Available under the Newfoundland and Labrador Public Drug Program via Special Authorization[1]

Prolia® (denosumab injection) 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 Amgen 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 (≥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

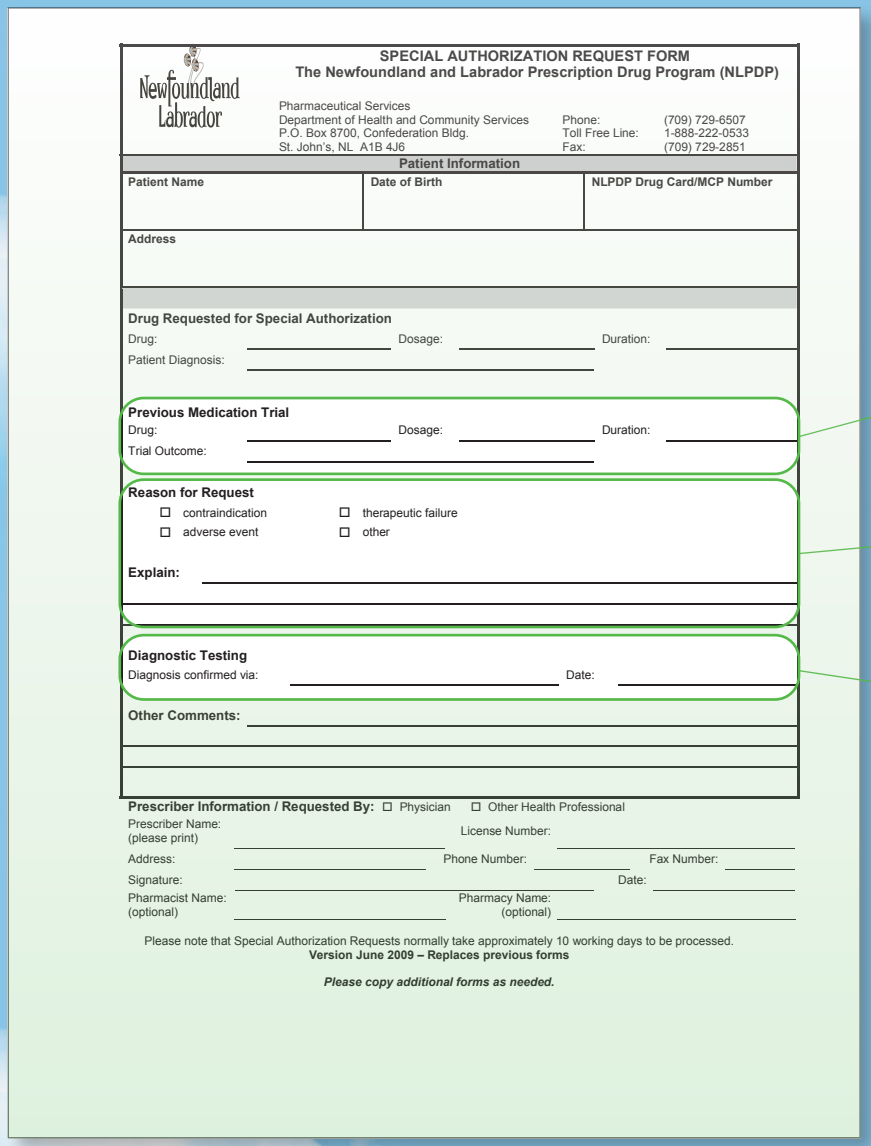
PRO-0148E-21

Pr prolia® denosumab injection

REVIEWED BY PAAB

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 (denosumab injection) Product Monograph. Amgen Canada Inc., **March 29, 2022.**

Newfoundland and Labrador Form – "How To"



Newfoundland Labrador

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

☐ contraindication ☐ therapeutic failure
☐ adverse event ☐ other

Explain: _____

Diagnostic Testing

Diagnosis confirmed via: _____ Date: _____

Other Comments: _____

Prescriber Information / Requested By: ☐ Physician ☐ Other Health Professional

Prescriber Name: (please print) _____ License Number: _____
Address: _____ Phone Number: _____ Fax Number: _____
Signature: _____ Date: _____
Pharmacist Name: (optional) _____ Pharmacy Name: (optional) _____

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.

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

Pr prolia® denosumab injection

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