Clinical Policy Title:	zoledronic acid
Policy Number:	RxA.263
Drug(s) Applied:	Reclast®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Osteoporosis and Paget's Disease of Bone (must meet all):

1. Request is for one of the following indications (a, b, or c):
   a. Treatment and prevention of PMO or GIO;
   b. Treatment of male osteoporosis;
   c. Treatment of Paget's disease of bone;
2. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
3. Prescribed by or in consultation with one of the following specialists: a gynecologist, endocrinologist, rheumatologist, geriatrician, orthopaedist, or physiatrist;
4. Trial and failure of a 12-month trial of an oral bisphosphonate (alendronate is preferred) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 5 mg.

Approval Duration

Commercial: 6 months

Medicaid: Postmenopausal osteoporosis prevention: 24 months (one infusion); all other indications: 12 months (one infusion).

II. Continued Therapy Approval

A. Osteoporosis and Paget's Disease of Bone (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy;
2. For osteoporosis-related indications, member is responding positively to therapy;
3. For Paget's disease, disease has relapsed or progressed (e.g., increases in or failure to achieve normalization of serum ALP, radiographic progression of disease);
4. If request is for a dose increase, new dose does not exceed 5 mg.

Approval Duration

Commercial: 6 months

Medicaid: Postmenopausal osteoporosis prevention: 24 months (one infusion); all other indications: 12 months (one infusion)

References

1. Endocrin Pract. 2016; 22(Suppl 4). Available at: https://pubmed.ncbi.nlm.nih.gov/27643923/. Accessed December 29, 2022.
2. Cosman F, de Beur SJ, LeBoff MS, et al. Clinician's guide to prevention and treatment of osteoporosis. Osteoporosis Int. 2014;25(10):2359-2381. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4176573/. Accessed December 29, 2022.
3. The North American Menopause Society. Management of osteoporosis in postmenopausal women: 2021 position statement of the North American Menopause Society. Menopause2010;17(1):22-54. Available at: http://www.menopause.org/docs/default-source/professional/2021-osteoporosis-position-statement.pdf. Accessed December 29, 2022.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of Business Policy Applies to was updated to all lines of business. 3. Updated Initial approval criteria: added closed epiphyses on x-ray in I.A.2 & I.B.2. 4. In Continued therapy criteria II.A.2 & II.B.2 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…" 5. Commercial duration was updated to 6 months and added HIM approval duration. 6. Added "Age ≥ 18 years or documentation of closed epiphyses on x-ray" to initial approval criteria. 7. References were reviewed and updated.	06/26/2020	09/14/2020
Policy was reviewed: 1. Clinical policy table was updated 2. Zometa removed from policy because it was discontinued in the market. 3. HIM approval duration is removed from the policy. 4. References were reviewed and updated.	03/24/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Request is for Reclast® for one of the following indications to Request is for one of the following indications. 2. Initial Approval Criteria, I.A.3: Updated to include new diagnostic criteria Member should have creatinine clearance ≥ 35 mL/min, in not more than last 3 days at the time of request.	01/20/2022	04/18/2022

3. Initial Approval Criteria, I.B: Updated to remove approval criteria for Hypercalcemia, Multiple Myeloma, and Bone Metastases. 4. Continued Therapy Approval Criteria, II.A.1: Updated to remove prior requested drug criteria Request is for Reclast®. 5. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 6. Continued Therapy Approval Criteria, II.A.4: Updated to include new diagnostic criteria Member should have creatinine clearance ≥ 35 mL/min, in not more than last 3 days at the time of request. 7. Continued Therapy Approval Criteria, II.B: Updated to remove approval criteria for Hypercalcemia, Multiple Myeloma, and Bone Metastases. 8. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Request is for one of the following indications (a, b, or c): a. Osteoporosis; b. Prevention of osteoporosis; c. Paget's disease of bone; to Request is for one of the following indications (a, b, or c): a. Treatment and prevention of PMO or GIO; b. Treatment of male osteoporosis; c. Treatment of Paget's disease of bone. 2. Initial Approval Criteria, I.A.3: Updated to remove prior lab values criteria "Member should have creatinine clearance ≥ 35 mL/min, in not more than last 3 days at the time of request." 3. Initial Approval Criteria, I.A.4: Updated to remove requesting criteria "For osteoporosis-related indications" as the criteria applies to both the indications Osteoporosis and Paget's Disease of Bone. 4. Continued Therapy Approval, II.A.4: Updated to remove prior lab values criteria "Member should have creatinine clearance ≥ 35 mL/min, in not more than last 3 days	12/29/2022	4/13/2023

at the time of request." 5. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023