Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

PROLIA® (denosumab)

GPI CODING:

30044530002020

DESCRIPTION:

Prolia is a monoclonal antibody indicated for the treatment of 1) osteoporosis in men and postmenopausal women at high risk for fracture, 2) bone loss in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer, and 3) bone loss in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. Prolia is administered as a subcutaneous injection every 6 months and should be given by a healthcare professional.

APPROVAL DURATION:

Approval duration: lifetime

CRITERIA FOR PROLIA

I. Patient has one of the following diagnoses:
   A. Patient is a woman with postmenopausal osteoporosis
   B. Patient is a woman with breast cancer who is receiving adjuvant aromatase inhibitor therapy
   C. Patient is a man with nonmetastatic prostate cancer who is receiving androgen deprivation therapy
   D. Patient is a man with osteoporosis

II. Patient meets all of the following criteria:
   A. Patient does not have uncorrected hypocalcaemia
   B. Patient's vitamin D status has been evaluated and corrected
   C. Patient will receive adequate intake of supplemental calcium and vitamin D

III. Patient has tried an oral bisphosphonate (e.g., Actonel, Fosamax, or Boniva tablets) or an intravenous bisphosphonate (e.g., Reclast, Boniva Injection) **AND**
   A. Patient had an inadequate response to at least one bisphosphonate:
      i. Osteoporosis-related fracture while on the bisphosphonate for at least one year **OR**
      ii. Significant decline in bone mineral density while on the bisphosphonate for at least one year **AND**
      iii. Patient was compliant with bisphosphonate therapy and received adequate calcium and vitamin D supplementation **OR**
   B. Patient was unable to tolerate at least two different bisphosphonates

OR

IV. If the patient has not tried any bisphosphonate therapy, they must meet one of the following criteria:
   A. Patient has a diagnosis of esophageal stricture, achalasia, or other severe esophageal dysmotility disorder
   B. Patient is unable to stand or sit upright for 60 minutes
   C. Patient has a history of severe malabsorption making the use of oral bisphosphonates ineffective
   D. Patient has renal impairment (creatinine clearance <35 mL/min)