I. Medication Description

Forteo is a recombinant form of human parathyroid hormone. It provides the same beneficial effect on the bone and kidney as the native parathyroid hormone (PTH). PTH works by stimulating both bone resorption and formation, to maintain normal bone mass. Age-related PTH level changes can lead to cortical bone loss or hip fractures. Forteo works by stimulating bone formation, therefore increasing bone mass and density.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Forteo is provided when the following criteria have been met:

- Forteo is being used:
  - For the treatment of osteoporosis in postmenopausal women at high risk for fracture OR
  - For the treatment of osteoporosis in men and women with sustained systemic glucocorticoid therapy at high risk of fracture OR
  - To increase bone mass in men with primary or hypogonadal osteoporosis at high risk of fracture AND
- Member is 18 years of age or older AND
- Member must have failed therapy with a bisphosphonate (defined by a fracture while on therapy or worsening bone density) unless such a trial is shown to be inappropriate or contraindicated (e.g., presence of severe osteoporosis [T-scores -3.0 or worse in lumbar spine, femoral neck, or total hip region], history of major osteoporotic fracture, presence of renal insufficiency, etc) AND
- Member has at least one of the following:
  - T-score equal to or worse than -2.5 in the lumbar spine, femoral neck, or total hip region OR
  - A FRAX calculator based 10-year risk of at least 20% for a major osteoporotic fracture (spine, shoulder, hip, or wrist), or a 10-year risk of at least 3% for a hip fracture OR
  - Presence or history of osteoporotic fracture

IV. Quantity Limitations

1 pen per each 28 days will be covered (to accommodate a dose of 20mcg per day)
V. Coverage Duration

Coverage is provided for up to 2 years and cannot be renewed

VI. Coverage Renewal Criteria

n/a

VII. Billing/Coding Information

Forteo Prefilled Pen 20mcg/dose Solution for injection (each pen delivers 28 subcutaneous doses)

VIII. Summary of Policy Changes

- 1/1/12: Requirement of diagnostic DXA scan and/or FRAX calculation added
- 9/15/12: no policy changes
- 3/15/13: loosened criteria requiring use of bisphosphonate prior to coverage
- 12/15/13: no policy changes
- 1/1/15: no policy changes
- 7/1/15: formulary distinctions made
- 3/15/16: no policy changes
- 1/1/17: no policy changes
- 1/1/18: no policy changes
- 2/15/19: added minimum member age to coverage criteria

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.