

<b>Clinical Policy Title:</b>	zoledronic acid
<b>Policy Number:</b>	RxA.263
<b>Drug(s) Applied:</b>	zoledronic acid
<b>Original Policy Date:</b>	02/07/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	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 or b):
  - a. Treatment and prevention of postmenopausal osteoporosis (PMO), glucocorticoid induced osteoporosis (GIO), or osteoporosis in males;
    - i. Trial and failure, contraindication, or intolerance to at least one bisphosphonate;
  - b. Treatment of Paget's disease of the bone

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

### II. Continued Therapy Approval

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

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

## 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.	06/26/2020	09/14/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<ol style="list-style-type: none"> <li>2. Line of Business Policy Applies to was updated to all lines of business.</li> <li>3. Updated Initial approval criteria: added closed epiphyses on x-ray in I.A.2 &amp; I.B.2.</li> <li>4. In Continued therapy criteria II.A.2 &amp; II.B.2 was rephrased to “Currently receiving medication that has been authorized by RxAdvance...”</li> <li>5. Commercial duration was updated to 6 months and added HIM approval duration.</li> <li>6. Added “Age ≥ 18 years or documentation of closed epiphyses on x-ray” to initial approval criteria.</li> <li>7. References were reviewed and updated.</li> </ol>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Clinical policy table was updated</li> <li>2. Zometa removed from policy because it was discontinued in the market.</li> <li>3. HIM approval duration is removed from the policy.</li> <li>4. References were reviewed and updated.</li> </ol>	03/24/2021	06/10/2021
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>3. Initial Approval Criteria, I.B: Updated to remove approval criteria for Hypercalcemia, Multiple Myeloma, and Bone Metastases.</li> <li>4. Continued Therapy Approval Criteria, II.A.1: Updated to remove prior requested drug criteria Request is for Reclast®.</li> <li>5. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".</li> <li>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.</li> </ol>	01/20/2022	04/18/2022

<p>7. Continued Therapy Approval Criteria, II.B: Updated to remove approval criteria for Hypercalcemia, Multiple Myeloma, and Bone Metastases.</p> <p>8. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Request is for one of the following indications (a, b, or c):             <ol style="list-style-type: none"> <li>a. Osteoporosis;</li> <li>b. Prevention of osteoporosis;</li> <li>c. Paget's disease of bone;</li> </ol>             to Request is for one of the following indications (a, b, or c):             <ol style="list-style-type: none"> <li>a. Treatment and prevention of PMO or GIO;</li> <li>b. Treatment of male osteoporosis;</li> <li>c. Treatment of Paget's disease of bone.</li> </ol> </li> <li>2. Initial Approval Criteria, I.A.3: Updated to remove prior lab values criteria "Member should have creatinine clearance <math>\geq</math> 35 mL/min, in not more than last 3 days at the time of request."</li> <li>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.</li> <li>4. Continued Therapy Approval, II.A.4: Updated to remove prior lab values criteria "Member should have creatinine clearance <math>\geq</math> 35 mL/min, in not more than last 3 days at the time of request."</li> <li>5. References were reviewed and updated.</li> </ol>	12/29/2022	4/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed. Removed the following:</p> <ol style="list-style-type: none"> <li>1. Prescriber specialty</li> <li>2. Age</li> <li>3. Documentation of epiphyses closure on xray</li> <li>4. Timeframe of t/f bisphosphonates</li> </ol> <p>Updated:</p> <ol style="list-style-type: none"> <li>1. Continuation criteria</li> </ol>	6/1/2024	6/1/2024
<p>Policy was reviewed:</p>	12/05/2024	N/A

1. Removed Reclast from the drug applied section.		
Policy reviewed	12/11/2025	12/11/2025