

Denosumab (PROLIA)

Criteria for Use - Osteoporosis

May 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive denosumab.

- Hypocalcemia or has a pre-existing disturbance of mineral metabolism, that has not been effectively corrected or treated ^{^1, ^2}
- Documentation of the need for an invasive dental procedure (e.g., tooth extraction, dental implant, and/or dental infection treatment) or recent procedure that has not fully healed
- Acute dental issue identified by history or clinician mouth examination
- Receiving denosumab (XGEVA)
- Pregnancy or lactating

1. Examples: hypoparathyroidism, thyroid or parathyroid surgery, vitamin D deficiency, malabsorption syndromes, excision of small intestine.
2. Exception: Patients with secondary or tertiary hyperparathyroidism because of chronic kidney disease and low bone mineral density who are nonsurgical candidates.

Inclusion Criteria

All of the following must be selected in order to meet criteria for use. ^{^3}

- Diagnosis of osteoporosis or is at risk for glucocorticoid-induced osteoporosis
- Prescriber is a VA/VA Community Care endocrinologist, rheumatologist, nephrologist, geriatrician, or locally designated expert
- Patient's total daily dietary and supplemental calcium intake is 1000 to 1200 mg/day
- Has a 25-hydroxyvitamin D concentration >30 ng/mL or > 20 ng/ml and appropriate intake (e.g., cholecalciferol \geq 800 international units per day)
- Prescriber has documented a discussion of the risk of severe hypocalcemia and the need for close monitoring if eGFR < 30ml/min
- For patients with an eGFR of < 35 ml/min, risks, and benefits of indefinite denosumab have been discussed with patients because they cannot transition to bisphosphonates

3. Requires transition to another antiresorptive agent if discontinued to prevent rebound fractures

Additional Criteria

One of the following must be selected in order to meet criteria

- Patient is allergic to, has a contraindication to, has not demonstrated a satisfactory response to, or experienced intolerable adverse events while taking a bisphosphonate
- Osteoporotic fracture and a T-score at the hip or spine of ≤ -2.5
- Very high fracture probability by Fracture Risk Assessment Tool (FRAX) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%)
- Patient has a T-score ≤ -3.0
- More than 2 osteoporotic fractures
- Continuing to lose bone mineral density or sustained an osteoporotic fracture while on other approved osteoporosis therapy

Prepared: January 2012; revised May 2018, November 2018, May 2024. Contact: Matthew A. Fuller, Pharm.D., BCPP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)
