Available under PEI Pharmacare when patients meet Special Authority criteria[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:

- 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-treatment baseline levels, despite adherence for one year to other available osteoporosis therapies.
- High fracture risk defined as:
  - 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
  - High 10-year fracture risk (≥ 20%) as defined by the CAROC or FRAX tool.

For full details regarding coverage, visit www.healthpei.ca/formulary.

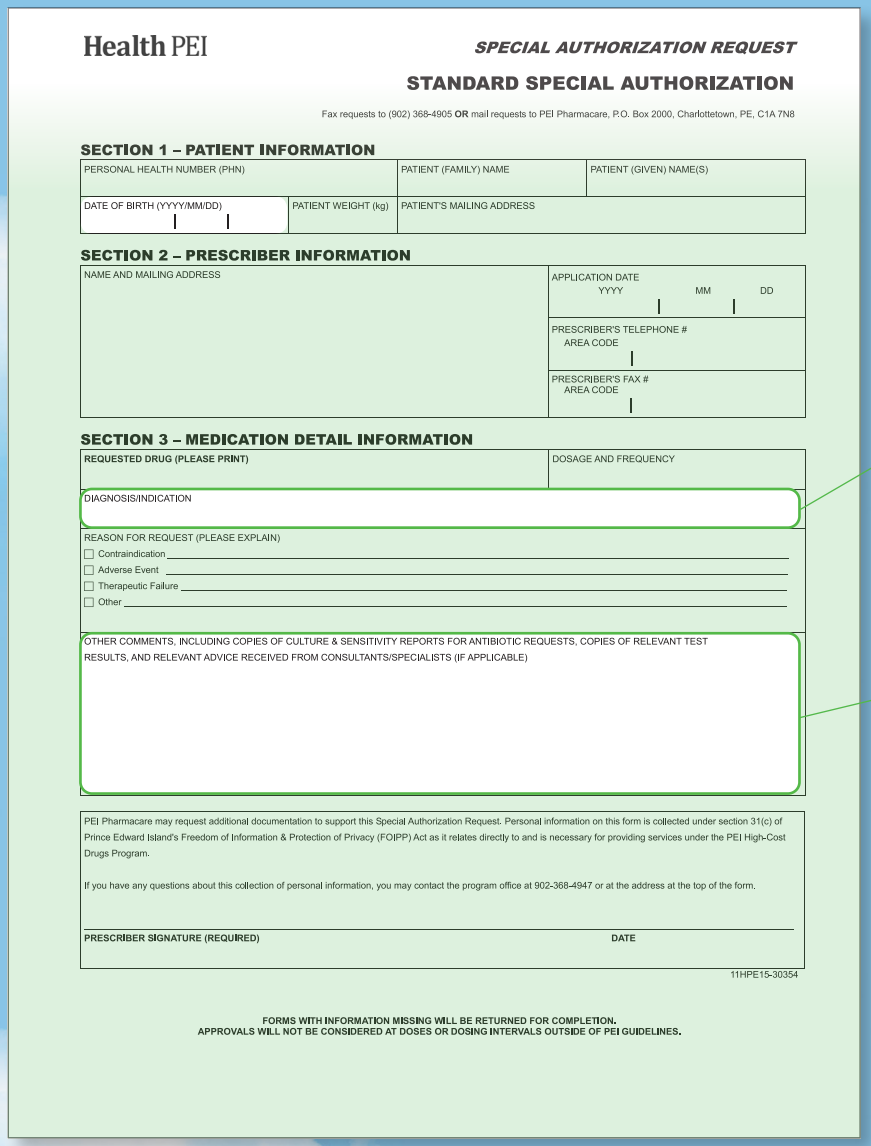
PRO-0148E-21

Pr prolia® denosumab injection

REVIEWED BY PAAB

References: 1. Health PEI: P.E.I. Pharmacare Formulary. Accessed November 11, 2021. http://www.gov.pe.ca/photos/original/hpei_formulary.pdf.
2. Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., **March 29, 2022.**

PEI Form – "How To"



Health PEI

SPECIAL AUTHORIZATION REQUEST

STANDARD SPECIAL AUTHORIZATION

Fax requests to (902) 368-4905 **OR** mail requests to PEI Pharmacare, P.O. Box 2000, Charlottetown, PE, C1A 7N8

SECTION 1 – PATIENT INFORMATION

PERSONAL HEALTH NUMBER (PHN)	PATIENT (FAMILY) NAME	PATIENT (GIVEN) NAME(S)
DATE OF BIRTH (YYYY/MM/DD)	PATIENT WEIGHT (kg)	PATIENT'S MAILING ADDRESS

SECTION 2 – PRESCRIBER INFORMATION

NAME AND MAILING ADDRESS	APPLICATION DATE YYYY MM DD
	PRESCRIBER'S TELEPHONE # AREA CODE
	PRESCRIBER'S FAX # AREA CODE

SECTION 3 – MEDICATION DETAIL INFORMATION

REQUESTED DRUG (PLEASE PRINT)	DOSAGE AND FREQUENCY

DIAGNOSIS/INDICATION

REASON FOR REQUEST (PLEASE EXPLAIN)

- ☐ Contraindication
- ☐ Adverse Event
- ☐ Therapeutic Failure
- ☐ Other

OTHER COMMENTS, INCLUDING COPIES OF CULTURE & SENSITIVITY REPORTS FOR ANTIBIOTIC REQUESTS, COPIES OF RELEVANT TEST RESULTS, AND RELEVANT ADVICE RECEIVED FROM CONSULTANTS/SPECIALISTS (IF APPLICABLE)

PEI Pharmacare may request additional documentation to support this Special Authorization Request. Personal information on this form is collected under section 31(c) of Prince Edward Island's Freedom of Information & Protection of Privacy (FOIPP) Act as it relates directly to and is necessary for providing services under the PEI High-Cost Drugs Program.

If you have any questions about this collection of personal information, you may contact the program office at 902-368-4947 or at the address at the top of the form.

PRESCRIBER SIGNATURE (REQUIRED) **DATE**

11HPE15-30354

FORMS WITH INFORMATION MISSING WILL BE RETURNED FOR COMPLETION.
APPROVALS WILL NOT BE CONSIDERED AT DOSES OR DOSING INTERVALS OUTSIDE OF PEI GUIDELINES.

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 that bisphosphonate use is contraindicated, and patient is at high risk for fracture or was refractory to or could not tolerate previous therapies.

Pr prolia® denosumab injection

REVIEWED BY PAAB