Reference number(s)
2391-A

Standard Medicare Part B Management zoledronic acid-Reclast

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Reclast	zoledronic acid

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[1,2]

- Treatment and prevention of osteoporosis in postmenopausal women
- Treatment to increase bone mass in men with osteoporosis
- Treatment and prevention of glucocorticoid-induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months
- 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 listed in the coverage criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Compendial Uses[3]

- For treatment-related bone loss in patients with prostate cancer receiving androgen deprivation therapy (ADT)

Coverage Criteria

Treatment and Prevention of Postmenopausal Osteoporosis

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

Osteoporosis in Men

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

Glucocorticoid-Induced Osteoporosis

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

Paget's Disease of Bone

Authorization of 1 month (one dose [5 mg]) may be granted for treatment of Paget's disease of bone.

Prostate Cancer[3]

Authorization of 12 months may be granted for members with prostate cancer for treatment-related bone loss when receiving androgen deprivation therapy (ADT) (e.g., goserelin, leuprolide, triptorelin).

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy, except for treatment of Paget's disease of bone, must be currently receiving therapy with the requested drug.

Treatment of Paget's Disease of Bone

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

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All Other Indications

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested drug.
- The member is receiving the requested drug for an indication listed in the coverage criteria other than treatment of Paget's disease of bone.
- The requested drug has been effective for treating the diagnosis or condition.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Reclast and zoledronic acid.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Prostate cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Reclast and zoledronic acid are covered in addition to treatment-related bone loss in prostate cancer due to androgen deprivation therapy.

Explanation of Rationale

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

Support for using Reclast or zoledronic acid for treatment-related bone loss in prostate cancer due to androgen deprivation therapy can be found in the National Comprehensive Cancer Network's guideline for Prostate Cancer. The NCCN Guideline for Prostate Cancer supports the use of Reclast or zoledronic acid for treatment-related bone loss in those receiving androgen deprivation therapy (ADT) when the absolute fracture risk warrants drug therapy.

References

1. Reclast [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2022.
2. Zoledronic acid [package insert]. Princeton, NJ: Fosun Pharma USA Inc.; May 2024.

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3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 8, 2025.

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