

denosumab (Prolia and biosimilars)

Commercial Medical Benefit Drug Policy

For oncology-related indications, medical necessity criteria can be found here: [Blue Shield Oncology-Related Medication Policies](#).

For PPO, Direct Contract HMO, and when applicable, ASO, and Shared Advantage: Please access Evolent's [CarePro Provider Portal](#) to submit your request.

denosumab (Prolia)
denosumab-bbdz (Jubbonti)
denosumab-bmwo (Stoboclo)
denosumab-bnht (Conexxence)
denosumab-dssb (Ospomyv)
denosumab-nxxp (Bildyos)

Place of Service

Home Infusion
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: METABOLIC BONE DISEASE AGENTS

Mechanism of Action: Monoclonal antibody that inhibits RANK ligand activity and prevents osteoclast formation

HCPCS:

C9399, J3490, J3590: denosumab-dssd (Ospomyv):

C9399, J3490, J3590: denosumab-nxxp (Bildyos):

J0897:Injection, denosumab, 1 mg

Q5136:Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg

Q5157:Injection, denosumab-bmwo (stoboclo/osenvelt), biosimilar, 1 mg

Q5158:Injection, denosumab-bnht (bomyntra/conexxence), biosimilar, 1 mg

How Supplied:

60 mg/mL in a single-dose prefilled syringe

Condition(s) listed in policy *(see coverage criteria for details)*

- Osteoporosis

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Jubbonti is the preferred denosumab product. Request for other denosumab products for members newly initiating therapy will require intolerance or contraindication to Jubbonti.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Osteoporosis

Meets medical necessity if all the following are met:

1. Meets ONE of the following:
 - a. One or more non-traumatic fractures
 - b. T-scores less than -2.5 S.D
 - c. T-score is between -1.0 and -2.5 and patient is at high risk for fracture [*e.g. multiple risk factors, 10-year hip fracture probability $\geq 3\%$, a 10-year major osteoporosis-related fracture probability $\geq 20\%$ based on USA-adapted WHO absolute fracture risk model (FRAX risk assessment)]*]
2. Meets ONE of the following:
 - a. Intolerance to prior oral and IV bisphosphonate therapy that would cause discontinuation, or contraindication to oral and IV bisphosphonates
 - b. Inadequate response, as evidenced by documented worsening BMD with a bisphosphonate
 - c. Patient is initiating or continuing long-term glucocorticoid treatment (≥ 3 months)
 - d. Patient is at very high risk of fracture by meeting at least ONE of the following:
 - i. Fracture while taking a bisphosphonate
 - ii. Patient has experienced a recent fracture (within the past 12 months) or history of multiple fractures
 - iii. Patient experienced a fracture while on long-term glucocorticoid therapy
 - iv. T-score less than -3.0
 - v. Patient is at high risk for falls
 - vi. 10-year hip fracture probability of $> 4.5\%$ based on FRAX score
 - vii. 10-year major osteoporosis-related fracture probability $> 30\%$ based on FRAX score
3. Not being used in combination with other drug therapy for osteoporosis (e.g., Forteo, Evenity, teriparatide, Tymlos)
4. Request for Bıldıyos, Conexence, Prolia, Ospomyv, or Stoboclo: Intolerable side effect or contraindication with preferred denosumab product (i.e. Jubbonti) that is not expected with the requested drug

Covered Doses:

denosumab (Prolia and biosimilars)

Up to 60 mg given subcutaneously once every 6 months

Coverage Period:

Yearly based on continued response to therapy

ICD-10:

M80.0-M81.9

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Bıldıys (denosumab-nxxp) Prescribing Information. Organon & Co., Jersey City, NJ: 8/2025.
4. Conexence (denosumab-bnht) Prescribing Information. Fresenius Kabi USA, LLC Lake Zurich, IL: 3/2025.
5. Cosman F, de Beur SJ, LeBoff MS et al. Clinician's guide to prevention and treatment of osteoporosis. *Osteoporosis Int* 2014;25(10):2359-81.
6. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and 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
7. Jubbonti (denosumab-bbdz) Prescribing Information. Sandoz Inc., Princeton, NJ: 10/2024.
8. National Comprehensive Cancer Network. Breast Cancer (Version 4.2024). Available at: www.nccn.org.
9. National Comprehensive Cancer Network. Prostate Cancer (Version 4.2024). Available at: www.nccn.org.
10. Ospomyv (denosumab-dssb) [prescribing information]. Yeonsu-gu. Incheon, South Korea: Samsung Bioepis Co Ltd; February 2025.
11. Prolia (denosumab) [Prescribing information]. Thousand Oaks, CA: Amgen Inc.; 3/2024.
12. Qaseem A, Forciea MA, McLean RM, Denberg TD, Clinical Guidelines Committee of the American College of Physicians. Treatment of Low Bone Density or Osteoporosis to Prevent Fractures in Men and Women: A Clinical Practice Guideline Update from the American College of Physicians. *Ann Intern Med*. 2017;166(11):818-839. doi:10.7326/M15-1361
13. 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; 105:587-594.
14. ACOG Committee on Clinical Practice Guidelines–Gynecology. Management of Postmenopausal Osteoporosis: ACOG Clinical Practice Guideline No. 2. *Obstet Gynecol*. 2022 Apr 1;139(4):698-717. doi: 10.1097/AOG.0000000000004730. Erratum in: *Obstet Gynecol*. 2022 Jul 01;140(1):138.
15. Stoboclo (denosumab-bmwo) Prescribing Information. CELLTRION USA, Inc., Jersey City, NJ: 2/2025

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- Effective 1/1/2026, medical necessity determinations will be made by Evolent for oncology-related indications

denosumab (Prolia and biosimilars)

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*