blue california
Promise Health Plan

denosumab (Prolia and biosimilars)

Medical Benefit Drug Policy

For oncology-related indications, coverage will be made based on medical necessity. Medical necessity determinations are made based on U.S. Food and Drug Administration (FDA) labeling, peer-reviewed medical literature, Medi-Cal coverage guidelines, and Centers for Medicare & Medicaid Services (CMS) approved compendia support (i.e., Clinical Pharmacology, National Comprehensive Cancer Network® (NCCN), American Hospital Formulary Service Drug Information, Thomson Micromedex DrugDex,® and Lexicomp®).

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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

Bildyos, Conexxence, Stoboclo, Ospomyv, and Jubbonti are the preferred denosumab products. Request for Prolia for members newly initiating therapy will require an intolerance or contraindication to all the preferred drugs.

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 >/= 3%, a 10-year major osteoporosis-related fracture probability >/= 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 Prolia: Intolerable side effect or contraindication with preferred denosumab products (i.e. Bildyos Jubbonti, Stoboclo, Ospomyv, and Conexxence) that is not expected with the requested drug

Covered Doses:
Up to 60 mg given subcutaneously once every 6 months

Coverage Period:
Yearly

ICD-10:
M80.0-M81.9

References

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Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- For oncology-related indications, coverage will be made based on medical necessity.

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