Denosumab

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Prolia (denosumab) 60 mg/1 mL prefilled syringe	60 mg (1 prefilled syringe) every 6 months
Jubbonti (denosumab-bbdz) 60 mg/1 mL prefilled syringe	60 mg (1 prefilled syringe) every 6 months
Ospomyv (denosumab-dssb) 60 mg/1 mL prefilled syringe	60 mg (1 prefilled syringe) every 6 months
Stoboclo (denosumab-bmwo) 60 mg/mL prefilled syringe	60 mg (1 prefilled syringe) every 6 months
Xgeva (denosumab) subcutaneous solution 120 mg/1.7mL (70 mg/mL) vial*	1 vial per 28 days
Osenvelt (denosumab-bmwo) 120 mg/1.7 mL vial*	1 vial per 28 days
Wyost (denosumab-bbdz) 120 mg/1.7 mL vial*	1 vial per 28 days
Xbryk (denosumab-dssb) 120 mg/1.7 mL vial*	1 vial per 28 days

*Requests for increased quantities may be approved for one (1) month, only during the first month of therapy for two (2) additional 120 mg doses for the diagnosis of Giant Cell Tumor of Bone or Hypercalcemia of Malignancy

APPROVAL CRITERIA

Xgeva (denosumab); Wyost (denosumab-bbdz); Osenvelt (denosumab-bmwo); Xbryk (denosumab-dssb)

Requests for Xgeva (denosumab), Wyost (denosumab-bbdz); Osenvelt (denosumab-bmwo); Xbryk (denosumab-dssb) may be approved when the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual is using for the prevention of skeletal-related events with one of the following conditions:
    A. Multiple myeloma; **OR**
    B. Bone metastases from solid tumor other than prostate cancer ; **OR**
    C. Bone metastases from castration resistant/recurrent prostate cancer;

OR

III. Individual is 18 years of age or older; **AND**

IV. Individual is using for the treatment of hypercalcemia of malignancy [defined as an albumin-corrected serum calcium level greater than 12.5 mg/dL (3.1 mmol/L)] and is refractory to recent (within last 30 days) treatment with intravenous bisphosphonate therapy (for example, pamidronate or zoledronic acid);

OR

V. Individual is using for the treatment of localized or metastatic giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity when either or the following criteria below are met:
   A. Individual is 18 years of age or older; **OR**
   B. Individual is a skeletally mature adolescents [defined by at least one mature long bone (for example; closed epiphyseal growth plate of the humerus)].

Prolia (denosumab); Jubbonti (denosumab-bbdz); Ospomyv (denosumab-dssb); Stoboclo (denosumab-bmwo)

Initial requests for Prolia (denosumab), Jubbonti (denosumab-bbdz), Ospomyv (denosumab-dssb), Stoboclo (denosumab-bmwo) may be approved when the following criteria are met:

I. Individual is a male or postmenopausal female with a diagnosis of osteoporosis (defined as a bone mineral density (BMD) T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population); **AND**
II. Individual has had at least one osteoporotic (minimal trauma) fracture; **OR**
III. Individual has two or more risk factors for osteoporotic fracture; **OR**
IV. Individual has failed, is intolerant to or has a medical contraindication to other available osteoporosis therapies (for example, bisphosphonates);

OR

V. Individual is a male or postmenopausal female with a diagnosis of osteoporosis based on history of at least one low trauma fracture (fragility fracture);

OR

VI. Individual has glucocorticoid-induced osteoporosis (defined as a bone mineral density (BMD) T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture)) and is initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5mg or greater of prednisone and expected to remain on glucocorticoids for a least 6 months;
AND
VII. Individual has had at least one osteoporotic (minimal trauma) fracture; **OR**
VIII. Individual has two or more risk factors for osteoporotic fracture; **OR**
IX. Individual has failed, is intolerant to or has a medical contraindication to other available osteoporosis therapies (for example, bisphosphonates);

OR

X. Individual is a postmenopausal (natural or induced) female receiving adjuvant aromatase inhibitor therapy for treatment of breast cancer;

OR

XI. Individual is a male receiving androgen deprivation therapy for non-metastatic prostate cancer; **AND**
XII. Individual has had at least one osteoporotic (minimal trauma) fracture; **OR**
XIII. Individual has one or more additional risk factors for osteoporotic fracture.

Continuation request for Prolia (denosumab) ,Jubbonti (denosumab-bbdz), Ospomyv (denosumab-dssb), Stoboclo (denosumab-bmwo) may be approved if the following criterion is met:

I. There is clinically significant response to therapy (including but not limited to confirmation of no new fractures or reduction of fractures, or no worsening vertebral fractures, or no clinically significant adverse reaction); **AND**
II. If individual has been on therapy ≥ 24 months of treatment, a repeat BMD demonstrates a stable or increase in BMD.

Request for denosumab agents (Prolia, Jubbonti, Osenvelt, Ospomyv, Stoboclo, Xgeva, Xbryk, Wyost) may not be approved when the above criteria are not met and for all other indications.

Key References:

1. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis – 2020 Update. Endocrine Practice. 2020;26(1):1-46.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2025. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
4. Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2024. Updated periodically.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Eastell R, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 5, May 2019, Pages 1595–1622, https://doi.org/10.1210/jc.2019-00221.
7. Fizazi K, et al. Denosumab versus zoledronic acid for treatment of bone metastases in men with castration-resistant prostate cancer: a randomized, double-blind study. Lancet. 2011;377:813-22.
8. Henry DH, Costa L, Goldwasser F, et al. Randomized, Double-Blind Study of Denosumab Versus Zoledronic Acid in the Treatment of Bone Metastases in Patients With Advanced Cancer (Excluding Breast and Prostate Cancer) or Multiple Myeloma. J Clin Oncol 2011 ;29: 1125-1132.
9. Kehoe T, Kordestani LA. “BLA 761362”. March 5, 2024 to Raheel Khan, MBA, RAC. Sandoz, Inc. December 5, 2022.
10. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
11. Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update, The Journal of Clinical Endocrinology & Metabolism, Volume 105, Issue 3, March 2020, Pages 587-594.
12. Stopeck AT, et al. Denosumab compared with zoledronic acid for the treatment of bone metastases in patients with advanced breast cancer : a randomized, double-blind study. J Clin Oncol. 2010 ;28 :1-10.
13. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 5, 2024.
    a. Bone Cancer. V2.2024. Revised March 12, 2024.
    b. Breast Cancer. V4.2024. Revised March 11, 2024.
    c. Kidney Cancer. V4.2024. Revised May 30, 2024.
    d. Multiple Myeloma. V4.2024. Revised April 26, 2024.
    e. Non-Small Cell Lung Cancer. V5.2024. Revised April 23, 2024.
    f. Prostate Cancer. V4.2024. Revised May 17, 2024.
    g. Systemic Mastocytosis. V3.2024. Revised April 24, 2024.
    h. Thyroid Cancer. V2.2024. Revised March 12, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.