Available for men and postmenopausal women with osteoporosis under the Saskatchewan Drug Plan's Exception Drug Status (EDS) Program[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 men and postmenopausal women with osteoporosis

To increase bone mass in men or postmenopausal women with osteoporosis who are 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:[1]

- High fracture risk*, **AND**
- Contraindication to oral bisphosphonates.†

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

OR
- High 10-year fracture risk (≥20%).

Fracture risks above as defined by either the CAROC tool or the World Health Organization's FRAX tool.

† 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. Contraindications include renal impairment, hypersensitivity and abnormalities of the esophagus (e.g. esophageal stricture or achalasia).

For men on ADT for prostate cancer and women on AI for breast cancer

For the treatment of osteoporosis in patients with moderate-high 10-year fracture risk (10% or more) and one of the following:[1]

- Men on androgen deprivation therapy for prostate cancer; **OR**
- Women on aromatase inhibitor therapy for breast cancer.

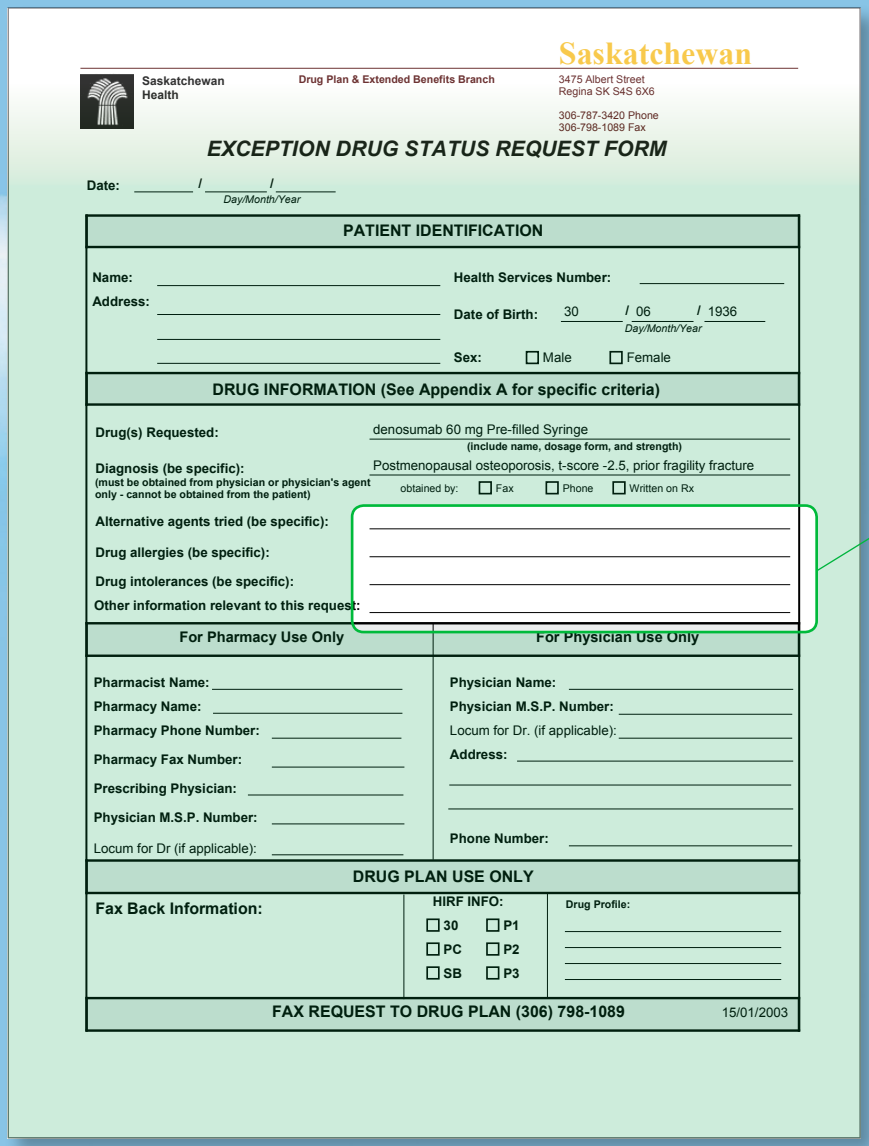
ADT=androgen deprivation therapy; AI=aromatase inhibitor; CAROC=Canadian Association of Radiologists and Osteoporosis Canada; EDS=exception drug status; FRAX=Fracture Risk Assessment

Pr prolia® denosumab

REVIEWED BY PAAB

References: 1. Saskatchewan Formulary Bulletin #168, January 1, 2018. Accessed February 7, 2018. http://formulary.drugplan.ehealthsask.ca/Bulletins/Bulletin168Jan2018.pdf. **2.** Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.

Saskatchewan Form – "How To"



Saskatchewan

Saskatchewan Health

Drug Plan & Extended Benefits Branch

3475 Albert Street
Regina SK S4S 6X6

306-787-3420 Phone
306-798-1089 Fax

EXCEPTION DRUG STATUS REQUEST FORM

Date: _____ / _____ / _____
Day/Month/Year

PATIENT IDENTIFICATION

Name: _____ Health Services Number: _____

Address: _____ Date of Birth: 30 / 06 / 1936
Day/Month/Year

_____ Sex: ☐ Male ☐ Female

DRUG INFORMATION (See Appendix A for specific criteria)

Drug(s) Requested: denosumab 60 mg Pre-filled Syringe
(include name, dosage form, and strength)

Diagnosis (be specific): Postmenopausal osteoporosis, t-score -2.5, prior fragility fracture
(must be obtained from physician or physician's agent only - cannot be obtained from the patient) obtained by: ☐ Fax ☐ Phone ☐ Written on Rx

Alternative agents tried (be specific): _____

Drug allergies (be specific): _____

Drug intolerances (be specific): _____

Other information relevant to this request: _____

For Pharmacy Use Only	For Physician Use Only
Pharmacist Name:	Physician Name:
Pharmacy Name:	Physician M.S.P. Number:
Pharmacy Phone Number:	Locum for Dr. (if applicable):
Pharmacy Fax Number:	Address:
Prescribing Physician:	
Physician M.S.P. Number:	
Locum for Dr (if applicable):	Phone Number:

DRUG PLAN USE ONLY

Fax Back Information:

HIRF INFO:
☐ 30 ☐ P1
☐ PC ☐ P2
☐ SB ☐ P3

Drug Profile:

FAX REQUEST TO DRUG PLAN (306) 798-1089 15/01/2003

Form **MUST** indicate that patient with osteoporosis is:

- At high risk of fracture or failed or is intolerant to other available osteoporosis therapies, where the following clinical criteria are met: high risk of fracture, **AND** contraindication to bisphosphonates (including renal impairment, hypersensitivity and abnormalities of the esophagus).
- On ADT for prostate cancer (men) or AI for breast cancer (women) and has moderate-high 10-year fracture risk.

Pr prolia® denosumab

REVIEWED BY PAAB