Mass General Brigham
Health Plan

Osteoporosis Agents
Prolia (denosumab)
Bildyos (denosumab-nxxp)
Bosaya (denosumab-kyqq)
Conexxence (denosumab-bnht)
Enoby (denosumab-qbde)
Jubbonti (denosumab-bbdz)
Ospomyv (denosumab-dssb)
Osvyrti (denosumab-desu)
Stoboclo (denosumab-bmwo)
Effective 01/04/2027

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 when all of the following criteria are met:
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), **BOTH** of the following:
    a. Inadequate response, adverse reaction, or contraindication to **ALL** of the following:
        i. Bildyos (denosumab-nxxp)
        ii. Enoby (denosumab-qbde)
        iii. Osvyrti (denosumab-desu)
    b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
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), **BOTH** of the following:
    a. Inadequate response, adverse reaction, or contraindication to **ALL** of the following:

i. Bildyos (denosumab-nxxp)
ii. Enoby (denosumab-qbde)
iii. Osvyrti (denosumab-desu)

b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents

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), **BOTH** of the following:
    a. Inadequate response, adverse reaction, or contraindication to **ALL** of the following:
        i. Bildyos (denosumab-nxxp)
        ii. Enoby (denosumab-qbde)
        iii. Osvyrti (denosumab-desu)
    b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
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

<u>Continuation of Therapy</u>
ONE of the following:

1. Resubmission by prescriber will infer positive response to therapy
2. **BOTH** of the following:
    a. Member is stabilized on Bildyos 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 Bildyos (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.
3. Management of osteoporosis in postmenopausal women: the 2021 position statement of The North American Menopause Society. Menopause 2021; 28:973
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, Kliewer 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. Conexxence [package insert]. Lake Zurich (IL): Fresenius Kabi USA, LLC; 2025 Mar.
14. Osvyrti [package insert]. Raleigh (NC): Accord BioPharma Inc; 2025 Oct.

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, Conexxence) 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

11/4/26 – Reviewed and updated for P&T. Added Osvyrti to criteria requiring PA through PB and MB. Osvyrti is now an additional preferred denosumab biosimilar. Updated formatting and references. Effective 1/4/27