

## 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 not medically necessary.

##### II. CRITERIA FOR INITIAL APPROVAL

###### A. **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:

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**

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**

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
2. Member meets ANY of the following criteria:

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- 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 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 meet all initial authorization criteria and experiences clinical benefit after at least 12 months of therapy with zoledronic acid or Reclast as evidenced by improvement or stabilization in T-score.

### IV. 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 (prednisone equivalent) per day.

### V. REFERENCES

1. Reclast [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2017.
2. Zoledronic acid injection [package insert]. Schaumburg, IL: Sagent Pharmaceuticals, Inc.; May 2018
3. Bisphosphonates. *Drug Facts and Comparisons*. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; March 21, 2019. Accessed April 10, 2019.
4. Cosman F, de Beur SJ, LeBoff MS, et al. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2014;25(10): 2359-2381.
5. Jeremiah MP, Unwin BK, Greenwald MH, et al. Diagnosis and management of osteoporosis. *Am Fam Physician*. 2015;92(4):261-268.

<b>Reference number(s)</b>
2380-A

6. Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. *Endocr Pract.* 2016;22 (Suppl 4):1-42.
7. ACOG Practice Bulletin Number 129: Osteoporosis. *Obstet Gynecol.* 2012;120(3):718-734.
8. National Institute for Health and Care Excellence. Osteoporosis Overview. Last updated February 2018. Available at: <http://pathways.nice.org.uk/pathways/osteoporosis>. Accessed April 10, 2019.
9. Treatment to prevent osteoporotic fractures: an update. Department of Health and Human Services, Agency for Healthcare Research and Quality. 2012; Publication No. 12-EHC023-EF. Available at [www.effectivehealthcare.ahrq.gov/lbd.cfm](http://www.effectivehealthcare.ahrq.gov/lbd.cfm).
10. 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.
11. Fink HA, Gordon G, Buckley L, et al. 2017 American College of Rheumatology Guidelines for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis Care Res.* 2017;69:1521-1537.
12. 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.
13. FRAX<sup>®</sup> WHO fracture risk assessment tool. © World Health Organization Collaborating Centre for Metabolic Bone Diseases: University of Sheffield, UK. Available at: <https://www.sheffield.ac.uk/FRAX/>. Accessed April 10, 2019.
14. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Bone Disorders Clinical Programs. December 2018.
15. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Bone Disorders Clinical Programs. April 2019.
16. Ensrud KE, Crandall CJ. Osteoporosis. *Ann Intern Med* 2017;167(03):ITC17–ITC32.
17. Clinical Consult. CVS/Caremark Clinical Programs Review : Focus on Bone Disorders Clinical Programs. December 29, 2019.