blue of california

abaloparatide subcutaneous injection (TYMLOS)

Diagnoses Considered for Coverage:

- Post-Menopausal Osteoporosis
- Increase bone mass in men with primary or hypogonadal osteoporosis

Coverage Criteria:

For diagnosis considered for coverage:

- Home Self-Injectables are under the Pharmacy Benefit, **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:
  - Provider attestation that patient has history of one or more non-traumatic fractures, **or**
  - 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**
  - 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, or III:**
  - I. Patient is at very high risk of fracture by meeting at least one of the following:
    - a. T-score less than -3.0, **or**
    - b. Fracture while on bisphosphonate therapy or Prolia, **or**
    - c. Provider attestation that patient has experienced a recent fracture (within the past 12 months) or history of multiple fractures, **or**
    - d. Provider attestation that patient experienced a fracture while on long-term glucocorticoid therapy, **or**
    - e. Provider attestation that 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.
  - II. Intolerable side effect to bisphosphonate (oral and IV) therapy or

Prolia, or contraindication to bisphosphonate (oral and IV) therapy and Prolia, **or**

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

Coverage Duration: 2 years

Effective Date: 11/30/2022