

Specialty Guideline Management

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 |
| Bomyntra | denosumab-bnht |
| Osenvelt | denosumab-bmwo |
| Wyost | denosumab-bbdz |
| Xbryk | denosumab-dssb |

Indications

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

FDA-Approved Indications¹⁻⁵

- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors
- Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy

Compendial Uses⁶

- Second-line therapy for osteopenia/osteoporosis in patients with systemic mastocytosis

- Thyroid cancer as palliative care for bone metastases

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Multiple Myeloma¹⁻⁶

Authorization of 12 months may be granted for prevention of skeletal-related events in members with multiple myeloma.

Bone Metastases From a Solid Tumor¹⁻⁶

Authorization of 12 months may be granted for either of the following:

- For prevention of skeletal-related events in members with bone metastases from a solid tumor (e.g., breast cancer, non-small cell lung cancer, thyroid carcinoma, kidney cancer, prostate cancer)
- As palliative care for bone metastases from thyroid carcinoma

Giant Cell Tumor of Bone¹⁻⁶

Authorization of 12 months may be granted for treatment of giant cell tumor of bone.

Hypercalcemia of Malignancy^{1-5,7}

Authorization of 2 months may be granted for treatment of hypercalcemia of malignancy that is refractory to intravenous (IV) bisphosphonate therapy OR there is a clinical reason to avoid IV bisphosphonate therapy (see Appendix).

Systemic Mastocytosis⁶

Authorization of 12 months may be granted for second-line therapy for osteopenia or osteoporosis in members with systemic mastocytosis that have not responded to therapy with bisphosphonates or who are not candidates for bisphosphonates because of renal insufficiency.

Continuation of Therapy

Hypercalcemia of Malignancy

Authorization of 2 months may be granted for continued treatment in members requesting reauthorization for hypercalcemia of malignancy who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

All Other Indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Appendix

Appendix: Clinical Reasons to Avoid IV Bisphosphonate Therapy⁸

- Renal insufficiency (creatinine clearance < 35 mL/min)
- Acute renal impairment
- History of intolerance to an IV bisphosphonate

References

1. Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2020.
2. Bomynta [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; March 2025.
3. Osenvelt [package insert]. Incheon, South Korea: Celltrion Inc.; February 2025.
4. Wyost [package insert]. Princeton, NJ: Sandoz Inc.; March 2024.
5. Xbryk [package insert]. Incheon, South Korea: Samsung Bioepis; February 2025.
6. The NCCN Drugs & Biologics Compendium™ © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed April 8, 2025.
7. Hu M, Glezerman IG, Leboulleux S, et al. Denosumab for treatment of hypercalcemia of malignancy. J Clin Endocrinol Metab. 2014;99(9):3144-3152.
8. Bisphosphonates. Drug Facts and Comparisons. Facts & Comparisons® eAnswers. Wolters Kluwer Health Inc. Riverwoods, IL. Accessed October 3, 2024. <https://online.factsandcomparisons.com>.