Reference number(s)
2382-A

SPECIALTY GUIDELINE MANAGEMENT

ZOMETA (zoledronic acid)
zoledronic acid

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 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 prevention of skeletal-related events in member with bone metastases from a solid tumor.

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 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 Diagnosis (excluding hypercalcemia of malignancy)
Authorization of 12 months will be granted for continued treatment in members requesting reauthorization for an indication listed in Section II (excluding hypercalcemia of malignancy) who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

IV. REFERENCES

1. Zometa [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2018.
2. Zoledronic acid [package insert]. Memphis, TN: Northstar Rx LLC; May 2020.
3. IBM Micromedex DRUGDEX (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ . Accessed October 10, 2022.
4. American Society of Health System Pharmacists. AHFS Drug Information (electronic version). Bethesda, MD. Available at: http://online.lexi.com. Accessed October 10, 2022.
5. The NCCN Drugs & Biologics Compendium 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 11, 2022.