Reference number(s)
5250-A

JURISDICTION SPECIFIC MEDICARE PART B

ZOMETA (zoledronic acid 4mg/100mL)
zoledronic acid 4mg/100mL

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. Hypercalcemia of Malignancy
B. Multiple Myeloma
C. Bone Metastases of Solid Tumors
D. Osteopenia
E. Osteoporosis
F. Langerhans Cell Histiocytosis
G. Breast Cancer

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. EXCLUSIONS

The following are exclusions to therapy:
A. Combination use of bisphosphonate and a monoclonal antibody for the treatment of osteoporosis during an episode of care
B. Combination use of IV and/or oral forms of bisphosphonate therapy
C. Hypocalcemia, hypovitaminosis D, and other disturbances of bone and mineral metabolism
D. Pregnancy and lactation
E. Members receiving Reclast
F. Hypersensitivity to zoledronic acid or any of its components

III. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. All documentation must be maintained in the patient's medical record and made available to the contractor upon request
B. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient

C. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed
D. Criteria for the diagnosis of osteoporosis
E. History of treatment as related to progression of disease and ongoing risk factors
F. Description of treatment failure, or contraindication, or adverse side effects, of oral or self-administered drugs for osteoporosis as applicable to the patient that supports IV therapy in lieu of standard oral treatment protocol
G. Serum creatinine measured prior to the administration of the drug
H. Oral health of the patient discussed

IV. CRITERIA FOR APPROVAL

A. Hypercalcemia of Malignancy

Authorization of 12 months may be granted for the treatment of hypercalcemia of malignancy when all of the following criteria is met:

1. Renal status of the patient is monitored
2. Albumin-corrected calcium is greater than or equal to 12mg/dL (3.0mmol/L)

Authorization of 12 months may be granted for the continuation of treatment of hypercalcemia of malignancy if serum calcium does not return to normal or remain normal after treatment.

B. Multiple Myeloma

Authorization of 12 months may be granted for the treatment of multiple myeloma when all of the following criteria is met:

1. Renal status of the patient is monitored
2. Therapy will be used in conjunction with standard antineoplastic therapy
3. The member will take 500mg of calcium and 400 IU of vitamin D per day

C. Bone Metastases of Solid Tumors

Authorization of 12 months may be granted for the treatment of bone metastases of solid tumors when all of the following criteria is met:

1. Renal status of the patient is monitored
2. Therapy will be used in conjunction with standard antineoplastic therapy
3. The member will take 500mg of calcium and 400 IU of vitamin D per day
4. If the member has prostate cancer, disease progression occurred after treatment with at least one hormonal therapy

D. Osteopenia or Osteoporosis

1. Authorization of 12 months may be granted for the prevention of osteopenia when all of the following criteria are met:
   i. Renal status of the patient is monitored
   ii. Member has prostate cancer and is on the requested medication as prophylaxis of drug-induced osteopenia, secondary to androgen-deprivation therapy

2. Authorization of 12 months may be granted for the treatment of osteopenia when all of the following criteria are met:
   i. Renal status of the patient is monitored
   ii. The member has one of the following conditions:

a. Monoclonal gammopathy of uncertain significance (MGUS)
b. Systemic mastocytosis

3. Authorization of 12 months may be granted for the prevention osteoporosis when all of the following criteria are met:
   i. Renal status of the patient is monitored
   ii. Member has prostate cancer and is on androgen deprivation therapy (ADT)

4. Authorization of 12 months may be granted for the treatment of osteoporosis when all of the following criteria is met:
   i. Renal status of the patient is monitored
   ii. The member has one of the following conditions:
      a. Monoclonal gammopathy of uncertain significance (MGUS)
      b. Systemic mastocytosis
      c. Prostate cancer and is on androgen deprivation therapy

E. **Langerhans Cell Histiocytosis**
Authorization of 12 months may be granted for the treatment of Langerhans cell histiocytosis with bone disease when the renal status of the patient is monitored.

F. 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 all of the following criteria is met:
1. Renal status of the patient is monitored
2. One of the following is met:
   i. The requested medication will be used to maintain or improve bone mineral density and reduce the risk of fractures
   ii. The requested medication will be used for risk reduction of distant metastasis in high-risk node negative or node positive tumors

V. REFERENCES

1. Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications (L33270) Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed October 18, 2022.
2. Billing and Coding: Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications (A57603) Version R2. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed October 18, 2022.
3. Zometa [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; December 2018.
4. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: https://www.micromedexsolutions.com. Accessed October 18, 2022.
5. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed October 18, 2022.

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