Zoledronic Acid (Reclast®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

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

- 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.

Compendial Uses

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

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- Chart notes or medical record documentation indicating a history of fractures, T-score, and Fracture Risk Assessment Tool (FRAX) probability (if applicable)
- Chart notes, medical record documentation, or claims history supporting use of androgen deprivation therapy.

COVERAGE CRITERIA

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:

- Member has a history of fragility fractures (e.g., low trauma fracture from force similar to a fall from standing position)
- Member has a pre-treatment T-score ≤-2.5
- Member has osteopenia (i.e., pre-treatment T-score between -1 and -2.5) with a high pre-treatment FRAX probability (see Appendix)

Osteoporosis in Men

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

- Member has a history of an osteoporotic vertebral or hip fracture
- Member has a pre-treatment T-score ≤-2.5
- Member has osteopenia (i.e., pre-treatment T-score between -1 and -2.5) with a high pre-treatment FRAX probability (see Appendix)

Glucocorticoid-Induced Osteoporosis

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

- Member is currently receiving or will be initiating glucocorticoid therapy at an equivalent prednisone dose of ≥2.5 mg/day for ≥3 months
- Member meets ANY of the following criteria:
  - Member has a history of a fragility fracture (e.g., low trauma fracture from force similar to a fall from standing position)
  - Member has a pre-treatment T-score of ≤-2.5
  - Member has osteopenia (i.e., pre-treatment T-score between -1 and -2.5) with a high pre-treatment FRAX probability (see Appendix)

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

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., gosarelin, leuprolide, triptorelin).

CONTINUATION OF THERAPY

Paget's Disease of Bone

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

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 criteria:

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

APPENDIX

FRAX Fracture Risk Assessment Tool (FRAX)

- FRAX© (fracture risk assessment tool) available at: https://fraxplus.org
- High FRAX probability: 10-year major osteoporotic fracture probability≥ 20% or hip fracture probability ≥ 3%
- FRAX Glucocorticoid correction: If glucocorticoid dose is greater than 7.5 mg (prednisone equivalent) per day, 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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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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.
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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. © Osteoporosis Research Ltd, UK. Available online :https://fraxplus.org. Accessed September 5, 2025.
9. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 8, 2025.

EFFECTIVE DATE 7/31/2026

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