

Jurisdiction Specific Medicare Part B Xgeva and Biosimilars

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC products) are not included unless otherwise stated.

Brand Name	Generic Name
Xgeva	denosumab
Aukelso	denosumab-kyqq
Bilprevda	denosumab-nxxp
Bomynta	denosumab-bnht
Osenvelt	denosumab-bmwo
Wyost	denosumab-bbdz
Xbryk	denosumab-dssb

Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

The FDA-labeled indications and recognized compendia (off-label) uses are below:

- Bone metastasis from solid tumors
- Giant cell tumor of bone
- Hypercalcemia of malignancy
- Skeletal-related events associated with multiple myeloma
- Systemic mastocytosis

Compendial Uses- ICD-10 Codes Supported by the Medicare Administrative Contractor

Reference number(s)
3836-A

- The list of covered ICD-10 codes is prohibitively long to include within this criteria. A complete list can be found at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in the coverage criteria section should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Bone Metastasis From Solid Tumors¹⁻⁹

Authorization of 12 months may be granted for treatment of bone metastasis from solid tumors when both of the following criteria are met:

- The member will receive supplemental calcium and vitamin D.
- Hypocalcemia will be corrected prior to initiation of therapy with the requested drug, if applicable.

Giant Cell Tumor of Bone¹⁻⁹

Authorization of 12 months may be granted for treatment of giant cell tumor of bone when both of the following criteria are met:

- The member will receive supplemental calcium and vitamin D.
- Hypocalcemia will be corrected prior to initiation of therapy with the requested drug, if applicable.

Hypercalcemia of Malignancy¹⁻⁹

Authorization of 2 months may be granted for treatment of hypercalcemia of malignancy.

Skeletal-Related Events Associated with Multiple Myeloma¹⁻¹⁰

Authorization of 12 months may be granted for treatment of skeletal-related events in members with multiple myeloma when both of the following criteria are met:

- The member will receive supplemental calcium and vitamin D.
- Hypocalcemia will be corrected prior to initiation of therapy with the requested drug, if applicable.

Reference number(s)
3836-A

Systemic Mastocytosis¹⁰

Authorization of 12 months may be granted for treatment of osteopenia or osteoporosis in members with systemic mastocytosis.

All Other Indications²

Authorization of 12 months may be granted for treatment of all other approvable indications listed in local coverage article (LCA) A52399.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, or evidence-based practice guidelines.

References

1. Drugs and Biologicals, Coverage of, for Label and Off-Label uses (L33394) Version R17. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed September 5, 2025.
2. Billing and Coding: Denosumab (A52399) Version R17. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed September 5, 2025.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R9. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed September 5, 2025.
4. Xgeva [package insert]. Thousand Oaks, CA: Amgen, Inc.: May 2025.
5. Aukelso [package insert]. Cambridge, MA: Biocon Biologics In.; September 2025.
6. Bilprevda [package insert]. Jersey City, NJ: Organon LLC.; August 2025.
7. Bomynta [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; March 2025.
8. Osenvelt [package insert]. Incheon, South Korea: Celltrion Inc.; February 2025.
9. Wyost [package insert]. Princeton, NJ: Sandoz, Inc.; October 2024.
10. Xbryk [package insert]. Incheon, South Korea: Samsung Bioepis; February 2025.
11. The NCCN Drugs & Biologics Compendium™ © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed September 5, 2025.