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. 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. Treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy
      a. Prostate cancer should have progressed after treatment with at least one hormonal therapy

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

B. Compendial Uses
Treatment or prevention of osteoporosis secondary to androgen-deprivation therapy (ADT) in prostate cancer patients at high risk for fracture

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 month may be granted for members who are prescribed zoledronic acid or Zometa for hypercalcemia of malignancy.

B. Multiple Myeloma
Authorization of 24 months may be granted for members who are prescribed zoledronic acid or Zometa for multiple myeloma.

C. Bone Metastases from a Solid Tumor (excluding prostate cancer)
Authorization of 24 months may be granted for members who are prescribed zoledronic acid or Zometa for bone metastases from a solid tumor other than prostate cancer.

D. Prostate Cancer
1. Authorization of 24 months may be granted for members with castration-recurrent prostate cancer who are prescribed zoledronic acid or Zometa for bone metastases.

2. Authorization of 24 months may be granted for members with prostate cancer who are prescribed zoledronic acid or Zometa for the treatment or prevention of osteoporosis secondary to androgen deprivation therapy (ADT).

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; March 2016.
2. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed October 16, 2016.
3. American Society of Health System Pharmacists. AHFS Drug Information (electronic version). Bethesda, MD. Available at: http://online.lexi.com. Accessed October 16, 2016.
4. The NCCN Drugs & Biologics Compendium™ © 2015 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 20, 2016.
5. Gralow JR, Biermann S, Farooki A, et al. NCCN Task Force Report: Bone Health in Cancer Care. *JNCCN*. 2013; 11(Suppl 3):S1-50.
6. World Health Organization Collaborating Centre for Metabolic Bone Diseases, University of Sheffield. FRAX WHO fracture risk assessment tool. Available at http://www.shef.ac.uk/FRAX/tool.jsp. Accessed October 16, 2016.