

Prior Authorization Tip Sheet

This tip sheet provides some suggestions that may help you when completing a PA request for Prolia®. However, because payer requirements differ, this list is not all inclusive. Consult the health plan's policy for specific PA criteria and documentation requirements.

Determine Fulfillment Pathway

Most payers have **different** PA forms for the pharmacy benefit and the medical benefit. It is important to determine the appropriate fulfillment pathway before starting the PA process.

Medical Benefit (Part B/commercial) fulfilled through:

- Physician Purchase (buy and bill)
- Specialty Pharmacy

Pharmacy Benefit (Part D/commercial) fulfilled through:

- Specialty Pharmacy
- Retail Pharmacy

Identify Diagnosis Details

Codes

- Determine appropriate ICD-10 diagnosis code
- HCPCS code (J-Code): J0897 (injection, denosumab)
- 60 mg every 6 months
- Determine administration code

DEXA results (BMD) T-score

- Original T-score
- Most recent T-score

FRAX® score 10-year fracture risk assessment (if available)

Document Treatment History

Be prepared to identify previous therapies that were tried, failed, or contraindicated, as some payers may require this. Record reasons for failure. Examples may include: gastrointestinal symptoms, no improvement or worsening of T-score, fractured on therapy, or other side effects.

Oral bisphosphonates¹

- FOSAMAX® (alendronate sodium)

IV bisphosphonates²

- Reclast® (zoledronic acid)

Parathyroid Hormone (PTH)³

- TYMLOS® (abaloparatide)
- FORTEO® (teriparatide injection)

Please document other failed therapies not listed, including calcium and vitamin D

Consider the Patient's Risk Factors for Fracture and Other Considerations

Common Risk Factors for Fracture³

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|---------------------------|-------------------------------|-----------------------------------|---|
| -Prior fragility fracture | -Low body weight | -Immobilization | -Excessive alcohol intake (>3 drinks/day) |
| -Low BMD (≤ -2.5) | -Long-term glucocorticoid use | -Parental history of hip fracture | -Diabetes |
| -Age >65 years | -Cigarette smoking | -Rheumatoid arthritis | -Risk of falling |

Very High Risk for Fracture (One is needed to be considered very high risk.)³

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|---|--|--|
| -Recent fracture (within past 12 months) | -Fracture while on approved therapy for osteoporosis | -Experienced multiple fractures |
| -Very high fracture probability per FRAX® (eg, >30% major osteoporotic fracture, >4.5% hip) | -Fractures while on drugs that may cause skeletal harm | -Very low T-score (eg, <-3.0) |
| | | -High risk for falls or history of injurious falls |

Other Potential Considerations

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|--|--|--|
| -Calcium and vitamin D supplementation ² | -Cognitive impairment ⁴ | -Lack of coordination ⁴ |
| -Recent calcium metabolic panel (CMP) results ³ | -Gastrointestinal disorder (eg, GERD) ⁵ | -Impaired kidney function ³ |
| -Height loss ³ | | |

BMD=bone mineral density; CMP=calcium metabolic panel; DEXA=dual x-ray absorptiometry; FRAX®=Fracture Risk Assessment Tool; GERD=gastroesophageal reflux disease; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; IV=intravenous; PA=prior authorization.

IMPORTANT SAFETY INFORMATION

SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE:

Patients with advanced chronic kidney disease are at greater risk of severe hypocalcemia following Prolia administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported. The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia. Prior to initiating Prolia in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with Prolia in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.

Please see additional Important Safety Information on next page.

INDICATIONS

Prolia® is indicated for the 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. In postmenopausal women with osteoporosis, Prolia® reduces the incidence of vertebral, nonvertebral, and hip fractures.

Prolia® is indicated for 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.

Prolia® is indicated for the 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.

Prolia® is indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia® also reduced the incidence of vertebral fractures.

Prolia® is indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

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Contraindications: Prolia® is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating Prolia®.

Prolia® is contraindicated in women who are pregnant and may cause fetal harm. In women of reproductive potential, pregnancy testing should be performed prior to initiating treatment with Prolia®. Prolia® is contraindicated in patients with a history of systemic hypersensitivity to any component of the product. Reactions have included anaphylaxis, facial swelling and urticaria.

Severe Hypocalcemia and Mineral Metabolism Changes: Prolia can cause severe hypocalcemia and fatal cases have been reported. Pre-existing hypocalcemia must be corrected prior to initiating therapy with Prolia. Adequately supplement all patients with calcium and vitamin D.

In patients without advanced chronic kidney disease who are predisposed to hypocalcemia and disturbances of mineral metabolism (e.g. treatment with other calcium-lowering drugs), assess serum calcium and mineral levels (phosphorus and magnesium) 10 to 14 days after Prolia injection.

Same Active Ingredient: Prolia® contains the same active ingredient (denosumab) found in XGEVA®. Patients receiving Prolia® should not receive XGEVA®.

Hypersensitivity: Clinically significant hypersensitivity including anaphylaxis has been reported with Prolia®. Symptoms have included hypotension, dyspnea, throat tightness, facial and upper airway edema, pruritus, and urticaria. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of Prolia®.

Osteonecrosis of the Jaw (ONJ): ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing, and has been reported in patients receiving Prolia®. An oral exam should be performed by the prescriber prior to initiation of Prolia®. A dental examination with appropriate preventive dentistry is recommended prior to treatment in patients with risk factors for ONJ such as invasive dental procedures, diagnosis of cancer, concomitant therapies (e.g. chemotherapy, corticosteroids, angiogenesis inhibitors), poor oral hygiene, and co-morbid disorders. Good oral hygiene practices should be maintained during treatment with Prolia®. The risk of ONJ may increase with duration of exposure to Prolia®.

References: 1. FOSAMAX® (alendronate sodium) prescribing information. Merck & Co., Inc. 2. Aetna. Medicare form: EVENTY (romosozumab-aqqg) injectable medication precertification request. <https://www.aetna.com/document-library/pharmacy-insurance/healthcare-professional/documents/medicare-gr-form-69492-3-evenity.pdf>. Accessed December 2, 2022. 3. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis—2020 update. *Endocr Pract.* 2020;26(suppl1):1-46. doi:10.4158/GL-2020-0524SUPPL. 4. Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. <https://www.cms.gov/files/zip/2022-code-tables-tabular-and-index-updated-02012022.zip>. Accessed December 2, 2022. 5. Cleveland Clinic. Do all osteoporosis drugs aggravate acid reflux? <https://health.clevelandclinic.org/which-osteoporosis-drugs-wont-worsen-my-acid-reflux/>. Published January 24, 2018. Accessed December 2, 2022.

For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. Extensive dental surgery to treat ONJ may exacerbate the condition. Discontinuation of Prolia® should be considered based on individual benefit-risk assessment.

Atypical Femoral Fractures: Atypical low-energy, or low trauma fractures of the shaft have been reported in patients receiving Prolia®. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated with antiresorptive agents.

During Prolia® treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be evaluated to rule out an incomplete femur fracture. Interruption of Prolia® therapy should be considered, pending a risk/benefit assessment, on an individual basis.

Multiple Vertebral Fractures (MVF) Following Discontinuation of Prolia® Treatment: Following discontinuation of Prolia® treatment, fracture risk increases, including the risk of multiple vertebral fractures. New vertebral fractures occurred as early as 7 months (on average 19 months) after the last dose of Prolia®. Prior vertebral fracture was a predictor of multiple vertebral fractures after Prolia® discontinuation. Evaluate an individual's benefit/risk before initiating treatment with Prolia®. If Prolia® treatment is discontinued, patients should be transitioned to an alternative antiresorptive therapy.

Serious Infections: In a clinical trial (N = 7808), serious infections leading to hospitalization were reported more frequently in the Prolia® group than in the placebo group. Serious skin infections, as well as infections of the abdomen, urinary tract and ear, were more frequent in patients treated with Prolia®. Endocarditis was also reported more frequently in Prolia®-treated patients. The incidence of opportunistic infections and the overall incidence of infections were similar between the treatment groups. Advise patients to seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis.

Patients on concomitant immunosuppressant agents or with impaired immune systems may be at increased risk for serious infections. In patients who develop serious infections while on Prolia®, prescribers should assess the need for continued Prolia® therapy.

Dermatologic Adverse Reactions: Epidermal and dermal adverse events such as dermatitis, eczema and rashes occurred at a significantly higher rate with Prolia® compared to placebo. Most of these events were not specific to the injection site. Consider discontinuing Prolia® if severe symptoms develop.

Musculoskeletal Pain: Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking Prolia®. Consider discontinuing use if severe symptoms develop.

Suppression of Bone Turnover: Prolia® resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry. The significance of these findings and the effect of long-term treatment are unknown. Monitor patients for consequences, including ONJ, atypical fractures, and delayed fracture healing.

Adverse Reactions: The most common adverse reactions (>5% and more common than placebo) in women with postmenopausal osteoporosis are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis. The most common adverse reactions (> 5% and more common than placebo) in men with osteoporosis are back pain, arthralgia, and nasopharyngitis. Pancreatitis has been reported with Prolia®.

In women with postmenopausal osteoporosis, the overall incidence of new malignancies was 4.3% in the placebo group and 4.8% in the Prolia® group. In men with osteoporosis, new malignancies were reported in no patients in the placebo group and 4 (3.3%) patients in the Prolia® group. A causal relationship to drug exposure has not been established.

The most common adverse reactions (> 3% and more common than active-control group) in patients with glucocorticoid-induced osteoporosis are back pain, hypertension, bronchitis, and headache.

The most common (per patient incidence ≥ 10%) adverse reactions reported with Prolia® in patients with bone loss receiving ADT for prostate cancer or adjuvant AI therapy for breast cancer are arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials. Additionally, in Prolia®-treated men with nonmetastatic prostate cancer receiving ADT, a greater incidence of cataracts was observed.

Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

Please see Prolia® full Prescribing Information, including Boxed Warning and Medication Guide.



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