

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.

A. FDA-Approved Indications^{1,2}

1. Treatment and prevention of postmenopausal osteoporosis
2. Treatment to increase bone mass in men with osteoporosis
3. Treatment and prevention of glucocorticoid-induced osteoporosis
4. 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

zoledronic acid-Reclast MedB P2020.docx

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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. REFERENCES

1. Reclast [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2020.
2. Zoledronic acid [package insert]. Schaumburg, IL: Sagent Pharmaceuticals; May 2018.