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
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. CRITERIA FOR INITIAL APPROVAL

A. Osteoporosis in Postmenopausal Women

Authorization of 24 months may be granted to postmenopausal female members when ANY of the following criteria are met:
1. Member has a history of fragility fractures
2. Member has a pre-treatment T-score of ≤ -2.5 OR member has osteopenia 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, 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 24 months may be granted to male members with osteoporosis when ANY of the following criteria are met:
a. Member has a history of an osteoporotic vertebral or hip fracture
b. Member has a pre-treatment T-score of ≤ -2.5
c. Member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B)

C. Glucocorticoid-induced Osteoporosis

Authorization of 24 months may be granted for members with glucocorticoid-induced osteoporosis when ALL of the following criteria are met:

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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 $\leq$ -2.5
   c. Member has osteopenia 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.

III. CONTINUATION OF THERAPY

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

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 (eg, 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 <30 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 ≥ 20% or hip fracture risk ≥ 3%
- 10-year probability; calculation tool available at: http://www.shef.ac.uk/FRAX/tool.jsp

V. REFERENCES

1. Reclast [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2017.
2. Bisphosphonates. *Drug Facts and Comparisons.* Facts & Comparisons® eAnswers [online]. 2015. Available from Wolters Kluwer Health, Inc. Accessed October 18, 2017.
3. 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.*
4. Jeremiah MP, Unwin BK, Greenwald MH, et al. Diagnosis and management of osteoporosis. *Am Fam Physician.* 2015;92(4):261-268.
5. 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.
6. ACOG Practice Bulletin Number 129: Osteoporosis. *Obstet Gynecol.* 2012;120(3):718-734.
7. National Institute for Health and Care Excellence. Osteoporosis Overview. Last updated August 2017. Available at: http://pathways.nice.org.uk/pathways/osteoporosis. Accessed October 18, 2017.
8. 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.
9. 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.
10. 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.

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11. 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.
12. FRAX® WHO fracture risk assessment tool. © World Health Organization Collaborating Centre for Metabolic Bone Diseases: University of Sheffield, UK. Available at: http://www.shef.ac.uk/FRAX. Accessed October 18, 2017.

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