Available under the Nova Scotia Health & Wellness Public Drug Plan – Exception Status Benefit[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 male patients 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 pretreatment 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 CAROC or FRAX tool.

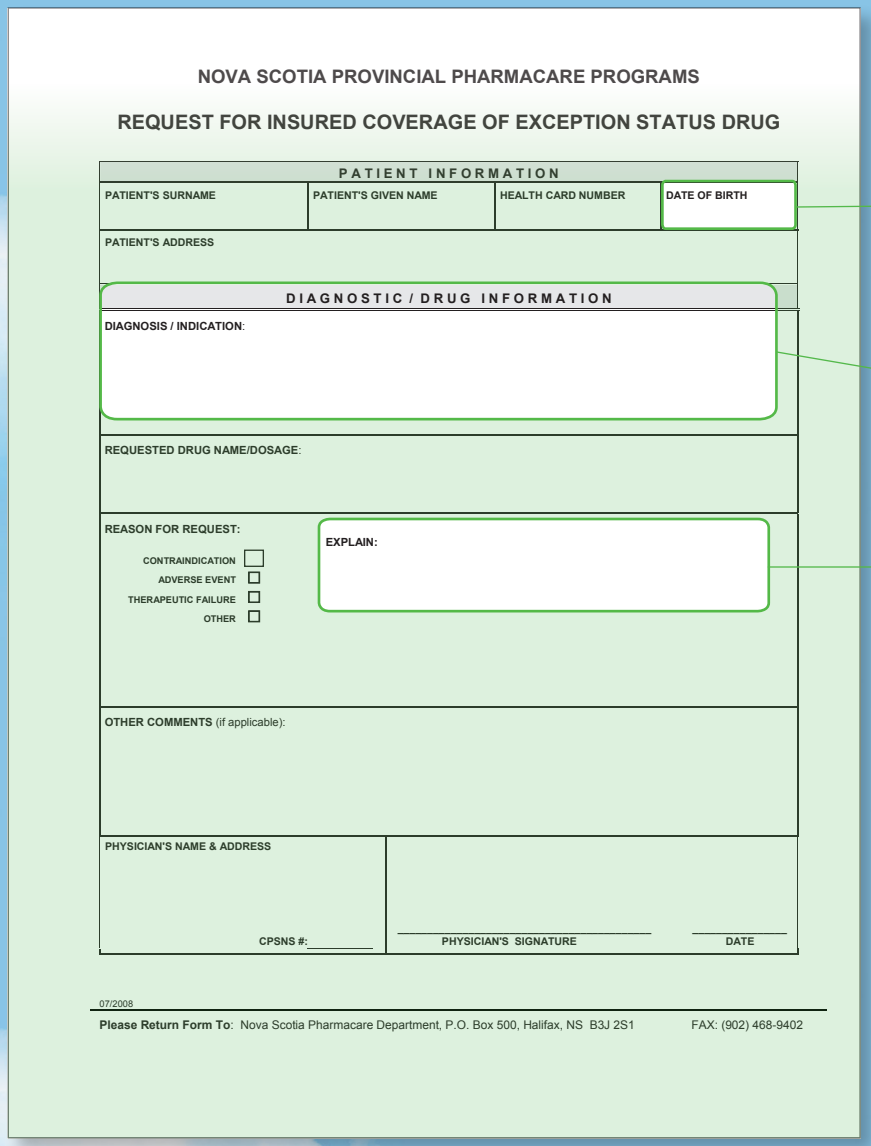
PRO-0148E-21

Pr prolia® denosumab injection

REVIEWED BY PAAB

References: 1. Government of Nova Scotia Health and Wellness. Nova Scotia Formulary. Accessed August 8, 2019. https://novascotia.ca/dhw/pharmacare/documents/formulary.pdf. **2.** Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., March 29, 2022.

Nova Scotia Form – "How To"



NOVA SCOTIA PROVINCIAL PHARMACARE PROGRAMS

REQUEST FOR INSURED COVERAGE OF EXCEPTION STATUS DRUG

PATIENT INFORMATION

PATIENT'S SURNAME	PATIENT'S GIVEN NAME	HEALTH CARD NUMBER	DATE OF BIRTH

PATIENT'S ADDRESS

DIAGNOSTIC / DRUG INFORMATION

DIAGNOSIS / INDICATION:

REQUESTED DRUG NAME/DOSAGE:

REASON FOR REQUEST:

- CONTRAINDICATION ☐
- ADVERSE EVENT ☐
- THERAPEUTIC FAILURE ☐
- OTHER ☐

EXPLAIN:

OTHER COMMENTS (if applicable):

PHYSICIAN'S NAME & ADDRESS

CPSNS #:_____

PHYSICIAN'S SIGNATURE _____ DATE _____

07/2008

Please Return Form To: Nova Scotia Pharmacare Department, P.O. Box 500, Halifax, NS B3J 2S1 FAX: (902) 468-9402

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

Pr prolia® denosumab injection

REVIEWED BY PAAB