

Reference number(s)
2380-A

SPECIALTY GUIDELINE 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 osteoporosis in postmenopausal women
- 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 are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Supporting chart notes or medical record indicating a history of fractures, T-score, and FRAX fracture probability as applicable to Section III.

III. CRITERIA FOR INITIAL APPROVAL

A. Postmenopausal osteoporosis, treatment and prevention

Authorization of 12 months may be granted to postmenopausal members for treatment or prevention of osteoporosis when ANY of the following criteria are met:

- 1. Member has a history of fragility fractures
- 2. Member has a pre-treatment T-score less than or equal to -2.5
- 3. Member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1)

B. Osteoporosis in men

Authorization of 12 months may be granted to male members with osteoporosis when ANY of the following criteria are met:

- 1. Member has a history of an osteoporotic vertebral or hip fracture
- 2. Member has a pre-treatment T-score less than or equal to -2.5

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3. Member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix)

C. Glucocorticoid-induced osteoporosis

Authorization of 12 months may be granted for members with glucocorticoid-induced osteoporosis when BOTH of the following criteria are met:

1. Member is currently receiving or will be initiating glucocorticoid therapy at an equivalent prednisone dose of greater than or equal to 2.5 mg/day for at least 3 months
2. Member meets ANY of the following criteria:
 - i. Member has a history of a fragility fracture
 - ii. Member has a pre-treatment T-score of less than or equal to -2.5
 - iii. Member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix)

D. Paget's disease of bone

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

IV. CONTINUATION OF THERAPY

A. Paget's disease of bone

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

B. All other indications

Authorization of 12 months may be granted for all members (including new members) who are currently receiving the requested medication through a previously authorized pharmacy or medical benefit, who meet either of the following:

1. Member has received less than 24 months of therapy and has not experienced clinically significant adverse events during therapy
2. Member has received 24 months of therapy or more and meets both of the following:
 - i. Member has experienced clinical benefit (i.e., improvement or stabilization in T-score since the previous bone mass measurement)
 - ii. Member has not experienced any adverse effects

V. APPENDIX

FRAX Fracture Risk Assessment Tool

- High FRAX fracture probability: 10-year major osteoporosis-related fracture risk \geq 20% or hip fracture risk \geq 3%
- 10-year probability; calculation tool available at: <https://www.sheffield.ac.uk/FRAX/>
- The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day.

VI. REFERENCES

1. Reclast [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2020.
2. Zoledronic acid injection [package insert]. Princeton, NJ: Fosun Pharma USA Inc.; June 2023.

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3. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2022;33(10):2049-2102.
4. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2020 update. *Endocr Pract*. 2020;26(Suppl 1):1-46.
5. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. *J Clin Endocr Metab*. 2012;97(6):1802-1822.
6. Fink HA, Gordon G, Buckley L, et al. 2017 American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis. *Arthritis Care Res*. 2017;69:1521-1537.
7. Singer FR, Bone HG, Hosking DJ, et al. Paget's disease of bone: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2014;99(12):4408-22.
8. FRAX® Fracture Risk Assessment Tool. © Centre for Metabolic Bone Diseases, University of Sheffield, UK. Available at: <https://www.shef.ac.uk/FRAX>. Accessed October 12, 2023.