Reference number(s)
2391-A

STANDARD MEDICARE PART B MANAGEMENT

Reclast (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.

FDA-Approved Indications
A. Treatment and prevention of postmenopausal osteoporosis
B. Treatment to increase bone mass in men with osteoporosis
C. Treatment and prevention of glucocorticoid-induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months
D. Treatment of Paget's disease of bone in men and women

Limitations of Use
Optimal duration of use has not been determined. For patients of low-risk for fracture, consider drug discontinuation after 3 to 5 years of use.

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. Treatment and prevention in postmenopausal osteoporosis
Authorization of 12 months may be granted for treatment and prevention of postmenopausal osteoporosis

B. Increasing bone mass in men with osteoporosis
Authorization of 12 months may be granted for treatment to increase bone mass in men with osteoporosis

C. Increase bone mass in glucocorticoid-induced osteoporosis
Authorization of 12 months may be granted for treatment to increase bone mass in glucocorticoid-induced osteoporosis

D. Treatment of Paget's disease of bone
Authorization of 12 months may be granted for treatment of Paget's disease of bone

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with Reclast or zoledronic acid.

Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with Reclast or zoledronic acid
2. The member is receiving Reclast or zoledronic acid for an indication listed in Section II
3. Reclast or zoledronic acid has been effective for treating the diagnosis or condition

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Reclast and zoledronic acid.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Reclast and zoledronic acid are covered.

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VI. REFERENCES

1. Reclast [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2020.
2. Zoledronic acid [package insert]. Schaumburg, IL: Sagent Pharmaceuticals; August 2021.