

Available under the Nova Scotia Health & Wellness Public Drug Plan – Exception Status Benefit¹

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 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 ($\geq 20\%$) as defined by CAROC or FRAX tool.



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 Product Monograph. Amgen Canada Inc., June 25, 2019.

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:		EXPLAIN:	
CONTRAINDICATION <input type="checkbox"/>			
ADVERSE EVENT <input type="checkbox"/>			
THERAPEUTIC FAILURE <input type="checkbox"/>			
OTHER <input type="checkbox"/>			
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