

## 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

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 are not a covered benefit.

##### 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 Sections III.A, III.B, and III.C.

##### III. CRITERIA FOR INITIAL APPROVAL

###### A. **Postmenopausal osteoporosis**

Authorization of 12 months may be granted to postmenopausal members with 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 OR 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) and meets ANY of the following criteria:
  - a. Member has indicators of higher fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores [less than or equal to -3.5], or increased fall risk)
  - b. Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., denosumab [Prolia], teriparatide [Forteo])
  - c. Member has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A)

###### 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 meets criteria BOTH of the following criteria:
  - a. Member has a pre-treatment T-score less than or equal to -2.5 OR 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)
  - b. Member has had an oral bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A)

#### C. Glucocorticoid-induced osteoporosis

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

1. Member has had an oral bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A)
2. Member is currently receiving or will be initiating glucocorticoid therapy
3. 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

Authorization of one dose (5 mg) may be granted for the 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 meet all initial authorization criteria and experiences clinical benefit after at least 24 months of therapy with zoledronic acid or Reclast as evidenced by improvement or stabilization in T-score.

### V. APPENDIX

#### Appendix A. Clinical reasons to avoid oral bisphosphonate therapy

- Esophageal abnormality that delays emptying such as stricture of achalasia
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
- 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

- 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 and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg per day.

## VI. REFERENCES

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