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 for osteopenia or osteoporosis in patients with systemic mastocytosis

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Hypercalcemia of Malignancy
Authorization of 1 months may be granted for members who are prescribed zoledronic acid or Zometa for hypercalcemia of malignancy.

B. Multiple Myeloma
Authorization of 12 months may be granted for members who are prescribed zoledronic acid or Zometa for multiple myeloma.

C. Bone Metastases from a Solid Tumor
Authorization of 12 months may be granted for members who are prescribed zoledronic acid or Zometa for bone metastases from a solid tumor.

D. Prostate Cancer
Authorization of 12 months may be granted for members with prostate cancer who are prescribed zoledronic acid or Zometa for the treatment or prevention of osteoporosis during androgen deprivation therapy (ADT).

E. Breast Cancer
Authorization of 12 months may be granted for members who are prescribed zoledronic acid or Zometa who are receiving adjuvant therapy for the treatment of breast cancer.

F. Systemic Mastocytosis
Authorization of 12 months may be granted for members who are prescribed zoledronic acid or Zometa for the treatment of osteopenia or osteoporosis in members with systemic mastocytosis.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Zometa [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2016.
2. Zoledronic acid [package insert]. Memphis, TN: Northstar Rx LLC; May 2018.
3. IBM Micromedex DRUGDEX (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ (cited: *09/24/2018*).
4. American Society of Health System Pharmacists. AHFS Drug Information (electronic version). Bethesda, MD. Available at: http://online.lexi.com. Accessed September 25, 2018.
5. The NCCN Drugs & Biologics Compendium 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed September 25, 2018.
6. Gralow JR, Biermann S, Farooki A, et al. NCCN Task Force Report: Bone Health in Cancer Care. *JNCCN*. 2013; 11(Suppl 3):S1-50.