Generic Name: Denosumab

Therapeutic Class or Brand Name: Prolia®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 1/15/2016

Date Last Reviewed / Revised: 5/20/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of one of the following conditions A through D AND must meet criteria listed under applicable diagnosis:
   A. Treatment of postmenopausal women with osteoporosis AND criterion 1 is met:
      1. Documented baseline bone mineral density (BMD) T-score at of -2.5 or less.
   B. Treatment to increase bone mass in men with osteoporosis AND criterion 1 is met:
      1. Documented baseline bone mineral density (BMD) T-score at of -2.5 or less.
   C. Treatment of glucocorticoid induced osteoporosis in both women and men AND criterion 1 thru 3 are met:
      1. Documented baseline bone mineral density (BMD) T-score at -2.5 or less.
      2. Documentation treatment is being continued or is being initiated with prednisone daily dose equivalent ≥ 7.5 mg.
      3. Documentation that treatment duration with glucocorticoids will be 6 months or longer
   D. Treatment to increase bone mass in men receiving androgen deprivation therapy for nonmetastatic prostate cancer.
   E. Treatment to increase bone mass in women receiving adjuvant aromatase inhibitor therapy for breast cancer.

II. Documented trial and failure (i.e., progression of bone loss as recorded by bone mineral density measurements or occurrence of an osteoporotic fracture after a minimum of a 12-month trial) of oral or IV bisphosphonate or contraindication to all bisphosphonate therapy (i.e., alendronate, ibandronate, risedronate, zoledronic acid, etc.).Documentation that patient is at high risk for fracture (i.e. history of osteoporotic fracture, multiple risk factors for fracture, etc.).

III. Documentation that patient will also take calcium 1000 mg daily and at least 400 IU vitamin D daily.

IV. Minimum age requirement: 18 years old.

V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Hypocalcemia
- Pregnancy
- Coadministration of Prolia ® with Xgeva ®

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- One 60 mg injection every 6 months

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. Prolia. Prescribing information. Amgen Inc.; 2023. Accessed August 15, 2023. http://pi.amgen.com/united_states/prolia/prolia_pi.pdf.
2. Qaseem A, Forciea MA, McLean RM, et al. Treatment of low bone density or osteoporosis to prevent fractures in men and women: A Clinical Practice Guideline Update From the American College of Physicians. Ann Intern Med. 2017 Sep 19;167(6):448]. *Ann Intern Med*. 2017;166(11):818-839. Accessed September 15, 2022. https://doi.org/10.7326/M15-1361.