AdvancedHealth
Bridging the Future of Healthcare

289 LaClair Coos Bay OR 97420
Phone: 541-269-7400 Fax: 541-269-7147

Denosumab – Xgeva® Drug Use Criteria

Created: 10/1/2025
Reviewed: 10/8/2025

Includes:
Xgeva ® (Denosumab)

GUIDELINE FOR USE:

Initial Request:

1. Does the member have a diagnosis of bone metastases from solid tumors or multiple myeloma?

    a. If yes, go to 2
    b. If no, go to 3

2. Has zoledronic acid been trialed or is there a contraindication to zoledronic acid that is not a contraindication to denosumab?

    a. If yes, go to 6
    b. If no, deny as not meeting criteria. Please trial with preferred least costly alternative, zoledronic acid (Zometa)

3. Does the member have a diagnosis of giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity?

    a. If yes, go to 6
    b. If no, go to 4

4. Does the member have a diagnosis of hypercalcemia of malignancy (HCM)?

    a. If yes, go to 5
    b. If no, deny as not meeting criteria. Off-label use is not a covered benefit of OHP.

5. Has a bisphosphonate such as zoledronic acid (Zometa) or pamidronate (Aredia) been trialed or is there a contraindication to either?

    a. If yes, go to 6
    b. If no, deny as not meeting criteria. Please trial with preferred least costly alternatives, zoledronic acid (Zometa) or pamidronate (Aredia)

289 LaClair Coos Bay OR 97420
Phone: 541-269-7400 Fax: 541-269-7147

6. Has the member had treatment failure or adverse reaction to preferred biosimilar (Wyost (denosumab-bbdz)?

    a. If yes, approve for up to 12 months
    b. If no, deny as not meeting criteria. Please change to preferred least costly biosimilar, Wyost (denosumab-bbdz)

Renewal Request:

1. Has the patient continued to receive clinical benefit (e.g., stable or improved bone lesions, maintained normocalcemia, or prevention of new skeletal events)?
    a. If yes, approve for up to 12 months
    b. If no deny as not meeting criteria. Reassessment is needed

Rationale: To support appropriate utilization, promotes clinical effectiveness, reduces unnecessary healthcare costs, and aligns with payer goals for formulary management and stewardship of specialty medications.

Mechanism of Action: Xgeva is a monoclonal antibody that binds to and inhibits RANK ligand (RANKL), a key mediator of osteoclast formation, function, and survival. By blocking RANKL, Xgeva reduces bone resorption and prevents skeletal-related events associated with bone metastases, giant cell tumor of bone, and malignancy-related hypercalcemia.

References:

1. Xgeva (denosumab) [package insert]. Thousand Oaks, CA: Amgen Inc; 2020. Accessed June 6, 2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125320s203lbl.pdf
2. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Bone Cancer. Version 1.2024. Accessed June 6, 2025. https://www.nccn.org/patients/guidelines/content/PDF/bone-patient.pdf
3. Amgen Inc. Why Choose Xgeva®: Mechanism of Action. Accessed June 6, 2025. https://www.xgevahcp.com/about-xgeva/why-choose-xgeva