Zoledronic Acid (Zometa®), Zoledronic Acid

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

I. 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.

A. FDA-Approved Indications
1. Zometa/zoledronic acid is indicated for the treatment of hypercalcemia of malignancy defined as an albumin-corrected calcium (cCa) of greater than or equal to 12mg/dL [3.0 mmol/L] using the formula: cCa in mg/dL=Ca in mg/dL + 0.8 (4.0 g/dL – patient albumin [g/dL]).
2. Zometa/zoledronic acid is indicated for the 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.

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

B. Compendial Uses
1. Treatment or prevention of osteoporosis during androgen-deprivation therapy (ADT) in prostate cancer patients with high fracture risk
2. Treatment in postmenopausal patients with breast cancer who are receiving adjuvant therapy to maintain or improve bone mineral density and reduce risk of fractures
3. Treatment in postmenopausal patients with breast cancer who are receiving adjuvant therapy to reduce the risk of distant metastases
4. Treatment for osteopenia or osteoporosis in patients with systemic mastocytosis
5. Langerhans Cell Histiocytosis with bone disease

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

II. CRITERIA FOR INITIAL APPROVAL

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

B. Multiple Myeloma

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

C. Bone Metastases from a Solid Tumor
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).

D. Prostate Cancer
Authorization of 12 months may be granted for members with prostate cancer for treatment or prevention of osteoporosis during androgen deprivation therapy (ADT)

E. Breast Cancer
Authorization of 12 months may be granted for postmenopausal (natural or induced by ovarian suppression) members receiving adjuvant therapy for treatment of breast cancer when either ~~one~~ of the following is met:

1. The requested medication will be used to maintain or improve bone mineral density and reduce the risk of fractures
2. The requested medication will be used for risk reduction of distant metastasis in high-risk node negative or node positive tumors

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

G. Langerhans Cell Histiocytosis
Authorization of 12 months may be granted for treatment of Langerhans Cell Histiocytosis with bone disease.

III. CONTINUATION OF THERAPY

A. Hypercalcemia of malignancy
Authorization of 2 months will 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.

B. All other indications
Authorization of 12 months will be granted for continued treatment in members requesting reauthorization for an indication listed in Section II who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Zometa [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2018.
2. Zoledronic acid [package insert]. Lake Zurich, IL: Fresenius Kabi; March 2023.
3. The NCCN Drugs & Biologics Compendium 2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 12, 2023.

EFFECTIVE DATE 7/31/2024

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