Mass General Brigham
Health Plan

Osteoporosis Agents
Xgeva (denosumab)
Aukelso (denosumab-kyqq)
Bilprevda (denosumab-nxxp)
Bomyntra (denosumab-bnht)
Jubereq (denosumab-desu)
Osenvelt (denosumab-bmwo)
Wyost (denosumab-bbdz)
Xtrenbo (denosum ab-qbde)
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
Xgeva (denosumab) is a monoclonal antibody approved for prevention of SREs in patients with bone metastases from solid tumors and multiple myeloma Additionally, Xgeva (denosumab) is FDA approved for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity and for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

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:
Prevention of skeletal-related events secondary to bone metastases in cancer related to solid tumors and in multiple myeloma;
Treatment of hypercalcemia of malignancy
ALL of the following:

1. Diagnosis is **ONE** of the following:

a. Prevention of skeletal-related events secondary to bone metastases in cancer related to solid tumors
b. Prevention of skeletal-related events secondary to multiple myeloma
c. Treatment of hypercalcemia of malignancy

2. Prescriber is an oncologist, hematologist, or orthopedic specialist or has provided consult notes from an oncologist, hematologist, or orthopedic specialist
3. Dosing is appropriate per FDA labeling
4. For Aukelso (denosumab-kyqq), Bomyntra (denosumab-bnht), Osenvelt (denosumab-bmwo), Wyost (denosumab-bbdz), or Xgeva (denosumab), **BOTH** of the following:
    a. Inadequate response, adverse reaction, or contraindication to **ALL** of the following:
        i. Bilprevda (denosumab-nxxp)
        ii. Jubereq (denosumab-desu)
        iii. Xtrenbo (denosumab-qbde)
    b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents.

Treatment of Giant Cell Tumor of the bone (GCTB)
ALL of the following:

1. Diagnosis of giant cell tumor of the bone (GCTB)
2. **ONE** of the following:
    a. The tumor or metastases are unresectable
    b. Surgical resection is likely to result in severe morbidity
    c. Surgery is not an option at this time
3. Dosing is appropriate per FDA labeling
4. For Aukelso (denosumab-kyqq), Bomyntra (denosumab-bnht), Osenvelt (denosumab-bmwo), Wyost (denosumab-bbdz), or Xgeva (denosumab), **BOTH** of the following:
    a. Inadequate response, adverse reaction, or contraindication to **ALL** of the following:
        i. Bilprevda (denosumab-nxxp)
        ii. Jubereq (denosumab-desu)
        iii. Xtrenbo (denosumab-qbde)
    b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents.

<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 Bilprevda and Xtrenbo
    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 Xgeva or another denosumab biosimilar (except Bilprevda and Xtrenbo)
    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 Bilprevda (denosumab-nxxp) and Xtrenbo (denosumab-qbde)

Limitations

1. Authorizations will be granted for 1 year.

References

1. Xgeva (denosumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; June 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. Wyost [package insert]. Princeton (NJ): Sandoz Inc; 2024 Mar.
12. Osenvelt [package insert]. Jersey City (NJ): Celltrion USA, Inc; 2025 Feb.
13. Bomyntra [package insert]. Lake Zurich (IL): Fresenius Kabi USA, LLC; 2025 Mar.
14. Jubereq® [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 – Policy separated and created for P&T. No clinical changes made. Formatting updates. Effective 8/11/25
10/8/25 – Reviewed and updated for P&T. Added Xgeva biosimilars (Wyost, Osenvelt, Bomyntra) to criteria. Effective 11/17/25
04/15/26 – Reviewed and updated for P&T. Added Xgeva biosimilars (Bilprevda,Xtrenbo) to policy. Xtrenbo was added as a step through for Xgeva and its biosimilars. Effective 5/11/26
9/9/26 – Reviewed and updated for P&T. Added Aukelso to criteria requiring PA through PB and MB. Bilprevda and Xtrenbo 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 Jubereq to criteria requiring PA through PB and MB. Jubereq is now an additional preferred denosumab biosimilar. Updated formatting and references. Effective 1/4/27