Reference number(s)
5249-A

JURISDICTION SPECIFIC MEDICARE PART B

RECLAST (zoledronic acid 5mg/100mL)
zoledronic acid 5mg/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. Postmenopausal Osteoporosis
B. Osteoporosis in Men
C. Glucocorticoid-Induced Osteoporosis
D. Paget's Disease

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 as treatment for osteoporosis during an episode of care
C. Severe renal impairment defined as serum creatinine clearance measured or estimated <35 mL/min
D. Hypocalcemia, hypovitaminosis D, and other disturbances of bone and mineral metabolism
E. Pregnancy and lactation
F. Members receiving Zometa
G. Hypersensitivity to the active substance (zoledronic acid) or to any of the excipients

III. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
B. All documentation must be maintained in the patient's medical record and made available to the contractor upon request
C. 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

CVS caremark®

D. 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
E. Criteria for the diagnosis of osteoporosis
F. History of treatment as related to progression of disease and ongoing risk factors
G. 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
H. Serum creatinine measured prior to administration of drug
I. Oral health of the patient discussed

IV. CRITERIA FOR APPROVAL

A. Postmenopausal Osteoporosis
Authorization of 12 months may be granted for the treatment of postmenopausal osteoporosis when the member is taking at least 1200mg of calcium and 800-1000 IU of vitamin D per day

B. **Osteoporosis in Men**
Authorization of 12 months may be granted for the treatment of osteoporosis in men when the member is taking at least 1200mg of calcium and 800-1000 IU of vitamin D per day

C. **Glucocorticoid-Induced Osteoporosis**
Authorization of 12 months may be granted for the treatment of glucocorticoid-induced osteoporosis when all of the following criteria are met:
1. The member is either initiating or continuing to take system glucocorticoids in a daily dosage of 7.5 mg or greater of prednisone
2. The member is expected to remain on glucocorticoids for at least 12 months
3. The member is taking at least 1200mg of calcium and 800-1000 IU of vitamin D per day

D. Paget's Disease
Authorization of 12 months may be granted for the initial treatment of Paget's disease when all of the following criteria are met:
1. The member will take 1,500 mg elemental calcium daily in divided doses and 800 IU vitamin D per day in the 2 weeks following administration of therapy
2. The member has one of the following:
    i. An elevated serum alkaline phosphatase of two times or higher than the upper limit of the age-specific normal reference range
    ii. The member is symptomatic
    iii. The member is at risk for complications from the disease, to induce remission (normalization of serum alkaline phosphatase) prior to treatment

Authorization of 12 months may be granted for the continuation of treatment of Paget's disease when the member has experienced one of the following:
1. Relapse based on serum alkaline phosphatase
2. Failed to achieve normalization of their serum alkaline phosphatase
3. Symptoms as dictated by current standard medical practice

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 05, 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 05, 2022.
3. Reclast [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; April 2020.

