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

- Documented diagnosis of osteoporosis with a DXA hip (femoral neck) or spine T-score ≤ -2.5 (dated within the past year). *(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

- 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:

- Recommended dose is 20 mcg subcutaneously once a day.
- Use of the drug for more than 2 years during a patient’s lifetime is not recommended.