Available under the Alberta Health & Wellness Drug Benefit List 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 patients who have a high 10-year risk (i.e. greater than 20%) of experiencing a major osteoporotic fracture OR a moderate 10-year fracture risk (10-20%) and have experienced a prior fragility fracture.

AND at least one of the following:

1) For whom oral bisphosphonates are contraindicated due to drug-induced hypersensitivity (i.e. immunologically mediated); **OR**

2) For whom oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying; **OR**

3) For whom bisphosphonates are contraindicated due to severe renal impairment (i.e. creatinine clearance <35 mL/min); **OR**

4) Who have demonstrated severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate; **OR**

5) Who had an unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pretreatment baseline level).

Note: Fracture risk can be determined by the World Health Organization's Fracture Risk Assessment Tool (FRAX) or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

Special authorization may be granted for 12 months. Patients will be limited to receiving one dose of denosumab per prescription at their pharmacy. Coverage cannot be provided for two or more osteoporosis medications (alendronate, denosumab, raloxifene, risedronate, zoledronic acid) when these medications are intended for use as combination therapy. Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe. Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/mL injection. All requests for denosumab must be completed using the Denosumab/Zoledronic Acid for Osteoporosis Special Authorization Request Form (ABC 60007).

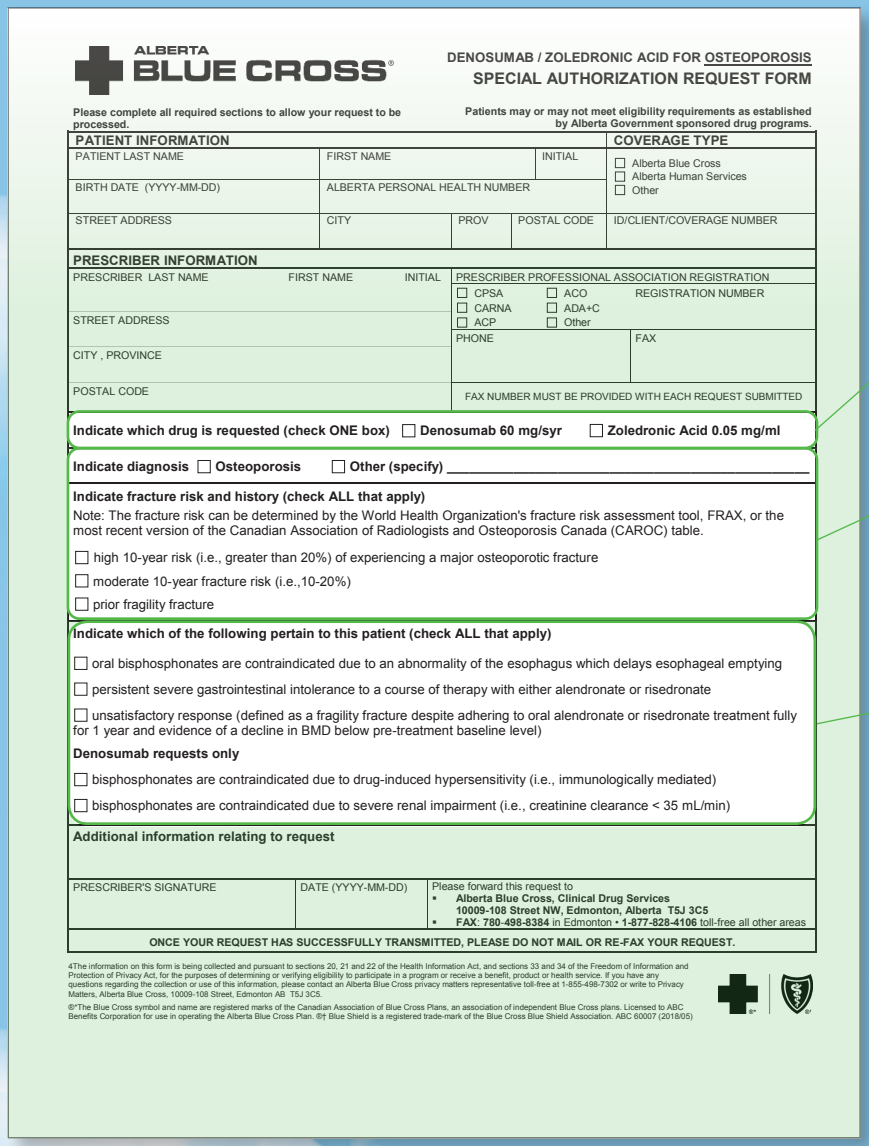
PRO-0148E-21

Pr prolia® denosumab injection

REVIEWED BY PAAB

References: 1. Government of Alberta Health and Wellness. Updates to the Alberta Health and Wellness Drug Benefit List, June 1, 2018. Accessed June 1, 2018. https://www.ab.bluecross.ca/dbl/pdfs/jun_dblupdate.pdf. **2.** Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., March 29, 2022.

Alberta Blue Cross Form – "How To"



ALBERTA BLUE CROSS®

DENOSUMAB / ZOLEDRONIC ACID FOR OSTEOPOROSIS
SPECIAL AUTHORIZATION REQUEST FORM

Please complete all required sections to allow your request to be processed.

Patients may or may not meet eligibility requirements as established by Alberta Government sponsored drug programs.

PATIENT INFORMATION

PATIENT LAST NAME	FIRST NAME	INITIAL	COVERAGE TYPE
			☐ Alberta Blue Cross ☐ Alberta Human Services ☐ Other
BIRTH DATE (YYYY-MM-DD)	ALBERTA PERSONAL HEALTH NUMBER		
STREET ADDRESS	CITY / PROV / POSTAL CODE		ID/CLIENT/COVERAGE NUMBER

PRESCRIBER INFORMATION

PRESCRIBER LAST NAME / FIRST NAME / INITIAL	PRESCRIBER PROFESSIONAL ASSOCIATION REGISTRATION
	☐ CPSA ☐ ACO ☐ CARNA ☐ ADA+C ☐ ACP ☐ Other — REGISTRATION NUMBER
STREET ADDRESS	PHONE / FAX
CITY , PROVINCE	
POSTAL CODE	FAX NUMBER MUST BE PROVIDED WITH EACH REQUEST SUBMITTED

Indicate which drug is requested (check ONE box) ☐ **Denosumab 60 mg/syr** ☐ **Zoledronic Acid 0.05 mg/ml**

Indicate diagnosis ☐ **Osteoporosis** ☐ **Other (specify)** _____

Indicate fracture risk and history (check ALL that apply)

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

☐ high 10-year risk (i.e., greater than 20%) of experiencing a major osteoporotic fracture
☐ moderate 10-year fracture risk (i.e.,10-20%)
☐ prior fragility fracture

Indicate which of the following pertain to this patient (check ALL that apply)

☐ oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying
☐ persistent severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate
☐ unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pre-treatment baseline level)

Denosumab requests only

☐ bisphosphonates are contraindicated due to drug-induced hypersensitivity (i.e., immunologically mediated)
☐ bisphosphonates are contraindicated due to severe renal impairment (i.e., creatinine clearance < 35 mL/min)

Additional information relating to request

PRESCRIBER'S SIGNATURE	DATE (YYYY-MM-DD)	Please forward this request to
		• **Alberta Blue Cross, Clinical Drug Services** **10009-108 Street NW, Edmonton, Alberta T5J 3C5** • **FAX**: **780-498-8384** in Edmonton • **1-877-828-4106** toll-free all other areas

ONCE YOUR REQUEST HAS SUCCESSFULLY TRANSMITTED, PLEASE DO NOT MAIL OR RE-FAX YOUR REQUEST.

4The information on this form is being collected and pursuant to sections 20, 21 and 22 of the Health Information Act, and sections 33 and 34 of the Freedom of Information and Protection of Privacy Act, for the purposes of determining or verifying eligibility to participate in a program or receive a benefit, product or health service. If you have any questions regarding the collection or use of this information, please contact an Alberta Blue Cross privacy matters representative toll-free at 1-855-498-7302 or write to Privacy Matters, Alberta Blue Cross, 10009-108 Street, Edmonton AB T5J 3C5.

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Indicate the requested drug

Form **MUST** indicate diagnosis and fracture risk/history for male and female patients

AND at least **ONE** of the following:

Pr prolia® denosumab injection

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