

Medical Policy:

Denosumabs

Last review date: 1/1/26

Last review date: 10/1/2025

Applicable Products:

Prolia (denosumab)	Xgeva (denosumab)
<p>Prolia Biosimilars:</p> <ul style="list-style-type: none"> • Jubbonti (denosumab-bbdz) • Stoboclo (denosumab-bmwo) • Conexence (denosumab-bnht) • Bildyos (denosumab-nxxp) • Ospomyv (denosumab-dssb) 	<p>Xgeva Biosimilars:</p> <ul style="list-style-type: none"> • Wyost (denosumab-bbdz) • Osenvelt (denosumab-bmwo) • Bomynta (denosumab-bnht) • Bilprevda (denosumab-nxxp) • Xbryk (denosumab-bbdz)

Initial Approval Criteria:

Coverage may be approved if all the following are met:

- Drug-specific criteria; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Prolia and biosimilars

- The patient must be 18 years of age or older; **AND**
- Must be prescribed by or in consultation with a provider; **AND**
- Patient is not taking Xgeva or an Xgeva biosimilar while taking this medication; **AND**
- **Patient must have a diagnosis of one of the following:**

Postmenopausal Osteoporosis (PMO)

- Patient must be 18 years of age or older; **AND**
- Patient is at very high risk for fracture; **AND**
- Patient must have a diagnosis of postmenopausal osteoporosis; **AND**
- Patient has had a T-score at or below –2.5 at the femoral neck, spine, total hip, and/or 33% radius (wrist); **AND** • Patient has failed or is intolerant to other available osteoporosis therapy; **OR**

Male Osteoporosis (MO)

- Patient must be 18 years of age or older; **AND**
- Patient is at very high risk for fracture; **AND**
- Patient must have a diagnosis of male osteoporosis; **AND**
- Patient has had a T-score at or below -2.5 at the femoral neck, spine, total hip, and/or 33% radius (wrist); **AND** • Patient has failed or is intolerant to other available osteoporosis therapy; **OR**

Glucocorticoid-Induced Osteoporosis (GIO)

- Patient must be 18 years of age or older; **AND**
- Patient is at very high risk for fracture; **AND**
- Patient has had a T-score at or below -2.5 at the femoral neck, spine, total hip, and/or 33% radius (wrist); **AND**
- Patient must have a diagnosis of glucocorticoid-induced osteoporosis; **AND**
- Patient is currently receiving or will be initiating glucocorticoid therapy; **AND**
- Patient has failed or is intolerant to other available osteoporosis therapy; **OR**

Therapeutic Management of Aromatase Inhibitor–Induced Bone Loss in Women Undergoing Adjuvant Therapy for Breast Cancer

- Patient must be 18 years of age or older; **AND**
- Must be prescribed by or in consultation with an oncologist; **AND**
- Patient must have a diagnosis of breast cancer; **AND**
- Patient is receiving aromatase inhibitor therapy; **AND**
- Patient has failed or is intolerant to other available osteoporosis therapy; **OR**

Therapeutic Management of Androgen Deprivation Therapy-Induced Bone Loss in Men Undergoing Treatment for Prostate Cancer

- Patient must be 18 years of age or older; **AND**
- Must be prescribed by or in consultation with an oncologist; **AND**
- Patient must have a diagnosis of non-metastatic prostate cancer; **AND**
- Patient is receiving androgen deprivation therapy; **AND**
- Patient has failed or is intolerant to other available osteoporosis therapy

Xgeva and biosimilars

- Patient must be 18 years of age or older; **AND**
- Must be prescribed by or in consultation with a provider; **AND**
- Patient is not taking Prolia or a Prolia biosimilar while taking this medication; **AND**
- **Patient must have a diagnosis of the following:**

Giant Cell Tumor of the Bone

- Patient must be 18 years of age or older; **AND**
- Patient must be a skeletally mature adolescent as defined by having at least 1 mature long bone (e.g., closed epiphyseal growth plate of the humerus); **AND**
- Patient disease is unresectable **OR** surgical resection is likely to result in severe morbidity; **OR**

Prevention of Skeletal-Related Events

- Patient must be 18 years of age or older; **AND**
- Patient must have a presence of bone metastases from solid tumors

OR diagnosis of multiple myeloma;**AND**

- Patient with prostate cancer must have castration-resistant prostate cancer; **AND**
- Must be prescribed by, or in consultation with, a hematologist or an oncologist; **OR**

Hypercalcemia of Malignancy

- Patient must be 18 years of age or older; **AND** • Patient has a current malignancy **AND**
- Patient has demonstrated refractory (within the past 30 days)

OR contraindication (including renal insufficiency) **OR** intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid);**AND**

- Must be prescribed by, or in consultation with, a hematologist or an oncologist

Renewal Criteria:**Coverage may be renewed if all the following are met:**

- Patient continues to meet the Initial Approval Criteria; **AND**
- Absence of unacceptable toxicity

Length of Authorization: 1 year

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.