

Specialty Guideline Management

zoledronic acid-Zometa

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
Zometa	zoledronic acid

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 Indications^{1,2}

- Treatment of hypercalcemia of malignancy defined as an albumin-corrected calcium (cCa) of greater than or equal to 12 mg/dL [3.0 mmol/L] using the formula: $cCa \text{ in mg/dL} = \text{calcium (Ca) in mg/dL} + 0.8 (4.0 \text{ g/dL} - \text{patient albumin [g/dL]})$.
- Treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy.

Limitations of Use

The safety and efficacy of Zometa or zoledronic acid in the treatment of hypercalcemia associated with hyperparathyroidism or with other non-tumor-related conditions have not been established.

Compendial Uses³

- Treatment in postmenopausal patients with breast cancer who are receiving adjuvant aromatase inhibition therapy to maintain or improve bone mineral density and reduce risk of fractures
- Treatment in postmenopausal patients with breast cancer who are receiving adjuvant therapy to reduce the risk of distant metastases
- Treatment for osteopenia or osteoporosis in patients with systemic mastocytosis
- Langerhans cell histiocytosis with bone disease

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review: Chart notes, medical record documentation, or claims history supporting use of aromatase inhibitor therapy, if applicable.

Coverage Criteria

Hypercalcemia of Malignancy¹⁻³

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

Multiple Myeloma¹⁻³

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

Bone Metastases From A Solid Tumor¹⁻³

Authorization of 12 months may be granted for treatment or 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).

Breast Cancer³

Authorization of 12 months may be granted for postmenopausal (natural or induced by ovarian suppression) members when either of the following criteria is met:

- The member is receiving adjuvant aromatase inhibition therapy for breast cancer and the requested medication will be used to maintain or improve bone mineral density and reduce the risk of fractures.
- The member is receiving adjuvant therapy for breast cancer and the requested medication will be used for risk reduction of distant metastasis in high-risk node positive or node negative tumors.

Systemic Mastocytosis³

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

Langerhans Cell Histiocytosis³

Authorization of 12 months may be granted for treatment of Langerhans cell histiocytosis with bone disease.

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.

References

1. Zometa [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2014.
2. Zoledronic acid [package insert]. Lake Zurich, IL: Fresenius Kabi; March 2023.
3. The NCCN Drugs & Biologics Compendium® 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed October 1, 2025.