Reference number(s)
3835-A

JURISDICTION SPECIFIC MEDICARE PART B

PROLIA (denosumab)

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. The FDA-labeled indications are listed below:

A. Treatment of postmenopausal women with osteoporosis at high risk for fracture
B. Treatment to increase bone mass in men with osteoporosis
C. Treatment of glucocorticoid-induced osteoporosis
D. Treatment of bone loss in men receiving androgen deprivation therapy for prostate cancer
E. Treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
B. Medical record with name of drug administered, route of administration, dosage, duration of the administration.
C. For treatment of postmenopausal osteoporosis, documentation should include:
    1. Menopausal status (for female beneficiaries only)
    2. Member's age and sex
    3. Documentation supporting the diagnosis of osteoporosis
    4. Previous treatment of osteoporosis, agents used, outcomes and adverse reactions, if any
    5. History of previous fractures, including type of fracture, cause and time of occurrence
    6. Risk factors for future fracture including preventative measures
    7. Adequate calcium levels
    8. Use of vitamin D, if indicated
D. For treatment of cancer-treatment induced bone loss (CTIBL), documentation should include:
    1. Documentation supporting the diagnosis of breast cancer or nonmetastatic prostate cancer
    2. Use of adjuvant aromatase inhibitor (AI) therapy or androgen deprivation therapy (ADT)
    3. Additional diagnosed risk factors, if any

4. Adequate calcium levels
5. Use of vitamin D, if indicated

E. For treatment of Osteoporosis in men and Glucocorticoid-induced Osteoporosis, documentation should include:
1. Adequate calcium levels
2. Use of vitamin D, if indicated

III. CRITERIA FOR APPROVAL

A. Treatment of Postmenopausal Osteoporosis
Authorization of 12 months may be granted for treatment of postmenopausal osteoporosis when all of the following criteria are met:
1. The member will receive supplemental calcium and vitamin D.
2. Hypocalcemia will be corrected prior to initiation of denosumab therapy, if applicable.
3. The member meets one of the following:
   i. The member is at high risk for fracture
   ii. The member has failed treatment with other available osteoporosis therapies
   iii. The member is intolerant to treatment with other available osteoporosis therapies

B. Treatment to Increase Bone Mass in Men with Osteoporosis
Authorization of 12 months may be granted for treatment to increase bone mass in men with osteoporosis when all of the following criteria are met:
1. The member will receive supplemental calcium and vitamin D.
2. Hypocalcemia will be corrected prior to initiation of denosumab therapy, if applicable.
3. The member meets one of the following:
   i. The member is at high risk for fracture
   ii. The member has failed treatment with other available osteoporosis therapies
   iii. The member is intolerant to treatment with other available osteoporosis therapies

C. Treatment of Glucocorticoid-induced Osteoporosis
Authorization of 12 months may be granted for treatment of glucocorticoid-induced osteoporosis when all of the following criteria are met:
1. The member will receive supplemental calcium and vitamin D.
2. Hypocalcemia will be corrected prior to initiation of denosumab therapy, if applicable.
3. The member meets one of the following:
   i. The member is at high risk for fracture
   ii. The member has failed treatment with other available osteoporosis therapies
   iii. The member is intolerant to treatment with other available osteoporosis therapies

D. Treatment of Bone Loss in Men Receiving Androgen Deprivation Therapy for Prostate Cancer
Authorization of 12 months may be granted for treatment of bone loss in men receiving androgen deprivation therapy for prostate cancer when both of the following criteria are met:
1. The member will receive supplemental calcium and vitamin D.
2. Hypocalcemia will be corrected prior to initiation of denosumab therapy, if applicable.

E. Treatment of Bone Loss in Women Receiving Adjuvant Aromatase Inhibitor Therapy for Breast Cancer
Authorization of 12 months may be granted for treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer when both of the following criteria are met:

1. The member will receive supplemental calcium and vitamin D.
2. Hypocalcemia will be corrected prior to initiation of denosumab therapy, if applicable.

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed October 7, 2021.
2. Billing and Coding: Denosumab (A52399) Version R11. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed October 7, 2021.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R8. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed October 7, 2021.
4. Prolia [package insert]. Thousand Oaks, CA; Amgen, Inc.: May 2021.

