

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.

###### A. FDA-Approved Indications<sup>1,2</sup>

1. Treatment and prevention of osteoporosis in postmenopausal women
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

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

##### II. CRITERIA FOR INITIAL APPROVAL

###### A. **Postmenopausal osteoporosis, treatment and prevention**<sup>1-8,14-17</sup>

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**<sup>1-4,10</sup>

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
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 B)

###### C. **Glucocorticoid-induced osteoporosis**<sup>1,2,10,11</sup>

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

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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 B)

**D. Paget's disease of bone<sup>1,2,12</sup>**

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

### III. 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 one of the following:

1. Member has experienced clinical benefit as evidenced by a bone mass measurement showing an improvement or stabilization in T-score compared with the previous bone mass measurement and member has not experienced any adverse effects.
2. Member has received less than 24 months of therapy and has experienced clinical benefit as evidenced by no adverse events during therapy (i.e., no clinically significant adverse reaction to the requested drug, no new fracture seen on radiography).

### IV. APPENDIX

Appendix A. Clinical reasons to avoid oral bisphosphonate therapy<sup>3,6</sup>

- Presence of anatomic or functional esophageal abnormalities that might delay transit of the tablet (e.g. achalasia, stricture, or dysmotility)
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
- Presence of documented or potential gastrointestinal malabsorption (e.g. gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders, etc.)
- Inability to stand or sit upright for at least 30 to 60 minutes
- Inability to take at least 30 to 60 minutes before first food, drink, or medication of the day
- Renal insufficiency (creatinine clearance <35 mL/min)
- History of intolerance to an oral bisphosphonate

Appendix B. WHO Fracture Risk Assessment Tool<sup>11, 12,13,17</sup>

- 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.

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## V. REFERENCES

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