Reference number(s)
1630-A

STANDARD MEDICARE PART B MANAGEMENT

ZOMETA (zoledronic acid)
zoledronic acid 4mg

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[1,2]
1. Hypercalcemia of malignancy
2. 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[3,4]
1. Breast cancer
2. Monoclonal gammopathy of uncertain significance, with osteopenia or osteoporosis
3. Osteopenia prophylaxis
   i. Secondary to androgen-deprivation therapy in patients with prostate cancer
   ii. Secondary to endocrine therapy in patients with breast cancer
   iii. Secondary to ovarian dysfunction induced by adjuvant chemotherapy
4. Treatment of osteopenia or osteoporosis in patients with systemic mastocytosis

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Hypercalcemia of Malignancy[1, 2]
Authorization of 6 months may be granted for the treatment of hypercalcemia of malignancy.

B. Multiple Myeloma and Metastatic Bone Disease[1, 2]
Authorization of 12 months may be granted for the prevention of skeletal complications in patients with bone metastases due to solid tumors (e.g., kidney cancer, non-small cell lung cancer, thyroid carcinoma) or multiple myeloma.

C. Breast Cancer[3]
Authorization of 12 months may be granted for the treatment of breast cancer.

D. Monoclonal gammopathy with osteopenia or osteoporosis[4]
Authorization of 12 months may be granted for the treatment of osteopenia or osteoporosis associated with monoclonal gammopathy.

E. Osteopenia prophylaxis[4]
1. Authorization of 12 months may be granted for the prophylactic treatment of osteopenia secondary to androgen-deprivation therapy in patients with prostate cancer.
2. Authorization of 12 months may be granted for the prophylactic treatment of osteopenia secondary to endocrine therapy in patients with breast cancer.
3. Authorization of 12 months may be granted for the prophylactic treatment of osteopenia secondary to ovarian dysfunction induced by adjuvant chemotherapy.

F. Systemic Mastocytosis[3]
Authorization of 12 months may be granted 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 be currently receiving therapy with zoledronic acid or Zometa.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with zoledronic acid or Zometa
B. Zoledronic acid or Zometa is being used to treat an indication enumerated in Section II
C. Zoledronic acid or Zometa has been effective for treating the diagnosis or condition

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 2018.
3. The NCCN Drugs & Biologics Compendium 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 14,2020.
4. IBM Micromedex DRUGDEX (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ (Accessed: 10/14/2020).