Reference number(s)
3835-A

Jurisdiction Specific Medicare Part B Prolia and Biosimilars

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Prolia	denosumab
Bildyos	denosumab-nxxp
Bosaya	denosumab-kyqq
Conexxence	denosumab-bnht
Jubbonti	denosumab-bbdz
Ospomyv	denosumab-dssb
Stoboclo	denosumab-bmwo

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 FDA-labeled indications and recognized compendia (off-label) uses are listed below:

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

Compendial Uses- ICD-10 Codes Supported by the Medicare Administrative Contractor

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

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

Coverage Criteria

Treatment of Postmenopausal Osteoporosis[1-9]

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

- The member will receive supplemental calcium and vitamin D (calcium 1000 mg daily and at least 400 IU vitamin D daily).
- Hypocalcemia will be corrected prior to initiation of the requested drug, if applicable.
- The member meets one of the following:
    - The member is at high risk for fracture
    - The member has failed treatment with other available osteoporosis therapies
    - The member is intolerant to treatment with other available osteoporosis therapies

Treatment to Increase Bone Mass in Men with Osteoporosis[1-9]

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:

- The member will receive supplemental calcium and vitamin D (calcium 1000 mg daily and at least 400 IU vitamin D daily).
- Hypocalcemia will be corrected prior to initiation of the requested drug, if applicable.
- The member meets one of the following:
    - The member is at high risk for fracture
    - The member has failed treatment with other available osteoporosis therapies
    - The member is intolerant to treatment with other available osteoporosis therapies

Treatment of Glucocorticoid-Induced Osteoporosis[1-9]

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

- The member will receive supplemental calcium and vitamin D (calcium 1000 mg daily and at least 400 IU vitamin D daily).
- Hypocalcemia will be corrected prior to initiation of the requested drug, if applicable.
- The member meets one of the following:
    - The member is at high risk for fracture
    - The member has failed treatment with other available osteoporosis therapies
    - The member is intolerant to treatment with other available osteoporosis therapies

Treatment of Prostate Cancer[1-10]

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:

- The member will receive supplemental calcium and vitamin D (calcium 1000 mg daily and at least 400 IU vitamin D daily).
- Hypocalcemia will be corrected prior to initiation of the requested drug, if applicable.

Treatment of Breast Cancer[1-10]

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:

- The member will receive supplemental calcium and vitamin D (calcium 1000 mg daily and at least 400 IU vitamin D daily).
- Hypocalcemia will be corrected prior to initiation of the requested drug, if applicable.

All Other Indications[2]

Authorization of 12 months may be granted for treatment of all other approvable indications listed in local coverage article (LCA) A52399.

Dosage and Administration

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

References

1. Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394) Version R17. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed September 5, 2025.
2. Billing and Coding: Denosumab (A52399) Version R17. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed September 5, 2025.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R9. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed September 5, 2025.
4. Prolia [package insert]. Thousand Oaks, CA; Amgen, Inc.; May 2025.
5. Bosaya [package insert]. Cambridge, MA: Biocon Biologics In.; September 2025.
6. Bildyos [package insert]. Jersey City, NJ: Organon LLC,; August 2025.
7. Conexxence [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC.; March 2025.
8. Jubbonti [package insert]. Princeton, NJ; Sandoz, Inc.; October 2024.
9. Ospomyv [package insert]. Incheon, South Korea: Samsung Bioepis; February 2025.
10. Stoboclo [package insert]. Incheon, South Korea: Celltrion Inc.; February 2025.
11. The NCCN Drugs & Biologics Compendium® 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed September 5, 2025.

