

Osteoporosis Agents
Prolia (denosumab)
Bildyos (denosumab-nxxp)
Bosaya (denosumab-kyqq)
Conexxence (denosumab-bnht)
Enoby (denosumab-qbde)
Jubbonti (denosumab-bbdz)
Ospomyv (denosumab-dssb)
Stoboclo (denosumab-bmwo)
Effective 10/01/2026

Plan	☒ MassHealth UPPL ☐ Commercial/Exchange	Program Type	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Notes	These medications are also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview

Prolia (denosumab) is a biologic monoclonal antibody indicated for the treatment of postmenopausal women and men with osteoporosis and glucocorticoid-induced osteoporosis in men and women at high risk for fracture, defined as: a history of osteoporotic fracture or multiple risk factors for fracture or patients who have failed or are intolerant to other available osteoporosis therapy. This agent is also indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer and as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer.

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when all the following drug-specific criteria are met, and documentation is provided:

Treatment/prevention of osteoporosis

ALL of the following:

1. Indication of treatment or prevention of osteoporosis
2. **ONE** of the following:
 - a. Inadequate response to an adequate trial or adverse reaction to **ONE** oral bisphosphonate
 - b. Contraindication to **ALL** oral bisphosphonates
 - c. Member is at very high risk for fracture indicated by at least **ONE** of the following:
 - i. History of fracture within the past 12 months
 - ii. History of fractures while on osteoporosis therapy
 - iii. History of multiple fractures
 - iv. History of fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids)
 - v. T-score less than -3.0
 - vi. High risk for falls
 - vii. History of injurious falls
 - viii. Very high fracture probability by FRAX (fracture risk assessment tool) or other validated fracture risk algorithm
3. For Bosaya (denosumab-kyqq), Conexxence (denosumab-bnht), Jubbonti (denosumab-bbdz), Ospomyv (denosumab-dssb), Prolia (denosumab), or Stoboclo (denosumab-bmwo), clinical rationale for use of the requested agent instead of Bildyos (denosumab-nxxp) and Enoby (denosumab-qbde)
4. For Ospomyv (denosumab-dssb), member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product

Treatment/prevention of glucocorticoid-induced osteoporosis

ALL of the following:

1. **ONE** of the following:
 - a. Indication of treatment or prevention of glucocorticoid-induced osteoporosis
 - b. Chronic glucocorticoid use determined by claims for >5 mg of prednisone equivalent for ≥ 3 months in paid claims history
2. **ONE** of the following:
 - a. Inadequate response to an adequate trial or adverse reaction to **ONE** oral bisphosphonate
 - b. Contraindication to oral bisphosphonates
 - c. Member is at very high risk for fracture indicated by at least **ONE** of the following:
 - i. History of fracture within the past 12 months
 - ii. History of fractures while on osteoporosis therapy
 - iii. History of multiple fractures
 - iv. History of fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids)
 - v. T-score less than -3.0
 - vi. High risk for falls
 - vii. History of injurious falls
 - viii. Very high fracture probability by FRAX (fracture risk assessment tool) or other validated fracture risk algorithm
3. For Bosaya (denosumab-kyqq), Conexxence (denosumab-bnht), Jubbonti (denosumab-bbdz), Ospomyv (denosumab-dssb), Prolia (denosumab), or Stoboclo (denosumab-bmwo), clinical rationale for use of the requested agent instead of Bildyos (denosumab-nxxp) and Enoby (denosumab-qbde)
4. For Ospomyv (denosumab-dssb), member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product



Treatment to increase bone mass in members at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer;

Treatment to increase bone mass in members at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer

ALL of the following:

1. Indication of **ONE** of the following:
 - a. To increase bone mass in members at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer
 - b. To increase bone mass in members at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer
2. **ONE** of the following:
 - a. Inadequate response to an adequate trial or adverse reaction to **ONE** bisphosphonate
 - b. Contraindication to **ALL** oral and injectable bisphosphonates
3. For Bosaya (denosumab-kyqq), Conexxence (denosumab-bnht), Jubbonti (denosumab-bbdz), Ospomyv (denosumab-dssb), Prolia (denosumab), or Stoboclo (denosumab-bmwo), clinical rationale for use of the requested agent instead of Bilydos (denosumab-nxxp) and Enoby (denosumab-qbde)
4. For Ospomyv (denosumab-dssb), member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product

Continuation of Therapy

ONE of the following:

1. Resubmission by prescriber will infer positive response to therapy
2. **BOTH** of the following:
 - a. Member is stabilized on Bilydos and Enoby
 - b. Submission of medical records documenting that member is still at high risk for fracture or clinical picture suggesting high risk for fracture
3. **ALL** of the following:
 - a. Member is stabilized on Prolia or another denosumab biosimilar (except Bilydos and Enoby)
 - b. Submission of medical records documenting that member is still at high risk for fracture or clinical picture suggesting high risk for fracture
 - c. Clinical rationale for use of the requested agent instead of Bilydos (denosumab-nxxp) and Enoby (denosumab-qbde)

Limitations

1. Authorizations will be granted for 1 year.

References

1. Prolia (denosumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2020.
2. Hu MI, Glezerman IG, Leboulleux S, et al. Denosumab for treatment of hypercalcemia of malignancy. J Clin Endocrinol Metab 2014; 99:3144.
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4. Eastell R, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society* Clinical Practice Guideline. J Clin Endocrinol Metab 2019; 104:1595



5. Terpos E, Zamagni E, Lentzsch S, et al. Treatment of multiple myeloma-related bone disease: recommendations from the Bone Working Group of the International Myeloma Working Group. *Lancet Oncol* 2021; 22:e119
6. Terpos E, Zamagni E, Lentzsch S, et al. Treatment of multiple myeloma-related bone disease: recommendations from the Bone Working Group of the International Myeloma Working Group. *Lancet Oncol* 2021; 22:e119
7. Salagame U, Kliwer EV, Demers A, et al. Trends in Prescribing Menopausal Hormone Therapy and Bisphosphonates in Australia and Manitoba, Canada and Adherence to Recommendations. *J Womens Health (Larchmt)* 2020; 29:177
8. Saag KG, Pannacciulli N, Geusens P, et al. Denosumab Versus Risedronate in Glucocorticoid-Induced Osteoporosis: Final Results of a Twenty-Four-Month Randomized, Double-Blind, Double-Dummy Trial. *Arthritis Rheumatol* 2019; 71:1174
9. Ishiguro S, Ito K, Nakagawa S, et al. The clinical benefits of denosumab for prophylaxis of steroid-induced osteoporosis in patients with pulmonary disease. *Arch Osteoporos* 2017; 12:44
10. Chawla S, Henshaw R, Seeger L, et al. Safety and efficacy of denosumab for adults and skeletally mature adolescents with giant cell tumour of bone: interim analysis of an open-label, parallel-group, phase 2 study. *Lancet Oncol* 2013; 14:901
11. Jubbonti [package insert]. Princeton (NJ): Sandoz Inc; 2024 Oct.
12. Stoboclo [package insert]. Jersey City (NJ): Celltrion USA, Inc; 2025 Feb.
13. Conexence [package insert]. Lake Zurich (IL): Fresenius Kabi USA, LLC; 2025 Mar

Review History

06/22/2022: Created and Reviewed June P&T, switched from CVS Standard to Custom criteria, updated approval duration for Prolia to 24 months; combined Prolia & Xgeva to single document. Effective 09/01/2022.

03/15/23 - Reviewed and updated for Mar P&T. Matched MH UPPL criteria. Effective 4/1/23.

12/11/24 – Reviewed and updated for P&T. Formatting updates. Effective 01/06/25

7/9/25 – Reviewed and updated for P&T. Separated criteria for Xgeva (will be its own policy). Updated overview to reflect current uses. Formatting updates. Removed appendices. No clinical changes to criteria. Effective 8/11/25

10/8/25 – Reviewed and updated for P&T. Added Prolia biosimilars (Jubbonit, Stoboclo, Conexence) to criteria. Effective 11/17/25

4/15/26 – Reviewed and updated for P&T. Added Prolia biosimilars (Bildyos, Ospomyv, Enoby) to policy. Enoby was added as a step through for Prolia and its biosimilars. Effective 5/11/26

9/9/26 – Reviewed and updated for P&T. Added Bosaya to criteria requiring PA through PB and MB. Bildyos and Enoby will become preferred. Updated reauth criteria to reflect MH's stability criteria. Effective 10/1/26

