CVS Caremark®

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| Reference number(s) |
| 2380-A |

# Specialty Guideline 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 Indications1,2

* 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.

### Compendial Uses9

* 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) fracture probability (where applicable)
* Chart notes, medical record documentation, or claims history supporting use of androgen deprivation therapy.

## Coverage Criteria

### Postmenopausal Osteoporosis, Treatment and Prevention1-4

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 less than or equal to -2.5
* Member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1)

### Osteoporosis in Men1-3,5

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 less than or equal to -2.5
* 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)

### Glucocorticoid-Induced Osteoporosis1,2,6

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 greater than or equal to 2.5 mg/day for at least 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 less than or equal to -2.5
  + 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)

### Paget’s Disease of Bone1,2,7

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

### Prostate Cancer9

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

### Fracture Risk Assessment Tool (FRAX)6,8

* High FRAX fracture probability: 10-year major osteoporosis-related fracture risk ≥ 20% or hip fracture risk ≥ 3%
* 10-year probability; calculation tool available at: https://frax.shef.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.

## 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.; February 2023.
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. Humphrey MB, Russell L, Danila MI, et al. 2022 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. Arthritis Rheumatol. 2023;75(12):2088-2102.
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://frax.shef.ac.uk/FRAX/. Accessed October 8, 2024.
9. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 8, 2024.