



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Prolia and Biosimilars

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Effective Date: 8/3/2026

Last Review Date: 6/2026

Applies to: ☐ Illinois
☒ Maryland

☒ Pennsylvania Kids
☒ Florida Kids

☒ New Jersey
☒ Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Prolia and biosimilars under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Treatment of postmenopausal women with osteoporosis 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.
- Treatment to increase bone mass in men with osteoporosis 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.
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (ADT) for nonmetastatic prostate cancer.
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Compendial Uses

- For treatment-related bone loss in patients with prostate cancer receiving androgen deprivation therapy (ADT).
- Treatment in postmenopausal (natural or induced) patients with breast cancer receiving adjuvant aromatase inhibition therapy to maintain or improve bone mineral density and reduce risk of fractures.
- To inhibit progression of bone erosion in patients with rheumatoid arthritis.

All other indications are considered experimental/investigational and not medically necessary.



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Applicable Drug List:

Preferred Agent:

Enoby (denosumab-qbde)

Non-Preferred Agents:

Prolia (denosumab)
Bildyos (denosumab-nxxp)
Bosaya (denosumab-kyqq)
Boncresa (denosumab-mobz)
Conexxence (denosumab-bnht)
Jubbonti (denosumab-bbdz)
Ospomyv (denosumab-dssb)
Osvyrti (denosumab-desu)
Ponlimsi (denosumab-adet)
Stoboclo (denosumab-bmwo)

Policy/Guideline:

Documentation for all indications:

Non-preferred denosumab products: The patient is unable to take Enoby (denosumab-qbde), where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation

Postmenopausal osteoporosis, osteoporosis in men, glucocorticoid-induced osteoporosis

- Chart notes or medical record documentation indicating a history of fractures, T-score, and Fracture Risk Assessment Tool (FRAX) fracture probability (if applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Prostate cancer

Chart notes, medical record documentation, or claims history supporting use of androgen deprivation therapy (ADT).

Breast cancer

Chart notes, medical record documentation, or claims history supporting use of aromatase inhibition therapy.

Coverage Criteria

Postmenopausal Osteoporosis

Authorization of 12 months may be granted to postmenopausal members with osteoporosis when EITHER of the following criteria is met:



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- Member has a history of fragility fractures (e.g., low trauma fracture from force similar to a fall from standing position).
- Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix) and meets ANY of the following criteria:
 - Member has indicators of very high fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores [less than or equal to -3], or increased fall risk)
 - Member has had an inadequate response or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo], abaloparatide [Tymlos])
 - Member has had an inadequate response or intolerance to previous oral bisphosphonate therapy.

Osteoporosis in Men

Authorization of 12 months may be granted to male members with osteoporosis when ANY of the following criteria is met:

- Member has a history of an osteoporotic vertebral or hip fracture
- Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix)
- Member has had an inadequate response or intolerance to previous oral bisphosphonate therapy.

Glucocorticoid-Induced Osteoporosis

Authorization of 12 months may be granted for members with glucocorticoid-induced osteoporosis when BOTH of the following criteria are met:

- Member is currently receiving or will be initiating glucocorticoid therapy at an equivalent prednisone dose of ≥ 2.5 mg/day for ≥ 3 months.
- Member meets EITHER of the following criteria:
 - Member has had an inadequate response or intolerance to previous oral bisphosphonate therapy.
 - Member meets ANY of the following criteria:
 - Member has a history of a fragility fracture (e.g., low trauma fracture from force similar to a fall from standing position).
 - Member has a pre-treatment T-score less than or equal to -2.5
 - Member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix)

Prostate Cancer

Authorization of 12 months may be granted to members who are receiving androgen deprivation therapy (ADT) for prostate cancer.



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Breast Cancer

Authorization of 12 months may be granted to members who are receiving adjuvant aromatase inhibition therapy for breast cancer.

Rheumatoid Arthritis

Authorization of 12 months may be granted to inhibit progression of bone erosion in members with rheumatoid arthritis.

Continuation of Therapy

Authorization of 12 months may be granted for all members (including new members) who are currently receiving the requested medication through a previously authorized pharmacy or medical benefit, who meet EITHER of the following:

- Member has received less than 24 months of therapy and has not experienced clinically significant adverse events during therapy
- Member has received 24 months of therapy or more and meets BOTH of the following:
 - Member has experienced clinical benefit (i.e., improvement or stabilization in T-score since the previous bone mass measurement)
 - Member has not experienced any adverse effects

Appendix

FRAX Fracture Risk Assessment Tool

- FRAX® (fracture risk assessment tool) available at: <https://fraxplus.org>
- High FRAX fracture probability: 10-year major osteoporosis-related fracture risk $\geq$ 20% or hip fracture risk $\geq$ 3%
- FRAX Glucocorticoid correction: If glucocorticoid dose is greater than 7.5 mg (prednisone equivalent) per day, 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

Approval Duration and Quantity Restrictions:

Approval: Initial and Renewal: 12 months

Quantity Level Limit: 1 syringe or vial (60 mg) per 6 months

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