



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name:	Reclast (zoledronic acid) Zometa (zoledronic acid) zoledronic Acid	Page:	1 of 6
Effective Date:	11/13/2023	Last Review Date:	10/16/2023
Applies to:	<input checked="" type="checkbox"/> Illinois <input checked="" type="checkbox"/> New Jersey <input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Florida <input checked="" type="checkbox"/> Maryland <input checked="" type="checkbox"/> Virginia	<input checked="" type="checkbox"/> Florida Kids <input type="checkbox"/> Michigan <input checked="" type="checkbox"/> Kentucky PRMD

### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Reclast, Zometa and zoledronic acid under the patient's prescription drug benefit.

### Description:

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.

#### Reclast 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

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

#### Zometa FDA-Approved Indications

- A. Zometa/zoledronic acid is indicated for the treatment of hypercalcemia of malignancy defined as an albumin-corrected calcium (cCa) of greater than or equal to 12mg/dL [3.0 mmol/L] using the formula:  $cCa \text{ in mg/dL} = Ca \text{ in mg/dL} + 0.8 (4.0 \text{ g/dL} - \text{patient albumin [g/dL]})$ .
- B. Zometa/zoledronic acid is indicated for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy.

*Limitation of Use: The safety and efficacy of Zometa/zoledronic acid in the treatment of hypercalcemia associated with hyperparathyroidism or with other non-tumor-related conditions have not been established.*

#### Zometa Compendial Uses



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- A. Treatment or prevention of osteoporosis during androgen-deprivation therapy (ADT) in prostate cancer patients with high fracture risk
- B. Treatment in postmenopausal patients with breast cancer who are receiving adjuvant therapy to maintain or improve bone mineral density and reduce risk of fractures
- C. Treatment in postmenopausal patients with breast cancer who are receiving adjuvant therapy to reduce the risk of distant metastases
- D. Treatment for osteopenia or osteoporosis in patients with systemic mastocytosis
- E. Langerhans Cell Histiocytosis with bone disease

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

### Applicable Drug List:

Reclast  
Zometa  
zoledronic Acid

### Policy/Guideline:

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 below:

#### A. Postmenopausal osteoporosis, treatment, and prevention [Reclast (zoledronic acid)]

Authorization 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 [Reclast (zoledronic acid)]

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



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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
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 A)

**C. Glucocorticoid-induced osteoporosis [Reclast (zoledronic acid)]**

Authorization 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:
  - a. Member has a history of a fragility fracture
  - b. Member has a pre-treatment T-score of less than or equal to -2.5
  - c. 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 A)

**D. Paget's disease of bone [Reclast (zoledronic acid)]**

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

**A. Hypercalcemia of Malignancy [Zometa (zoledronic acid)]**

Authorization may be granted for treatment of hypercalcemia of malignancy.

**B. Multiple Myeloma [Zometa (zoledronic acid)]**

Authorization may be granted for prevention of skeletal-related events in members with multiple myeloma.

**C. Bone Metastases from a Solid Tumor [Zometa (zoledronic acid)]**

Authorization may be granted for prevention of skeletal-related events in member with bone metastases from a solid tumor.

**D. Prostate Cancer [Zometa (zoledronic acid)]**

Authorization may be granted for members with prostate cancer for treatment or prevention of osteoporosis during androgen deprivation therapy (ADT)

**E. Breast Cancer [Zometa (zoledronic acid)]**



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Authorization may be granted for postmenopausal (natural or induced by ovarian suppression) members receiving adjuvant therapy for treatment of breast cancer when ONE of the following is met:

1. The requested medication will be used to maintain or improve bone mineral density and reduce the risk of fractures
2. The requested medication will be used for risk reduction of distant metastasis in high-risk node negative or node positive tumors

**F. Systemic Mastocytosis [Zometa (zoledronic acid)]**

Authorization may be granted for treatment of osteopenia or osteoporosis in members with systemic mastocytosis.

**G. Langerhans Cell Histiocytosis [Zometa (zoledronic acid)]**

Authorization may be granted for treatment of Langerhans Cell Histiocytosis with bone disease.

**CONTINUATION OF THERAPY:**

**A. Paget's disease of bone [Reclast (zoledronic acid)]:**

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

**B. Postmenopausal osteoporosis treatment and prevention, Osteoporosis in men, Glucocorticoid-induced osteoporosis [Reclast (zoledronic acid)]:**

Authorization 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 ONE 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:
  - a. Member has experienced clinical benefit (i.e., improvement or stabilization in T-score since the previous bone mass measurement)
  - b. Member has not experienced any adverse effects

**C. Hypercalcemia of malignancy [Zometa (zoledronic acid)]:**

Member is experiencing benefit from therapy as evidenced by disease stability or disease improvement.



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**D. Multiple Myeloma, Bone Metastases from a Solid Tumor, Prostate Cancer, Breast Cancer, Systemic Mastocytosis, Langerhans Cell Histiocytosis [Zometa (zoledronic acid)]:**

Member is experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Appendix A. WHO Fractures Risk Assessment Tool

- High FRAX fracture probability: 10-year major osteoporotic 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.

**Approval Duration and Quantity Restrictions:**

**Initial and Renewal Approval:**

- Zometa, Zoledronic Acid:
  - Hypercalcemia of Malignancy: 2 months
  - All other indications: 12 months
- Reclast, Zoledronic Acid:
  - Paget's Disease of Bone: 1 month
  - All other indications: 12 months

**Quantity Level Limit:** Reference Formulary for drug specific quantity level limits

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