Available under PEI Pharmacare when patients meet Special Authority criteria[1]

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 who were previously approved or would otherwise be eligible for coverage of oral bisphosphonates and who:

1. Have experienced a further significant decline in bone mineral density (BMD) after 1 year of continuous bisphosphonate therapy and meet at least **TWO** of the following:
   - Age >75 years old
   - Prior fragility fracture
   - BMD T-score ≤-2.5

OR

2. Have a contraindication to bisphosphonates due to hypersensitivity or abnormalities of the esophagus (e.g. esophageal stricture or achalasia) and have at least **TWO** of the following:
   - Age >75 years old
   - Prior fragility fracture
   - BMD T-score ≤-2.5

NOTE: Hypersensitivity or abnormalities are defined as esophageal ulceration, erosion or stricture, or lower gastrointestinal symptoms severe enough to cause discontinuation of oral bisphosphonates, or swallowing disorders that will increase the risk of esophageal ulceration from oral bisphosphonates.

In all cases, patients receiving Prolia (denosumab) must not be receiving concomitant bisphosphonate therapy.

The recommended dose of Prolia (denosumab) is a single subcutaneous injection of 60 mg, once every 6 months.

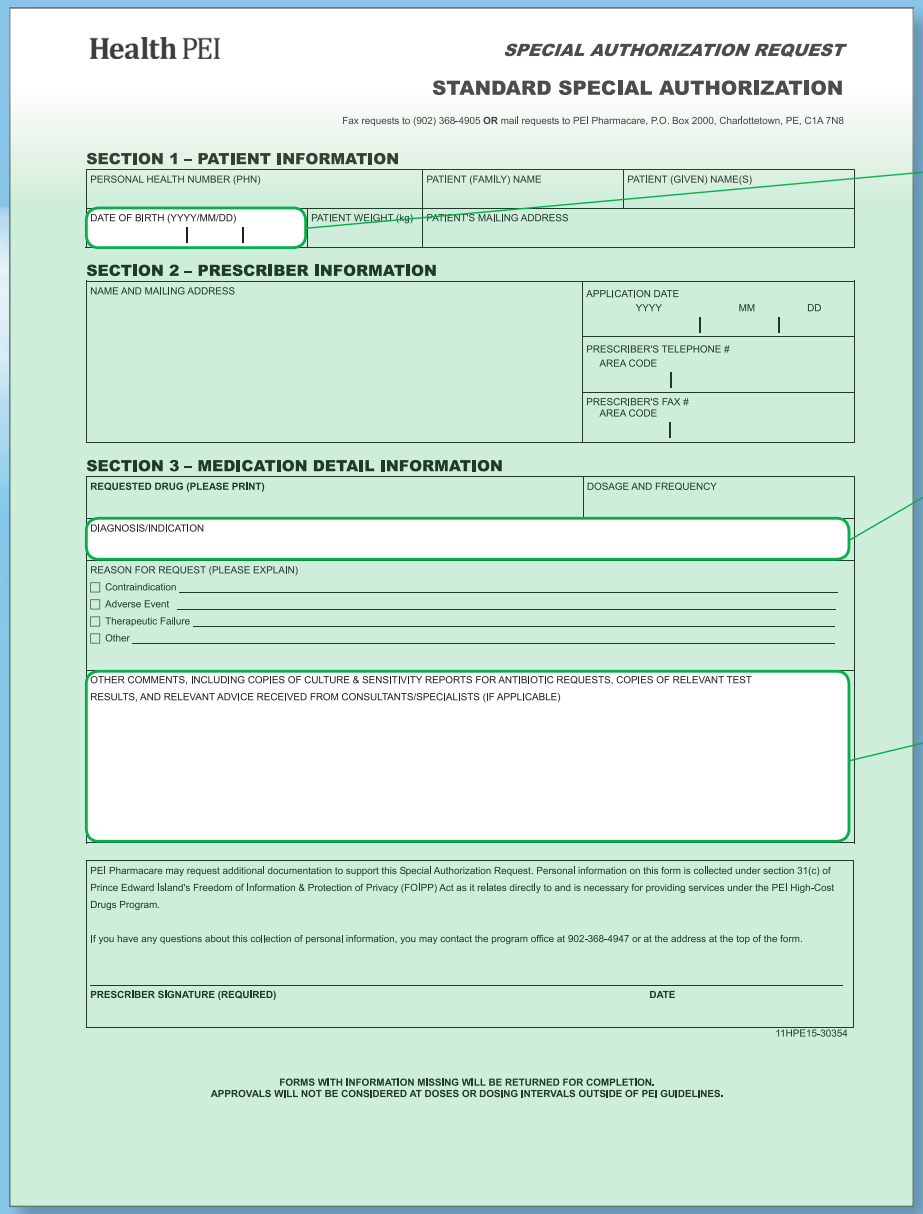
For full details regarding coverage, visit www.healthpei.ca/formulary.

Pr prolia® denosumab

PAAB

References: 1. Health PEI: P.E.I. Pharmacare Formulary. Accessed March 13, 2014. http://www.gov.pe.ca/photos/original/hpei_formulary.pdf.
2. Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.

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.

Age: If older than 75 years, the patient meets one of the 3 additional criteria.

If older than 75 years of age, the patient must indicate that **EITHER** the T-score is ≤-2.5 or they have had a prior fragility fracture.

Otherwise patients **MUST** meet **BOTH** of these additional criteria.

Form **MUST** indicate that the patient has experienced a significant decline in bone mineral density (BMD), in which case bisphosphonate use is contraindicated due to hypersensitivity or patient having abnormalities of the esophagus.

Pr prolia® denosumab

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