

## Specialty Pharmacy Program

### Prolia™ (denosumab)

#### DESCRIPTION

Prolia is a monoclonal antibody indicated for the treatment of postmenopausal osteoporosis. Prolia is administered as a subcutaneous injection every 6 months and should be given by a healthcare professional.

#### APPROVAL DURATION

Approval duration: lifetime

#### APPROVAL CRITERIA

Prolia will be approved if the patient meets the following criteria:

- I. Patient is a woman with a diagnosis of postmenopausal osteoporosis **AND**
- II. Patient does not have uncorrected hypocalcemia **AND**
- III. Patient's vitamin D status has been evaluated and corrected **AND**
- IV. Patient will receive adequate intake of supplemental calcium and vitamin D **AND**
- V. Patient is intolerant of at least 2 oral bisphosphonates (e.g., Actonel, Fosamax, or Boniva tablets) **OR**
- VII. Patient has a diagnosis of esophageal stricture, achalasia, or other severe esophageal dysmotility disorder **OR**
- VIII. Patient is unable to stand or sit upright for 60 minutes **OR**
- IX. Patient has a history of severe malabsorption making the use of oral bisphosphonates ineffective **OR**
- X. Patient has renal impairment (creatinine clearance <30 mL/min).