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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	December 19, 2014
Subject:	Prolia	**Page:**	1 of 7

Last Review Date: December 12, 2025

Prolia

Description

Prolia (denosumab)

Bildyos* (denosumab-nxxp)

Bosaya* (denosumab-kyqq)

Conexxence* (denosumab-bnht)

Enoby* (denosumab-qbde)

Jubbonti* (denosumab-bbdz)

Ospomyv* (denosumab-dssb)

Stoboclo* (denosumab-bmwo)

*This medication is currently pending tier determination and may not be available at this time

Background
Prolia and its biosimilars are used to treat osteoporosis in women after menopause who are at high risk for fracture (broken bone) and cannot use another osteoporosis medicine or other osteoporosis medicines did not work well. Prolia and its biosimilars may also be used to increase bone mass in men with osteoporosis who are at high risk for fracture; treat bone loss in men who are at high risk for fracture receiving certain treatments for prostate cancer that has not spread to other parts of the body; and treat bone loss in women who are at high risk for fracture receiving certain treatments for breast cancer that has not spread to other parts of the

body. Additionally, Prolia and its biosimilars are used to treat glucocorticoid-induced osteoporosis in men and women at high risk for fracture (1-8).

Regulatory Status

FDA-approved indications: Prolia and its biosimilars are RANK ligand (RANKL) inhibitors indicated for: (1-8)

- Treatment of postmenopausal women with osteoporosis at high risk for fracture
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

Prolia and its biosimilars carry a boxed warning for severe hypocalcemia in patients with advanced kidney disease. The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia. Prior to initiation of treatment, the presence of CKD-MBD should be determined and treatment should be supervised by a healthcare professional with expertise in the diagnosis and management of CKD-MBD (1-8).

Pre-existing hypocalcemia must be corrected prior to initiating therapy with Prolia or its biosimilars and patients must adequately supplement with calcium and vitamin D (1-8).

Prolia and its biosimilars may cause fetal harm when administered to a pregnant woman. Prolia and its biosimilars are contraindicated in women who are pregnant. If these drugs are used during pregnancy, or if the patient becomes pregnant while taking these drugs, the patient should be apprised of the potential hazard to a fetus (1-8).

Prolia and its biosimilars may increase risks for osteonecrosis of the jaw, hypocalcemia, and atypical femoral fracture (1-8).

The safety and effectiveness of Prolia and its biosimilars in pediatric patients has not been established (1-8).

Related policies

Evenity, Parathyroid Hormone Analogs, Xgeva

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Prolia and its biosimilars may be considered **medically necessary** if the conditions indicated below are met.

Prolia and its biosimilars may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Osteoporosis
2. Breast cancer in female patients receiving aromatase-inhibitor therapy
3. Non-metastatic prostate cancer in male patients receiving androgen deprivation therapy

AND ALL of the following for **ALL** diagnoses:

a. Inadequate treatment response, intolerance, or contraindication to bisphosphonate therapy
b. Pre-existing hypocalcemia must be corrected prior to initiating therapy
c. High risk for bone fracture(s)
d. **NO** concurrent therapy with another RANKL-inhibitor (see Appendix 1)
e. **NO** concurrent therapy with another Prior Authorization (PA) medication for osteoporosis (see Appendix 2)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Osteoporosis
2. Breast cancer in female patients receiving aromatase-inhibitor therapy
3. Non-metastatic prostate cancer in male patients receiving androgen deprivation therapy

AND ALL of the following for **ALL** diagnoses:

a. **NO** concurrent therapy with another RANKL-inhibitor (see Appendix 1)
b. **NO** concurrent therapy with another Prior Authorization (PA) medication for osteoporosis (see Appendix 2)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 2 syringes per 12 months

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Prolia and its biosimilars are osteoclast inhibitors used to treat osteoporosis, breast cancer in female patients receiving aromatase-inhibitor therapy, or non-metastatic prostate cancer in male patients receiving androgen deprivation therapy and who are at high risk of bone fractures and not receiving Xgeva. They may increase risks for osteonecrosis of the jaw, hypocalcemia, and atypical femoral fracture. The safety and effectiveness of Prolia and its biosimilars in pediatric patients has not been established (1-8).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Prolia and its biosimilars while maintaining optimal therapeutic outcomes.

References

1. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2025.
2. Conexxence [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; March 2025.
3. Jubbonti [package insert]. Princeton, NJ: Sandoz Inc.; October 2024.
4. Ospomyv [package insert]. Incheon, Republic of Korea: Samsung Bioepis Co., Ltd.; February 2025.
5. Stoboclo [package insert]. Jersey City, NJ: Celtrion USA, Inc.; February 2025.
6. Bildyos [package insert]. Jersey City, NJ: Organon LLC; August 2025.
7. Bosaya [package insert]. Cambridge, MA: Biocon Biologics Inc.; September 2025.
8. Enoby [package insert]. Cherry Hill, NJ: Hikma Pharmaceuticals USA Inc.; September 2025.

Policy History

Date	Action
December 2014	Addition to PA
March 2015	Annual editorial review and reference update
December 2015	Annual review and reference update Removal of high risk of bone fracture from renewal Addition of inadequate treatment response, intolerance, or contraindication to bisphosphonate therapy and quantity of 2 syringes per year, per PMPC
March 2016	Annual review Policy number changed from 5.07.17 to 5.30.17
September 2016	Annual editorial review and reference update
December 2017	Annual editorial review and reference update Addition of the age requirement to the renewal section
August 2018	Update of regulatory section per package insert: treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
November 2018	Annual review and reference update
April 2019	Addition of requirement of no concurrent therapy with another PA osteoporosis medication and addition of Appendices 1 and 2
June 2019	Annual review
September 2019	Annual review and reference update
December 2020	Annual review and reference update
September 2021	Annual review and reference update
September 2022	Annual review and reference update
December 2022	Annual review
September 2023	Annual editorial review and reference update
September 2024	Annual review and reference update

September 2025	Annual editorial review and reference update. Added biosimilars to policy: Conexxence, Jubbonti, Ospomyv, and Stoboclo
December 2025	Annual editorial review and reference update. Added biosimilars to policy: Bildyos, Bosaya, and Enoby

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.

Appendix 1 - List of RANKL Inhibitors

Generic Name	Brand Name
denosumab	Prolia
denosumab	Xgeva

Appendix 2 - List of PA Osteoporosis Medications

Generic Name	Brand Name
abaloparatide	Tymlos
denosumab	Prolia
romosuzumab-aqqg	Evenity
teriparatide	Bonsity
teriparatide	Forteo
teriparatide	Teriparatide