

# 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
Boncresta	denosumab-mobz
Bosaya	denosumab-kyqq
Conexence	denosumab-bnht
Enoby	denosumab-qbde
Jubbonti	denosumab-bbdz
Ospomyv	denosumab-dssb
Osvyrti	denosumab-desu
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

Reference number(s)
3835-A

- 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<sup>1-13</sup>

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<sup>1-13</sup>

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

Reference number(s)
3835-A

## Treatment of Glucocorticoid-Induced Osteoporosis<sup>1-13</sup>

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<sup>1-14</sup>

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<sup>1-14</sup>

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<sup>2</sup>

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 December 12, 2025.
2. Billing and Coding: Denosumab (A52399) Version R19. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed December 19, 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 December 9, 2025.
4. Prolia [package insert]. Thousand Oaks, CA; Amgen, Inc.; May 2025.
5. Bildyos [package insert]. Jersey City, NJ: Organon LLC,; August 2025.
6. Boncresa [package insert]. Piscataway, NJ: Amneal Pharmaceuticals LLC; October 2025.
7. Bosaya [package insert]. Cambridge, MA: Biocon Biologics In.; September 2025.
8. Conexence [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC.; March 2025.
9. Enoby [package insert]. Cherry Hill, NJ: Hikma Pharmaceuticals USA Inc.; September 2025.
10. Jubbonti [package insert]. Princeton, NJ; Sandoz, Inc.; October 2024.
11. Ospomyv [package insert]. Incheon, South Korea: Samsung Bioepis; February 2025.
12. Osvyrti [package insert]. Raleigh, NC; Accord BioPharma Inc.; October 2025.
13. Stoboclo [package insert]. Incheon, South Korea: Celltrion Inc.; February 2025.
14. The NCCN Drugs & Biologics Compendium® 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed December 8, 2025.