Available for both men and postmenopausal women with osteoporosis under the New Brunswick Prescription 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 in men who meet the following criteria:[1]

- Have a contraindication to oral bisphosphonates;

AND

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

CLINICAL NOTES:

- Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pre-treatement baseline levels, despite adherence for one year to other available osteoporosis therapies.
- High fracture risk defined as:
  - A moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or
  - A high 10-year fracture risk (≥20%) as defined by either the CAROC or FRAX tool.

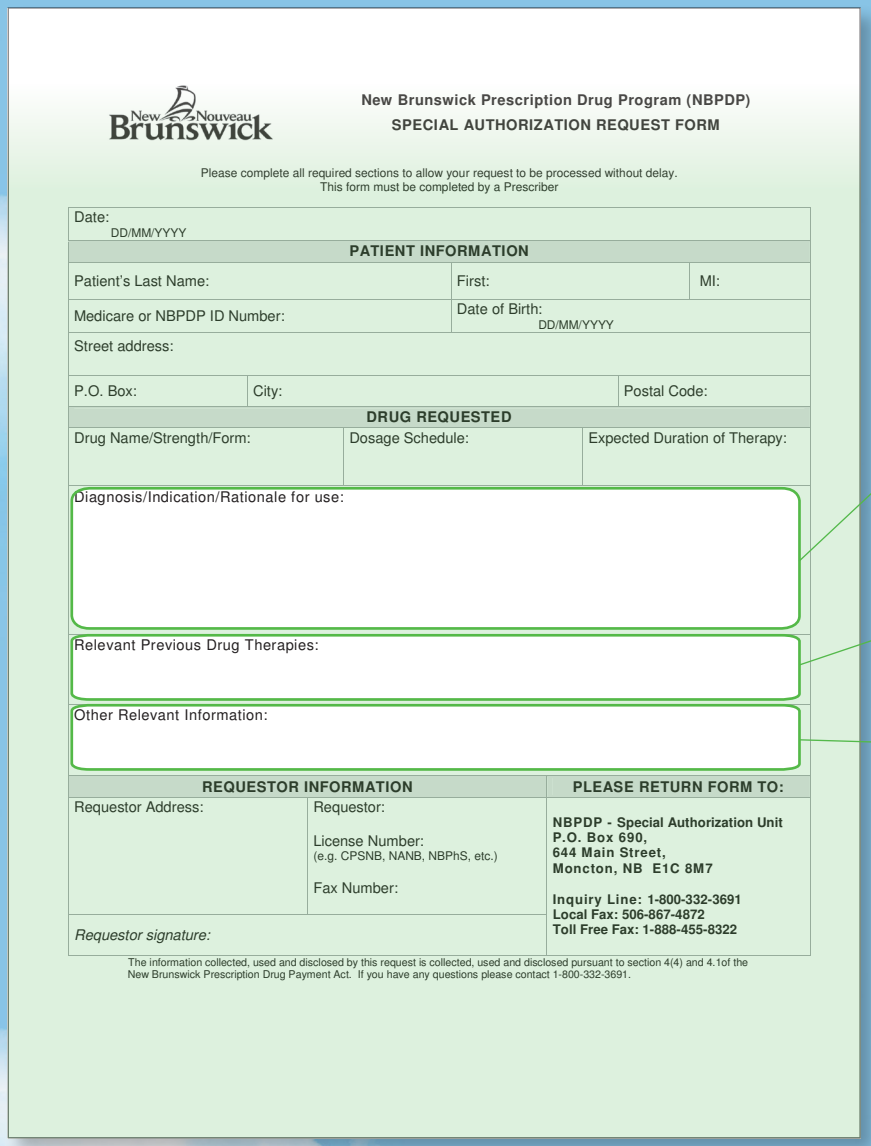
PRO-0148E-21

Pr prolia® denosumab injection

REVIEWED BY PAAB

References: 1. New Brunswick Drug Plans Formulary, November 2021. Accessed November 11, 2021. https://www2.gnb.ca/content/dam/gnb/Departments/h-s/pdf/en/NBDrugPlan/NewBrunswickDrugPlansFormulary.pdf. **2.** Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., March 29, 2022.

New Brunswick Form – "How To"



New Brunswick Nouveau-Brunswick

New Brunswick Prescription Drug Program (NBPDP)
SPECIAL AUTHORIZATION REQUEST FORM

Please complete all required sections to allow your request to be processed without delay.
This form must be completed by a Prescriber

Date: DD/MM/YYYY

PATIENT INFORMATION

Patient's Last Name:	First:	MI:
Medicare or NBPDP ID Number:	Date of Birth: DD/MM/YYYY	
Street address:		
P.O. Box:	City:	Postal Code:

DRUG REQUESTED

Drug Name/Strength/Form:	Dosage Schedule:	Expected Duration of Therapy:

Diagnosis/Indication/Rationale for use:

Relevant Previous Drug Therapies:

Other Relevant Information:

REQUESTOR INFORMATION		PLEASE RETURN FORM TO:
Requestor Address:	Requestor: License Number: (e.g. CPSNB, NANB, NBPhS, etc.) Fax Number:	**NBPDP - Special Authorization Unit** **P.O. Box 690,** **644 Main Street,** **Moncton, NB E1C 8M7** **Inquiry Line: 1-800-332-3691** **Local Fax: 506-867-4872** **Toll Free Fax: 1-888-455-8322**
Requestor signature:		

The information collected, used and disclosed by this request is collected, used and disclosed pursuant to section 4(4) and 4.1of the New Brunswick Prescription Drug Payment Act. If you have any questions please contact 1-800-332-3691.

For use in female patients with postmenopausal osteoporosis or male patients with osteoporosis in whom bisphosphonate use is contraindicated and where the patient is at high risk of fracture, or refractory or intolerant to other available osteoporosis therapies.

Form **MUST** indicate previous therapies that the patient was refractory to or could not tolerate.

Form **MUST** indicate that bisphosphonate use is contraindicated.

Pr prolia® denosumab injection

REVIEWED BY PAAB