Mass General Brigham
Health Plan

Denosumab: Jubbonti, Stoboclo, Osenvelt, Wyost, Prolia, Xgeva, Bildyos, Connexxence, Bomyntra, Bilprevda Effective 01/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Denosumab is a type of monoclonal antibody used to treat osteoporosis and prevention of bone issues caused by certain cancers. Denosumab is available as two branded products (Prolia and Xgeva), each with specific FDA indications. Several biosimilars are available for both Prolia and Xgeva.

Preferred Denosumab Products	Nonpreferred Denosumab Products
Jubbonti Stoboclo Osenvelt Wyost	Prolia Bildyos Conexxence Xgeva Bomyntra Bilprevda

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted for members when the following diagnosis-specific criteria are met:

Jubbonti, Stoboclo, Prolia, Bildyos, Conexxence
<u>Postmenopausal osteoporosis, Increase Bone Mass in Men with Osteoporosis, Glucocorticoid-Induced Osteoporosis</u>

1. One of the following diagnoses:
    a. Postmenopausal osteoporosis
    b. Osteoporosis
    c. Glucocorticoid-induced osteoporosis
2. Documentation member meets ONE of the following:
    a. Pre-treatment T-score less than or equal to -2.5

b. BOTH of the following:
    i. Pre-treatment T-score greater than -2.5 and less than -1
    ii. ONE of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:
        1. Major osteoporotic fracture at 20% or more
        2. Hip fracture at 3% or more
c. History of fracture

3. Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate)
4. **Nonpreferred product:** Trial and failure, intolerance, or contraindication to BOTH of the following:
    a. Jubbonti
    b. Stoboclo

Breast cancer

1. Member has a diagnosis of breast cancer
2. Member is receiving adjuvant aromatase inhibitor therapy (e.g., anastrozole, exemestane, letrozole)
3. **Nonpreferred product:** Trial and failure, intolerance, or contraindication to BOTH of the following:
    a. Jubbonti
    b. Stoboclo

Prostate cancer

1. Member has a diagnosis of prostate cancer
2. Member is receiving androgen deprivation therapy (e.g., luteinizing hormone-release hormone (LHRH)/gonadotropin release hormone (GnRH) agonist [leuprolide, triptorelin, histrelin, goserelin) or has had bilateral orchiectomy (i.e., surgical castration)
3. **Nonpreferred product:** Trial and failure, intolerance, or contraindication to BOTH of the following:
    a. Jubbonti
    b. Stoboclo

Osenvelt, Wyost, Bomyntra, Bilprevda, Xgeva
Multiple myeloma

1. Diagnosis of multiple myeloma
2. Trial and failure, intolerance, or contraindication to one bisphosphonate therapy (e.g., zoledronic acid)
3. **Nonpreferred product:** Trial and failure, intolerance, or contraindication to BOTH of the following:
    a. Osenvelt
    b. Wyost

Bone Metastases

1. Diagnosis of solid tumors (e.g., breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer)
2. Member has one or more metastatic bone lesions
3. **Nonpreferred product:** Trial and failure, intolerance, or contraindication to BOTH of the following:
    a. Osenvelt
    b. Wyost

Giant Cell Tumor of Bone

1. Diagnosis of giant cell tumor of bone
2. Member meets ONE of the following:
    a. Member's tumor is unresectable
    b. Surgical resection is likely to result in severe morbidity

3. **Nonpreferred product:** Trial and failure, intolerance, or contraindication to BOTH of the following:
    a. Osenvelt
    b. Wyost

Hypercalcemia of Malignancy

1. Diagnosis of hypercalcemia of malignancy
2. Member meets ONE of the following:
    a. Member is refractory to intravenous bisphosphonate (e.g., pamidronate, zoledronic acid)
    b. Clinical rationale for avoiding IV bisphosphonate therapy (see Appendix)
3. **Nonpreferred product:** Trial and failure, intolerance, or contraindication to BOTH of the following:
    a. Osenvelt
    b. Wyost

Systemic Mastocytosis

1. Diagnosis of systemic mastocytosis
2. ONE of the following:
    a. Member has not responded to therapy with bisphosphonates
    b. Member is not a candidate for bisphosphonate therapy due to renal insufficiency
3. **Nonpreferred product:** Trial and failure, intolerance, or contraindication to BOTH of the following:
    a. Osenvelt
    b. Wyost

Continuation of Therapy

Jubbonti, Stoboclo, Prolia, Bildyos, Conexxence

Requests for reauthorization will be approved when the following criteria are met:

1. Member meets ONE of the following:
    a. Member has experienced clinical benefit (e.g., no new fracture seen on radiography) and has not experienced clinically significant adverse events during therapy
    b. Member has experienced clinical benefit as evidenced by a bone mass measurement showing an improvement or stabilization in T-score compared with the previous bone mass measurement and member has not experienced any adverse effects
2. **Nonpreferred products** Trial and failure, intolerance, or contraindication to BOTH of the following:
    a. Jubbonti
    b. Stoboclo

Osenvelt, Wyost, Bomyntra, Bilprevda, Xgeva

Requests for reauthorization will be approved when the following criteria are met:

1. Member demonstrates a positive clinical response to therapy
2. **Nonpreferred products:** Trial and failure, intolerance, or contraindication to BOTH of the following:
    a. Osenvelt
    b. Wyost

Limitations

1. Approval durations are as follows:
    a. Prolia and biosimilars:
        i. Initial and reauthorization approvals for all diagnoses will be granted for 24 months.
    b. Xgeva and biosimilars:

i. Initial and reauthorizations approvals for Hypercalcemia of malignancy will be granted for 2 months.=
ii. All other diagnosis: Initial and reauthorizations approvals will be granted for 12 months

Appendix

Appendix A.

Clinical reasons to avoid IV bisphosphonate therapy

- Renal insufficiency (creatinine clearance < 35mL/minute)
- Acute renal impairment
- History of intolerance to an IV bisphosphonate

Clinical reasons to avoid oral bisphosphonate therapy

- Presence of anatomic or functional esophageal abnormalities that might delay transit of the tablet (e.g., achalasia, stricture, or dysmotility
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
- Presence of documented or potential gastrointestinal malabsorption (e.g., gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders, etc.)
- Inability to stand or sit upright for at least 30 to 60 minutes
- Inability to take at least 30 to 60 minutes before first food, drink, or medication of the day
- Renal insufficiency (creatinine clearance < 35 mL/min)
- History of intolerance to an oral bisphosphonate

Appendix B. WHO Fracture Risk Assessment Tool

- High FRAX fracture probability: 10-year major osteoporotic fracture risk ≥ 20% or hip fracture risk ≥ 3%.
- 10-year probability; calculation tool available at: https://www.sheffield.ac.uk/FRAX/
- The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine (clinical), hip, wrist, or humerus) and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day.

References

1. Bildyos (denosumab-nxxp) [prescribing information]. August 2025.
2. Bilprevda (denosumab-nxxp) [prescribing information]. Jersey City, NJ: Organon LLC; August 2025.
3. Bomyntra (denosumab-bnht) [prescribing information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; March 2025.
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5. Conexxence (denosumab-bnht) [prescribing information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; March 2025.
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12. Prolia (denosumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; May 2025.
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16. 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
17. Wyost (denosumab-bbdz) [prescribing information]. Princeton, NJ: Sandoz; March 2024.
18. Xgeva (denosumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; May 2025.

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.
10/08/2025 – Reviewed and updated at October P&T. Updated policy to reflect that Jubbonti, Stoboclo, Osenvelt and Wyost are the preferred denosumab products. Updated policy to reflect that it no longer applies to the medical benefit. Combined criteria for postmenopausal osteoporosis, osteoporosis in men, and glucocorticoid-induced osteoporosis, requiring trial and failure with a bisphosphonate and either T score less than or equal to -2.5, T-score -1 to 2.5 and FRAX risk assessment score probabilities, or history of fracture. Updated criteria for multiple myeloma to require trial and failure with one bisphosphonate. Updated criteria for bone metastases to require diagnosis of solid tumors (e.g., breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) and that member has one or more metastatic bone lesions. Updated renewal criteria for Xgeva and its biosimilars to require that the member has had a positive clinical response to therapy. Initial and renewal criteria for all nonpreferred agents updated to require trial and failure with both preferred biosimilars for the reference product. Effective 01/01/2026.