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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	December 19, 2014
Subject:	Prolia	**Page:**	1 of 6

Last Review Date: September 6, 2024

Prolia

Description

Prolia (denosumab)

Background
Prolia is 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 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 is used to treat glucocorticoid-induced osteoporosis in men and women at high risk for fracture (1).

Regulatory Status
FDA-approved indications: Prolia is a RANK ligand (RANKL) inhibitor indicated for: (1)

- 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 carries 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).

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

Prolia may cause fetal harm when administered to a pregnant woman. Prolia is contraindicated in women who are pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus (1).

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

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

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 may be considered **medically necessary** if the conditions indicated below are met.

Prolia 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 is an osteoclast inhibitor 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. It may increase risks for osteonecrosis of the jaw, hypocalcemia, and atypical femoral fracture. The safety and effectiveness of Prolia in pediatric patients has not been established (1).

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

References

1. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; March 2024.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.

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