teriparatide, SQ (FORTEO)

Diagnoses Considered for Coverage:

- Osteoporosis
- Hypocalcemia associated with hypoparathyroidism *(teriparatide products only)*

Coverage Criteria:

2. For Osteoporosis, approve if:

Initial use
• ***For Forteo/teriparatide:*** intolerance with or unable to use Tymlos, **and** • Dose does not exceed FDA label maximum, **and** • Total parathyroid hormone analog therapy (i.e. Forteo, Tymlos) does not exceed an initial 2 years of therapy, **and** • Not used in combination with other osteoporosis therapy (i.e., bisphosphonates, Prolia, Tymlos), **and** • One of the following: a. Patient has history of one or more non-traumatic fractures, **or** b. Evidence of T-score **more than or equal to 2.5** standard deviations (SD) below the young normal (T-score at or below -2.5), **or** c. Evidence of T-score between -1.0 and -2.5 and patient is at high risk for fracture *[e.g. multiple risk factors or 10-year hip fracture probability >/= 3% or a 10-year major osteoporosis-related fracture probability >/= 20% based on USA-adapted WHO absolute fracture risk model (FRAX risk assessment)]* **and** • One of the following **I, II, III, or IV**: I. Patient is initiating or continuing long-term glucocorticoid treatment (≧ 3 months), **or** II. Patient is at very high risk of fracture by meeting at least one of the following: i. T-score less than -3.0, **or** **b.** Fracture while on bisphosphonate therapy or Prolia, **or** **c.** Patient has experienced a recent fracture (within the past 12 months) or history of multiple fractures, **or** **d.** Patient experienced a fracture while on long-term glucocorticoid therapy, **or** **e.** Patient is at high risk for falls, **or** **f.** 10-year hip fracture probability of > 4.5% based on FRAX® score, **or** **g.** 10-year major osteoporosis-related fracture probability >

30% based on FRAX® score.

III. Intolerable side effect to bisphosphonate (oral and IV) therapy or Prolia, or contraindication to bisphosphonate (oral and IV) therapy and Prolia, **or**

IV. Inadequate response, as evidenced by documented worsening BMD, following at least two years therapy with a bisphosphonate or Prolia.

Coverage Duration: 2 years

For requests beyond the initial 2 years of treatment

- Request is for Forteo/teriparatide, **and**
- Patient remains at, or has returned to, having a high risk for fractures.

Coverage Duration: 12 months

3. **For teriparatide/Forteo and diagnosis of hypocalcemia associated with hypoparathyroidism**:

- Being used as an adjunct to calcium and Vitamin D therapy, **and**
- Patient is unable to achieve target serum calcium level (8 to 9mg/L) with maximally tolerated doses of oral calcium and vitamin D analogs alone, **and**
- Dose does not exceed 20 mcg given three times per day.

Coverage Duration: 6 months

Effective Date: 11/29/2023