

## Specialty Pharmacy Program

### Forteo<sup>®</sup> (teriparatide)

#### DESCRIPTION

Forteo is a recombinant human parathyroid hormone drug that is indicated for the treatment of the following conditions in individuals who are at high risk for fracture: 1) postmenopausal osteoporosis in women; 2) primary or hypogonadal osteoporosis in men; and 3) glucocorticoid-induced osteoporosis in men and women.

The FDA requires a black box warning regarding the risk of osteosarcoma with the use of Forteo due to an increased incidence of osteosarcoma in male and female rats that was dependent on dose and treatment duration. The use of Forteo for more than 2 years is not recommended.

#### APPROVAL DURATION

Approval duration: Up to 2 years

#### APPROVAL CRITERIA

- I. Forteo requests may be approved based on the following criteria:
  - A. Patient has very low bone mineral density ( $-3$  or below), OR
  - B. Patient has sustained a fragility fracture or compression fracture due to osteoporosis despite treatment with antiresorptive therapy, OR
  - C. Patient has osteoporosis and is intolerant or has a contraindication to bisphosphonates.
    1. Intolerance or contraindications to bisphosphonates are defined as having at least one of the following:
      - i. Allergy to both Actonel and Fosamax.
      - ii. Inability to sit or stand upright for at least 30 minutes.
      - iii. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, etc.).
- II. Bone mineral density (BMD) must be provided with all requests.
  - A. Osteoporosis is defined as a BMD T-Score of  $\leq -2.5$  as compared to young normal adults.
  - B. BMD T-Scores  $> -2.5$  (closer to 0 or positive) are not considered osteoporotic.
- III. Site of fragility or compression fractures will be documented; the following are NOT considered as strongly associated with the progression of osteoporosis:
  - A. Feet
  - B. Toes
  - C. Fingers
  - D. Ribs
- V. Requests to continue therapy beyond 24 months (2 years) will not be approved.