Reference number(s)
5272-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.

A. Postmenopausal Osteoporosis
B. Osteoporosis in Men
C. Glucocorticoid-Induced Osteoporosis
D. Bone Loss in Men with Prostate Cancer
E. Bone Loss in Women with 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. EXCLUSIONS

The following are exclusions to therapy:
A. Combination use of bisphosphonate and a monoclonal antibody for the treatment of osteoporosis during an episode of care
B. Hypocalcemia, hypovitaminosis D, and other disturbances of bone and mineral metabolism
C. Patients receiving Xgeva
D. Hypersensitivity to Prolia

III. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. All documentation must be maintained in the patient's medical record and made available to the contractor upon request
B. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient
C. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed
D. Criteria for the diagnosis of osteoporosis
E. History of treatment as related to progression of disease and ongoing risk factors

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F. Description of treatment failure, or contraindication, or adverse side effects, of oral or self-administered drugs for osteoporosis as applicable to the member that supports monoclonal antibodies via SQ injection therapy in lieu of standard oral treatment protocol

IV. CRITERIA FOR APPROVAL

A. Postmenopausal Osteoporosis

Authorization of 12 months may be granted for the treatment of postmenopausal osteoporosis when all of the following criteria are met:

1. Oral health is discussed with the member
2. The member will take 1,000 mg of calcium and at least 400 IU vitamin D per day
3. The member has history of progression of disease while on therapy and ongoing risk factors
4. The member has one of the following:
    i. Osteoporosis with high risk for fracture
    ii. Member has failed/intolerant to other available osteoporotic therapy

B. Osteoporosis in Men

Authorization of 12 months may be granted for the treatment of osteoporosis in men when all of the following criteria are met:

1. Oral health is discussed with the member
2. The member will take 1,000 mg of calcium and at least 400 IU vitamin D per day
3. The member has history of progression of disease while on therapy and ongoing risk factors
4. The member has one of the following:
    i. Osteoporosis with high risk for fracture
    ii. Member has failed/intolerant to other available osteoporotic therapy

C. Glucocorticoid-Induced Osteoporosis

Authorization of 12 months may be granted for the treatment of glucocorticoid-induced osteoporosis when all of the following criteria are met:

1. Oral health is discussed with the member
2. The member will take 1,000 mg of calcium and at least 400 IU vitamin D per day
3. The member is either initiating or continuing to take system glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone
4. The member is expected to remain on glucocorticoids for at least 6 months

D. Bone Loss in Men with Prostate Cancer

Authorization of 12 months may be granted for the treatment of bone loss in men with prostate cancer when all of the following criteria are met:

1. Oral health is discussed with the member
2. The member will take 1,000 mg of calcium and at least 400 IU vitamin D per day
3. The male member has non-metastatic prostate cancer
4. The male member is receiving androgen deprivation therapy

E. Bone Loss in Women with Breast Cancer

Authorization of 12 months may be granted for the treatment of bone loss in women with breast cancer when all of the following criteria are met:

1. Oral health is discussed with the member
2. The member will take 1,000 mg of calcium and at least 400 IU vitamin D per day
3. The female member is receiving adjuvant aromatase inhibitor therapy

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V. REFERENCES

1. Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications (L33270) Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed October 18, 2022.
2. Billing and Coding: Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications (A57603) Version R2. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed October 18, 2022.
3. Prolia [package insert]. Thousand Oaks, CA: Amgen, Inc; May 2022.

DOCUMENT HISTORY

Created:	Specialty Clinical Development (TSD) 02/2022
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