

Available under the Newfoundland and Labrador Public Drug Program via Special Authorization¹

Prolia® is indicated:²

- 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.
- As a 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.
- As a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- As a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- As a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- As a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling us at 1-866-502-6436.

CRITERIA:¹

For the treatment of osteoporosis in postmenopausal women and male patients who meet the following criteria:

- Have a contraindication to oral bisphosphonates

AND

- High risk for fracture, or refractory or intolerant to other available osteoporosis therapies


Clinical criteria:

- High fracture risk defined as either: a moderate 10-year fracture risk (10-20%) with a prior fragility fracture OR a high 10-year fracture risk ($\geq 20\%$) as defined by either the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool
- Refractory is defined as an unsatisfactory response to bisphosphonates and is typically defined as a fragility fracture and/or evidence of a decline in bone mineral density below pretreatment baseline levels, despite adherence for one year



References: 1. Government of Newfoundland and Labrador. Department of Health and Community Services. Special Authorization Drug Products. Updated March 2018. Accessed May 31, 2018. <http://www.health.gov.nl.ca/health/prescription/newformulary.asp>. 2. Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.

Newfoundland and Labrador Form – “How To”

 SPECIAL AUTHORIZATION REQUEST FORM The Newfoundland and Labrador Prescription Drug Program (NLPDP)		
Pharmaceutical Services Department of Health and Community Services P.O. Box 8700, Confederation Bldg. St. John's, NL A1B 4J6		Phone: (709) 729-6507 Toll Free Line: 1-888-222-0533 Fax: (709) 729-2851
Patient Information		
Patient Name	Date of Birth	NLPDP Drug Card/MCP Number
Address		
Drug Requested for Special Authorization Drug: _____ Dosage: _____ Duration: _____ Patient Diagnosis: _____		
Previous Medication Trial Drug: _____ Dosage: _____ Duration: _____ Trial Outcome: _____		
Reason for Request <input type="checkbox"/> contraindication <input type="checkbox"/> therapeutic failure <input type="checkbox"/> adverse event <input type="checkbox"/> other		
Explain: _____ _____ _____		
Diagnostic Testing Diagnosis confirmed via: _____ Date: _____		
Other Comments: _____ _____ _____		
Prescriber Information / Requested By: <input type="checkbox"/> Physician <input type="checkbox"/> Other Health Professional Prescriber Name: _____ License Number: _____ (please print)		
Address: _____ Phone Number: _____ Fax Number: _____ Signature: _____ Date: _____		
Pharmacist Name: _____ Pharmacy Name: _____ (optional) (optional)		

Indicate previous treatment(s) and outcome

Form **MUST** indicate contraindication to bisphosphonate use **AND** high fracture risk OR patient is intolerant OR refractory to available therapies

Form **MUST** indicate the clinical criteria indicating high fracture risk

Please note that Special Authorization Requests normally take approximately 10 working days to be processed.
Version June 2009 – Replaces previous forms
 Please copy additional forms as needed.