PRIOR AUTHORIZATION POLICY

POLICY: Bone Modifiers – Denosumab Products (Xgeva) Prior Authorization Policy
- Wyost® (denosumab-bbdz subcutaneous injection – Sandoz)
- Xgeva® (denosumab subcutaneous injection – Amgen)

REVIEW DATE: 03/19/2025; selected revision 05/14/2025

OVERVIEW

Denosumab products (Xgeva, biosimilar) are receptor activator of nuclear factor kappa-B ligand inhibitors indicated for the following uses:[1,2]

- **Giant cell tumor of bone**, treatment of adults and skeletally mature adolescents with disease that is unresectable or where surgical resection is likely to result in severe morbidity.
- **Hypercalcemia of malignancy**, treatment of, that is refractory to bisphosphonate therapy.
- **Skeletal-related events**, prevention in patients with multiple myeloma and in those with bone metastases from solid tumors.

Another injectable formulation of denosumab subcutaneous injection is available (Prolia®, biosimilar) but it is not included in this policy.[3,4]

Guidelines

Several guidelines address denosumab products (Xgeva, biosimilar).

- **Cancer:** Various guidelines from the National Comprehensive Cancer Network (NCCN) [e.g., breast cancer, prostate cancer, lung cancer, multiple myeloma] recommend denosumab products (Xgeva, biosimilar), for the prevention of skeletal related adverse events.[5-8]
- **Hypercalcemia of Malignancy:** Guidelines from the Endocrine Society for the treatment of hypercalcemia of malignancy in adults (2023) have several recommendations.[9] In adults with hypercalcemia of malignancy, treatment with denosumab products (Xgeva, biosimilar) over an intravenous bisphosphonate is recommended.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of denosumab products (Xgeva, biosimilar). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with denosumab products (Xgeva, biosimilar) as well as the monitoring required for adverse events and long-term efficacy, approval requires denosumab products (Xgeva, biosimilar) to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of denosumab products (Xgeva, biosimilar) is recommended in those who meet one of the following criteria:

1. **Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   Note: Some examples of cancer in this clinical scenario include breast cancer, prostate cancer, and non-small cell lung cancer.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has bone metastases; AND
   C) Patient with prostate cancer must have castration-resistant prostate cancer; AND
   Note: This includes patients who have progressed after treatment with hormonal therapy or after surgical castration (e.g., bilateral orchiectomy). Examples of hormonal therapies for prostate cancer include Lupron Depot (leuprolide for depot suspension), Eligard (leuprolide acetate for injectable suspension), Trelstar (triptorelin pamoate for injectable suspension), or Zoladex (goserelin implant).
   D) The medication is prescribed by or in consultation with a hematologist or an oncologist.

2. **Giant Cell Tumor of Bone.** Approve for 1 year.

3. **Hypercalcemia of Malignancy.** Approve for 2 months if the patient meets BOTH of the following (A and B):
   A) Patient has a current malignancy; AND
   B) Patient has an albumin-corrected calcium (cCa) ≥ 11.5 mg/dL.

4. **Multiple Myeloma – Prevention of Skeletal-Related Events.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Medication is prescribed by or in consultation with a hematologist or an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of denosumab products (Xgeva, biosimilar) are not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Xgeva® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; June 2020.
2. Wyost® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; March 2024.
3. Prolia® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; March 2024.
4. Jubbonti® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; October 2024.
5. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – December 4, 2024). © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 14, 2025.
6. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – March 5, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 14, 2025.
7. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 1.2025 – September 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 14, 2025.
8. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – January 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 14, 2025.
9. Ghada El-Hajj Fuleihan, Clines GA, Hu MI, et al. Treatment of hypercalcemia of malignancy in adults: an Endocrine Society Clinical Practice guideline. *J Clin Endocrinol Metab*. 2023;108(3):507-528.