Reference number(s)
2026-A

Specialty Guideline Management
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
Boncresa	denosumab-mobz
Bosaya	denosumab-kyqq
Conexxence	denosumab-bnht
Enoby	denosumab-qbde
Jubbonti	denosumab-bbdz
Ospomyv	denosumab-dssb
Osvyrti	denosumab-desu
Ponlimsi	denosumab-adet
Stoboclo	denosumab-bmwo

Indications

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

FDA-Approved Indications[1-11]

- Treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (ADT) for nonmetastatic prostate cancer.
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Compendial Uses[12,23]

- For treatment-related bone loss in patients with prostate cancer receiving androgen deprivation therapy (ADT).
- Treatment in postmenopausal (natural or induced) patients with breast cancer receiving adjuvant aromatase inhibition therapy to maintain or improve bone mineral density and reduce risk of fractures.
- To inhibit progression of bone erosion in patients with rheumatoid arthritis.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Postmenopausal Osteoporosis, Osteoporosis in Men, Glucocorticoid-Induced Osteoporosis

- Chart notes or medical record documentation indicating a history of fractures, T-score, and Fracture Risk Assessment Tool (FRAX) probability (if applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Prostate Cancer

Chart notes, medical record documentation, or claims history supporting use of androgen deprivation therapy (ADT).

Breast Cancer

Chart notes, medical record documentation, or claims history supporting use of aromatase inhibition therapy.

Coverage Criteria

Postmenopausal Osteoporosis[1-11,13-18,22]

Authorization of 12 months may be granted to postmenopausal members with osteoporosis when EITHER of the following criteria is met:

- Member has a history of fragility fractures (e.g., low trauma fracture from force similar to a fall from standing position).
- Member has a pre-treatment T-score ≤ -2.5 OR member has osteopenia (i.e., pre-treatment T-score between -1 and -2.5) with a high pre-treatment FRAX probability (see Appendix) and meets ANY of the following criteria:
    - Member has indicators of very high fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores [≤ -3], or increased fall risk)
    - Member has had an inadequate response or intolerance to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo], abaloparatide [Tymlos])
    - Member has had an inadequate response or intolerance to previous oral bisphosphonate therapy.

Osteoporosis in Men[1-11,13-14,18-19,22]

Authorization of 12 months may be granted to male members with osteoporosis when any of the following criteria is met:

- Member has a history of an osteoporotic vertebral or hip fracture
- Member has a pre-treatment T-score ≤ -2.5 OR member has osteopenia (i.e., pre-treatment T-score between -1 and -2.5)) with a high pre-treatment FRAX probability (see Appendix).
- Member has had an inadequate response or intolerance to previous bisphosphonate therapy.

Glucocorticoid-Induced Osteoporosis[1-11,18-19,21-22]

Authorization of 12 months may be granted for members with glucocorticoid-induced osteoporosis when BOTH of the following criteria are met:

- Member is currently receiving or will be initiating glucocorticoid therapy at an equivalent prednisone dose of ≥ 2.5 mg/day for ≥ 3 months.
- Member meets EITHER of the following criteria:
  - Member has had an inadequate response or intolerance to previous bisphosphonate therapy
  - Member meets ANY of the following criteria:
    - Member has a history of a fragility fracture (e.g., low trauma fracture from force similar to a fall from standing position).
    - Member has a pre-treatment T-score ≤ -2.5.
    - Member has osteopenia (i.e., pre-treatment T-score between -1 and -2.5) with a high pre-treatment FRAX probability (see Appendix).

Prostate Cancer[1-12,20]

Authorization of 12 months may be granted to members who are receiving androgen deprivation therapy (ADT) for prostate cancer.

Breast Cancer[1-12,20]

Authorization of 12 months may be granted to members who are receiving adjuvant aromatase inhibition therapy for breast cancer.

Rheumatoid Arthritis[23]

Authorization of 12 months may be granted to inhibit progression of bone erosion in members with rheumatoid arthritis.

Continuation of Therapy[1-11]

Authorization of 12 months may be granted for all members (including new members) who are currently receiving the requested medication through a previously authorized pharmacy or medical benefit, who meet either of the following:

- Member has received less than 24 months of therapy and has not experienced clinically significant adverse events during therapy
- Member has received 24 months of therapy or more and meets both of the following:
  - Member has experienced clinical benefit (i.e., improvement or stabilization in T-score

since the previous bone mass measurement)
- Member has not experienced any adverse effects

Appendix

FRAX© (Fracture Risk Assessment Tool)[14-16,19,21-22]

- FRAX© (fracture risk assessment tool) available at: https://fraxplus.org
- High FRAX probability: 10-year major osteoporotic fracture probability ≥ 20% or hip fracture probability ≥ 3%
- FRAX Glucocorticoid correction: If glucocorticoid dose is greater than 7.5 mg (prednisone equivalent) per day, the estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture

References

1. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2025.
2. Bildyos [package insert]. Jersey City, NJ: Organon LLC,; August 2025.
3. Boncresa [package insert]. Piscataway, NJ: Amneal Pharmaceuticals LLC; October 2025.
4. Bosaya [package insert]. Cambridge, MA: Biocon Biologics Inc.; September 2025.
5. Conexxence [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; October 2025.
6. Enoby [package insert]. Cherry Hill, NJ: Hikma Pharmaceuticals USA Inc.; September 2025.
7. Jubbonti [package insert]. Princeton, NJ: Sandoz Inc.; October 2025.
8. Ospomyv [package insert]. Incheon, South Korea: Samsung Bioepis; October 2025.
9. Osvyrti [package insert]. Raleigh, NC: Accord BioPharma Inc.; October 2025.
10. Ponlimsi [package insert]. Parsippany, NJ: Teva Pharmaceuticals, Inc.; March 2026.
11. Stoboclo [package insert]. Jersey City, New Jersey: Celltrion USA, Inc.; October 2025.
12. The NCCN Drugs & Biologics Compendium® 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed April 21, 2026.
13. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. Osteoporos Int. 2022;33(10):2049-2102.
14. Ensrud KE, Crandall CJ. Osteoporosis. Ann Intern Med. 2024;177(1):ITC1-ITC16.
15. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis-2020 update. Endocr Pract. 2020;26 (Suppl 1):1-46.
16. Eastell R, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2019;401(5):1595-1622.

17. Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update. J Clin Endocrinol Metab. 2020;105(3):587-594.
18. Carey JJ. What is a 'failure' of bisphosphonate therapy for osteoporosis? Cleve Clin J of Med. 2005;72(11):1033-1039.
19. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. J Clin Endocr Metab. 2012;97(6):1802-1822.
20. Gralow JR, Biermann JS, Farooki A, et al. NCCN Task Force Report: Bone Health in Cancer Care. J Natl Compr Canc New. 2013;11(Suppl 3):S1-50.
21. Humphrey MB, Russell L, Danila MI, et al. 2022 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. Arthritis Rheumatol. 2023;75(12):2088-2012.
22. FRAX® Fracture Risk Assessment Tool. © Osteoporosis Research Ltd, UK. Available online: https://fraxplus.org. Accessed April 21, 2026.
23. [denosumab]. In: Merative™ Micromedex® DRUGDEX® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com. Accessed April 21, 2026.