

<b>Clinical Policy Title:</b>	denosumab
<b>Policy Number:</b>	RxA.313
<b>Drug(s) Applied:</b>	Jubbonti
<b>Original Policy Date:</b>	02/07/2020
<b>Last Review Date:</b>	01/01/2026
<b>Line of Business Policy Applies to:</b>	All lines of Business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Osteoporosis (must meet all):

1. Diagnosis of postmenopausal osteoporosis, glucocorticoid-induced osteoporosis (GIO), or male osteoporosis and one of the following (a or b):
  - a. Member is at high risk for fracture (i ,ii or iii):
    - i. BMD T-score at hip or spine  $\leq$  -3.0;
    - ii. BMD T-score at hip or spine  $\leq$  -2.5 and major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus);
    - iii. Recent osteoporotic fracture (within the past 12 months);
  - b. Trial and failure, contraindication, or intolerance to at least one bisphosphonate.

#### Approval duration

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

#### B. Prostate or Breast Cancer Treatment-Induced Bone Loss (must meet all):

1. Trial and failure of zoledronic acid, unless contraindicated, or clinically significant adverse effects are experienced;

#### Approval duration

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

### II. Continued Therapy Approval

#### A. All Indications in Section I (must meet all):

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met initial approval criteria.

#### Approval duration

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

## References

1. Gralow JR, Biermann JS, Farooki A, et al. Nccn task force report: bone health in cancer care. Journal of the National Comprehensive Cancer Network. 2009;7(Suppl\_3) :S-S-32. Available at: [https://jncn.org/view/journals/jncn/7/Suppl\\_3/article-pS-1.xml](https://jncn.org/view/journals/jncn/7/Suppl_3/article-pS-1.xml). Accessed March 21, 2025.
2. Cosman F, de Beur SJ, LeBoff MS, et al. Clinician’s guide to prevention and treatment of osteoporosis. Osteoporos Int. 2014;25(10):2359-2381. Available at: <https://link.springer.com/article/10.1007/s00198-014-2794-2>. Accessed March 21, 2025.

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.

3. Camacho PM, Petak SM, Binkley N, et al. American association of clinical endocrinologists/american college of endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis—2020 update. *Endocrine Practice*. 2020; 26:1-46. Available at: [https://www.endocrinepractice.org/article/S1530-891X\(20\)42827-7/fulltext](https://www.endocrinepractice.org/article/S1530-891X(20)42827-7/fulltext). Accessed March 21, 2025.
4. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2012; 97(6): 1802-1822. Available at: <https://pubmed.ncbi.nlm.nih.gov/22675062/>. Accessed March 21, 2025.
5. Buckley L, Guyatt G, Fink HA, et al. 2017 American college of rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis: ACR guideline for glucocorticoid-induced osteoporosis prevention and treatment. *Arthritis & Rheumatology*. 2017;69(8):1521-1537. Available at: <https://pubmed.ncbi.nlm.nih.gov/28585373/>. Accessed March 21, 2025.
6. Sozen T, Ozisik L, Basaran NC. An overview and management of osteoporosis. *Eur J Rheumatol*. 2017;4(1):46-56. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5335887/>. Accessed March 21, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Policy title table was updated.</li> <li>2. Line of Business Policy Applies to was update to “All lines of business”.</li> <li>3. Initial approval duration for all indications was updated to 6 months, and continued approval duration was updated to 12 months.</li> <li>4. Continued Therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance...”</li> <li>5. APPENDIX D: General Information added.</li> <li>6. References were updated.</li> </ol>	07/31/2020	09/14/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Osteoporosis: Initial criteria I.A.4 was updated.</li> <li>2. Initial approval duration was updated to 12 months.</li> <li>3. Approval criteria for systemic mastocytosis and other NCCN recommended off-label indications were added.</li> <li>4. References were reviewed and updated</li> </ol>	01/19/2021	03/09/2021
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Dosing Information, Maximum Dose, Xgeva®: Updated to maximum dosing information from 20 mg/dose to 120 mg/dose for indication Multiple myeloma and bone metastasis from solid tumors.</li> <li>2. Statement about provider sample “The provision of provider samples does not guarantee coverage...” was added to Clinical Policy.</li> </ol>	11/29/2021	01/17/2021

<ol style="list-style-type: none"> <li>3. Initial Approval Criteria I.A.2.a.ii updated from BMD T-score at hip or spine <math>\leq -3.5</math> to BMD T-score at hip or spine <math>\leq -3.0</math>.</li> <li>4. Initial Approval Criteria: Updated             <ol style="list-style-type: none"> <li>a. I.B.2.b: Updated trial and failure criteria from Nilandron® to nilutamide (Nilandron®).</li> <li>b. I.D.4: Updated to include new trial and failure criteria Member not responding to bisphosphonates or for patients who are not candidates for bisphosphonates because of renal insufficiency.</li> </ol> </li> <li>5. Appendix B: Updated             <ol style="list-style-type: none"> <li>a. Drug Name: Updated to remove unavailable generic therapeutic alternative alendronate/ cholecalciferol.</li> <li>b. Statement about drug listing format in Appendix B is rephrased to “Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only”.</li> </ol> </li> <li>6. Disclaimer about contraindications,” Contraindications listed reflect statements made in the manufacturer’s package insert..” was added to Appendix C.</li> <li>7. References were reviewed and updated.</li> </ol>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.2.a.iii: Updated to include new dosing criteria Recent osteoporotic fracture (within the past 12 months).</li> <li>2. Initial Approval Criteria, I.A.2.b: Updated trial and failure criteria from 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 to Trial and failure of a 3-year trial of bisphosphonate (alendronate is preferred) , unless one of the following (i-v):             <ol style="list-style-type: none"> <li>i. All bisphosphonates are contraindicated;</li> <li>ii. Clinically significant adverse effects are experienced to both oral and intravenous formulations;</li> <li>iii. Member has experienced a loss of BMD</li> </ol> </li> </ol>	<p>10/18/2022</p>	<p>01/17/2023</p>

<p>while receiving bisphosphonate therapy;</p> <p>iv. Member experienced an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy.</p> <p>3. Initial Approval Criteria, I.B.3: Updated to include new trial and failure criteria Trial and failure of zoledronic acid* (prostate or breast cancer) or pamidronate* (breast cancer) at up to maximally indicated doses unless both are contraindicated, or clinically significant adverse effects are experienced. *Prior authorization may be required.</p> <p>4. Updated Multiple Myeloma or Solid tumour, Giant Cell Tumor of Bone and Hypercalcemia of Malignancy criteria to form separate criteria for each indication as I.C, I.D. and I.E.</p> <p>5. Initial Approval Criteria, I.F.8: Updated dosing criteria from Dose is supported by peer-reviewed literature (prescriber must submit supporting evidence) to Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence) *Prescribed regimen must be FDA-approved or recommended by NCCN.</p> <p>6. Initial Approval Criteria, I.G.6: Updated dosing criteria from Dose is within FDA maximum limit for any FDA-approved indication or is supported by peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence to Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence) *Prescribed regimen must be FDA-approved or recommended by NCCN.</p> <p>7. Continued Therapy Approval Criteria, II.A.3.b: Updated dosing criteria from Xgeva®: 120 mg every 4 weeks to Xgeva®: 120 mg every 4 weeks or is supported by practice guidelines or peer reviewed literature for the relevant off-label use (prescriber must submit supporting evidence) *Prescribed regimen must be FDA-approved or recommended by NCCN.</p> <p>8. Appendix D, General Information: Updated to include new information IV/PO Bisphosphonates: Examples of Contraindications and Adverse Effects.</p> <p>9. References were reviewed and updated.</p>		
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Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed. <ol style="list-style-type: none"> <li>1. Removed Xgeva from policy.</li> <li>2. Removed dosing criteria.</li> <li>3. Removed restrictions on concurrent prescribing.</li> <li>4. Removed reauthorization requirement for positive response to therapy.</li> </ol>	12/14/2023	11/30/2023
Policy was reviewed.  Removed (osteoporosis) <ol style="list-style-type: none"> <li>1. Timeframe of T/F of bisphosphonate and criteria of T/F of the agent</li> <li>2. Prescriber specialist</li> <li>3. Age</li> <li>4. Criteria for close epiphyses</li> </ol> Removed (Prostate or Breast Cancer Treatment-Induced Bone Loss) <ol style="list-style-type: none"> <li>5. Criteria of dx and subsequent medications to confirm dx for BC and PC.</li> <li>6. Pamidronate, medication is NF</li> <li>7. Prescriber specialist</li> <li>8. Criteria for close epiphyses</li> </ol>	6/1/2024	6/1/2024
Policy was reviewed. <ol style="list-style-type: none"> <li>1. Updated Continuation of therapy language.</li> <li>2. References were updated.</li> </ol>	03/21/2025	04/10/2025
Policy was reviewed. <ol style="list-style-type: none"> <li>1. Jubbonti added to policy.</li> </ol>	09/10/2025	09/10/2025
Policy was reviewed. <ol style="list-style-type: none"> <li>1. Prolia was removed from policy.</li> </ol>	01/01/2026	N/A