Available under the Manitoba Drug Benefits and Interchangeability Formulary's Exception Drug Status Program[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]

To increase bone mass in men or postmenopausal women with osteoporosis at a high risk for fracture OR who have failed OR are intolerant to other available osteoporosis therapy, where the following clinical criteria are met:

- High fracture risk defined as either:
  - Moderate 10-year fracture risk (10-20%) 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 with a prior fragility fracture

OR

  - High 10-year fracture risk (≥20%) as defined by either the CAROC or FRAX tool

AND

- Contraindication to oral bisphosphonates

Notes: Bisphosphonate failure will be defined as a fragility fracture and/or evidence of a decline in bone mineral density below pretreatment baseline levels, despite adherence for one year. Contraindication to oral bisphosphonates will be considered, including: renal impairment, hypersensitivity and abnormalities of the esophagus (e.g. esophageal stricture or achalasia).

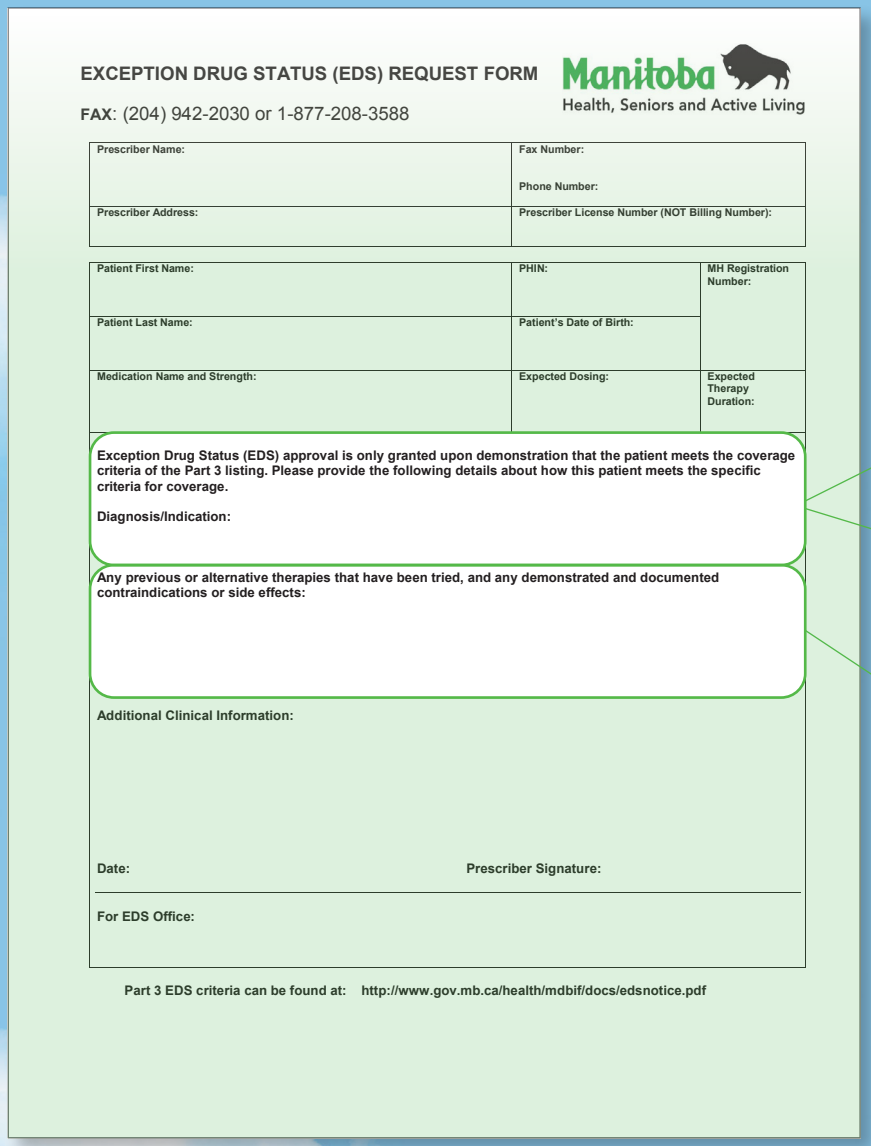
PRO-0148E-21

Pr prolia® denosumab injection

REVIEWED BY PAAB

References: 1. Government of Manitoba. Exception Drug Status (EDS) Formulary Update. Accessed May 31, 2018. https://www.gov.mb.ca/health/mdbif/docs/edsnotice.pdf. **2.** Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., **March 29, 2022.**.

Manitoba Form – "How To"



EXCEPTION DRUG STATUS (EDS) REQUEST FORM

Manitoba
Health, Seniors and Active Living

FAX: (204) 942-2030 or 1-877-208-3588

Prescriber Name:	Fax Number: Phone Number:
Prescriber Address:	Prescriber License Number (NOT Billing Number):

Patient First Name:	PHIN:	MH Registration Number:
Patient Last Name:	Patient's Date of Birth:	
Medication Name and Strength:	Expected Dosing:	Expected Therapy Duration:

Exception Drug Status (EDS) approval is only granted upon demonstration that the patient meets the coverage criteria of the Part 3 listing. Please provide the following details about how this patient meets the specific criteria for coverage.

Diagnosis/Indication:

Any previous or alternative therapies that have been tried, and any demonstrated and documented contraindications or side effects:

Additional Clinical Information:

Date: Prescriber Signature:

For EDS Office:

Part 3 EDS criteria can be found at: http://www.gov.mb.ca/health/mdbif/docs/edsnotice.pdf

For use in men or postmenopausal women with osteoporosis at high risk of fracture **OR** who have failed **OR** are intolerant to other available osteoporosis therapy

Form **MUST** include clinical criteria indicating high fracture risk

AND previous therapies tried and any contraindications and/or side effects to bisphosphonates

Requests can be submitted by telephone, mail or fax. A toll-free line with an electronic message system is available exclusively for requests on a 24-hour basis. The telephone number to access this line is (204) 788-6388 or 1-800-557-4303.

Pr prolia® denosumab injection

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