

**Osteoporosis Agents**  
**Prolia (denosumab)**  
**Jubbonti (denosumab-bbdz)**  
**Stoboclo (denosumab-bmwo)**  
**Conexxence (denosumab-bnht)**  
**Effective 11/17/2025**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Medical Benefit</b> <b>Pharmacy Benefit</b>	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
<b>Exceptions</b>	<p>These medications are also available on the pharmacy benefit. Please see the <a href="#">MassHealth Drug List</a> for coverage and criteria.</p> <p>Additional agents from this class are available through the pharmacy benefit. Please see the <a href="#">MassHealth Drug List</a> for coverage and criteria.</p>		

## 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

Authorization may be granted for members who are new to the plan currently receiving treatment with Prolia 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 Conexxence (denosumab-bnht), Jubbonti (denosumab-bbdz) or Stoboclo (denosumab-bmwo), clinical rationale for use of the requested agent instead of Prolia (denosumab)

*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  $\geq 3$  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 Conexxence (denosumab-bnht), Jubbonti (denosumab-bbdz) or Stoboclo (denosumab-bmwo), clinical rationale for use of the requested agent instead of Prolia (denosumab)

*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 Conexxence (denosumab-bnht), Jubbonti (denosumab-bbdz) or Stoboclo (denosumab-bmwo), clinical rationale for use of the requested agent instead of Prolia (denosumab)

### **Continuation of Therapy**

Resubmission by prescriber will infer positive response to therapy.

### **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

### **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

