VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Bone Modifiers – Denosumab Products (Xgeva) Utilization Management Medical Policy

- Aukelso™ (denosumab-kyqq subcutaneous injection – Biocon)
- Bilprevda® (denosumab-nxxp subcutaneous injection – Organon)
- Bomyntra® (denosumab-bnht subcutaneous injection – Fresenius Kabi)
- Osenvelt® (denosuamb-bmwo subcutaneous injection – Celltrion)
- Wyost® (denosumab-bbdz subcutaneous injection – Sandoz)
- Xbryk™ (denosumab-dssb subcutaneous injection – Samsung Bioepis)
- Xgeva® (denosumab subcutaneous injection – Amgen)
- Xtrenbo™ (denosumab-qbde subcutaneous injection – Hikma)

REVIEW DATE: 03/04/2026

OVERVIEW

Denosumab products (Xgeva, biosimilars) are receptor activators of nuclear factor kappa-B ligand inhibitors indicated for the following uses:[1-8]

- **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.

Of note, denosumab subcutaneous injection is also available under the brand name Prolia® (and biosimilars) but is not included in this policy.[9]

Dosing Information

Denosumab products (Xgeva, biosimilars) should be administered by a healthcare provider.[1] Xgeva is intended for subcutaneous route only and should not be administered intravenously, intramuscularly, or intradermally.

Guidelines

Several guidelines address denosumab products (Xgeva, biosimilars).

- **Cancer:** Various guidelines from the National Comprehensive Cancer Network (NCCN) [e.g., breast cancer, kidney cancer, prostate cancer, lung cancer, multiple myeloma, thyroid carcinoma] recommend denosumab products (Xgeva, biosimilars), for the prevention of skeletal related adverse events.[10-15]
- **Hypercalcemia of Malignancy:** Guidelines from the Endocrine Society for the treatment of hypercalcemia of malignancy in adults (2023) have several recommendations.[16] In adults with hypercalcemia of malignancy, treatment with denosumab products (Xgeva, biosimilars) over an intravenous bisphosphonate is recommended.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of denosumab products (Xgeva, biosimilars). Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-

by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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, biosimilars) as well as the monitoring required for adverse events and long-term efficacy, approval requires denosumab products (Xgeva, biosimilars) 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, biosimilars) is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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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, kidney cancer, prostate cancer, non-small cell lung cancer, and thyroid carcinoma.

- **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)** Medication is prescribed by or in consultation with a hematologist or an oncologist.

Dosing. Approve 120 mg administered subcutaneously no more frequently than once every 4 weeks.

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

Dosing. Approve 120 mg administered subcutaneously no more frequently than once every 4 weeks with loading doses on Day 8 and Day 15 of Month 1.

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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.

Dosing. Approve 120 mg administered subcutaneously no more frequently than once every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy.

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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) The medication is prescribed by or in consultation with a hematologist or an oncologist.

Dosing. Approve 120 mg administered subcutaneously no more frequently than once every 4 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of denosumab products (Xgeva, biosimilars) is not recommended in the following situations:

1. **Concurrent Use with Other Denosumab Products.**
   Note: Examples of other denosumab products include Prolia, biosimilars.
   The prescribing information contains a Warning that a patient receiving denosumab subcutaneous injection (Xgeva, biosimilars) should not receive other denosumab products concomitantly.[1]

2. 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; September 2025.
2. Wyost® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; March 2024.
3. Osenvelt® subcutaneous injection [prescribing information]. Jersey City, NJ: Celltrion; February 2025.
4. Bomyntra® subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; March 2025.
5. Bilprevda® subcutaneous injection [prescribing information]. Jersey City, NJ: Organon; September 2025.
6. Xbryk™ subcutaneous injection [prescribing information]. Incheon, Republic of Korea: Samsung Bioepis; February 2025.
7. Xtrenbo™ subcutaneous injection [prescribing information]. Cherry Hill, NJ: Hikma, September 2025.
8. Aukelso™ subcutaneous injection [prescribing information]. Cambridge, MA: Biocon; September 2025.
9. Prolia® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; March 2024.
10. The NCCN **Prostate** Cancer Clinical Practice Guidelines in Oncology (version 5.2026 – January 23, 2026). © 2026 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 2, 2026.
11. The NCCN **Breast** Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – February 27, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 2, 2026.
12. The NCCN **Multiple Myeloma** Clinical Practice Guidelines in Oncology (version 5.2026 – January 9, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 2, 2026.
13. The NCCN Non-Small Cell **Lung** Cancer Clinical Practice Guidelines in Oncology (version 3.2026 – December 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 2, 2026.
14. The NCCN **Kidney** Cancer Clinical Practice Guidelines in Oncology (version 1.2026 – July 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 2, 2026.
15. The NCCN **Thyroid** Carcinoma Clinical Practice Guidelines in Oncology (version 1.2025 – March 27, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 2, 2026.
16. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/13/2024
Annual Revision	No criteria changes.	03/19/2025
Selected Revision	Wyost was added to the policy with the same criteria as Xgeva. The Policy name was changed from "Bone Modifiers – Xgeva" to "Bone Modifiers – Denosumab Products (Xgeva)". Throughout the policy, wording was changed from Xgeva to denosumab products (Xgeva, biosimilar).	05/14/2025
Selected Revision	Osenvelt was added to the policy with the same criteria as Xgeva. Throughout the policy, wording was changed to note that there are multiple biosimilars to Xgeva.	06/11/2025
Selected Revision	Bomyntra was added to the policy with the same criteria as the other denosumab (Xgeva, biosimilars) products.	07/09/2025
Selected Revision	Bilprevda was added to the policy with the same criteria as the other denosumab (Xgeva, biosimilars) products.	09/17/2025
Selected Revision	Xbryk was added to the policy with the same criteria as other denosumab (Xgeva, biosimilars) products.	10/29/2025
Selected Revision	Xtrenbo was added to the policy with the same criteria as other denosumab (Xgeva, biosimilars) products.	01/14/2026
Annual Revision	Aukelso was added to the policy with the same criteria as other denosumab (Xgeva, biosimilars) products. **Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events:** The Note with examples of cancers was updated to include kidney cancer and thyroid carcinoma. **Conditions Not Recommended for Approval:** The condition "Concurrent Use with Other Denosumab Products" was added. **Dosing**: The verbiage "up to" and "by subcutaneous injection" were replaced with "no more frequently" and "subcutaneously", respectively.	03/04/2026