

## 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 (Conexence)  
denosumab-dssb (Ospomyv)  
denosumab-kyqq (Bosaya)  
denosumab-nxxp (Bildyos)  
denosumab-qbde (Enoby)

#### **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-qbde (Enoby):

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 (bomynta/conexence), biosimilar, 1 mg

Q5161: Injection, denosumab-kyqq (aukelso/bosaya), biosimilar, 1 mg

Q5162: Injection, denosumab-nxxp (bildyos/bilprevda), 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 ( $\geq 3$  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 a non-preferred denosumab product: Intolerable side effect or contraindication with preferred denosumab product (i.e. Jubbonti) that is not expected with the requested drug

**Covered Doses:**

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**

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4. Bosaya (denosumab-kyqq) Prescribing Information. Biocon Biologics Inc., Cambridge, MA: 9/2025.
5. Conexence (denosumab-bnht) Prescribing Information. Fresenius Kabi USA, LLC Lake Zurich, IL: 3/2025.
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8. Enoby (denosumab-qbde) Prescribing Information. Hikma Pharmaceuticals USA Inc., Cherry Hill, NJ: 9/2025.
9. Jubbonti (denosumab-bbdz) Prescribing Information. Sandoz Inc., Princeton, NJ: 10/2024.
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11. National Comprehensive Cancer Network. Prostate Cancer (Version 4.2024). Available at: [www.nccn.org](http://www.nccn.org).
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13. Prolia (denosumab) [Prescribing information]. Thousand Oaks, CA: Amgen Inc.; 3/2024.
14. Qaseem A, Forcica 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
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16. 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.
17. 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:

- Added new biosimilar Enoby and Bosaya (FDA approval)
- Added new HCPCS Q5161 for Bosaya and HCPCS Q5162 for Bilyos, effective 4/1/2026.

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