (*Must be confirmed in medical records or pharmacy claims);* **AND**
- Documented diagnosis of osteoporosis with A DXA hip (femoral neck) or spine T-score ≤ -2.5 (dated within the past 2 years). ***(Must be confirmed in medical records.);*** **OR**
- History of a fracture of the spine or hip. ***(Must be confirmed in medical records.);*** **OR**
- History of T-score between -1.0 and -2.5 if FRAX (WHO Fracture Risk Assessment Tool) major osteoporotic fracture probability is ≥ 20% or hip fracture probability is 3%. ***(Must be confirmed in medical records.);*** **AND**
- Trial (minimum of 12 months) and failure of zoledronate:
    - Failure may be defined as an intolerance (adverse reaction, contraindication…) to other bisphosphonates, or no increase from baseline bone mineral density (BMD) as indicated by T-score history, or recurring fractures (in the absence of major trauma) following at least one year of therapy.

CONTINUATION OF THERAPY

- The patient is taking calcium and vitamin D (*Must be confirmed in medical records or pharmacy claims);* **AND**
- Medical records must demonstrate a stable BMD (within interventional goals) or an increasing BMD after a minimum trial of one year of therapy.
    - T-score test results may date back as far as five years.
    - Depending on level of BMD progression retesting may be done from every one to five years.
    - Medical records should demonstrate improvement by providing reference to the sequential progression or stability of the BMD.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/

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- Available as 600 mcg/2.4 mL (250 mcg/mL) in a single-patient-use prefilled delivery device (pen) containing 28 daily doses of 20 mcg.