Available under BC PharmaCare when patients meet Special Authority criteria[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 women with postmenopausal osteoporosis or men with osteoporosis with clinical or radiographically-documented fracture due to osteoporosis, and who are contraindicated to oral bisphosphonates for one of the following reasons:

- Immune-mediated hypersensitivity reaction to oral bisphosphonates; **OR**
- Abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia.

SPECIAL NOTES:

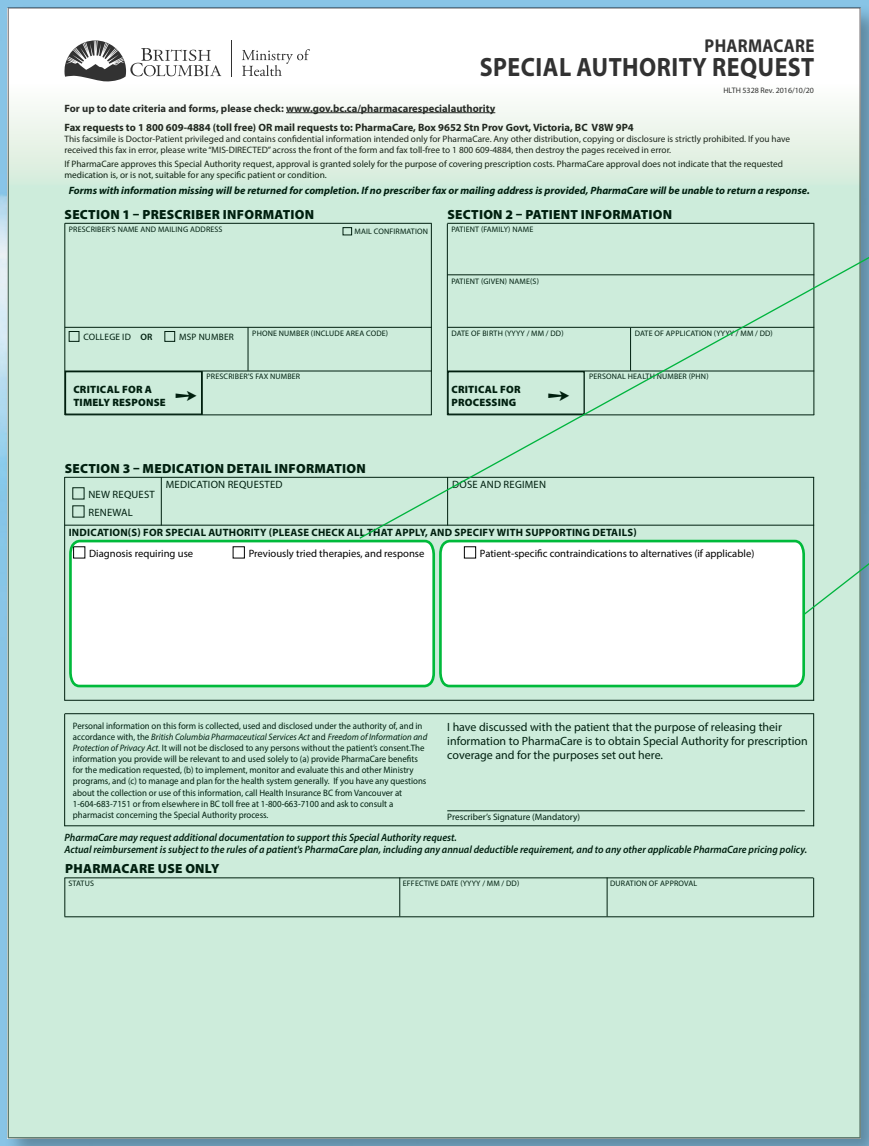
- Details regarding a patient's contraindication to oral bisphosphonates are required as part of the Special Authority request
- Clinical fracture is defined as a symptomatic (painful) fracture
- Radiographically-documented fracture is defined as a fracture identified by X-ray (e.g. vertebral compression fracture). This may be asymptomatic

Pr prolia® denosumab

REVIEWED BY PAAB

References: 1. British Columbia PharmaCare program. Limited Coverage Drugs – Denosumab. Accessed May 31, 2018. https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/limited-coverage-drug-program/limited-coverage-drugs-denosumab. **2.** Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.

British Columbia Form – "How To"



BRITISH COLUMBIA | Ministry of Health

PHARMACARE
SPECIAL AUTHORITY REQUEST

HLTH 5328 Rev. 2016/10/20

For up to date criteria and forms, please check: www.gov.bc.ca/pharmacarespecialauthority

Fax requests to 1 800 609-4884 (toll free) OR mail requests to: PharmaCare, Box 9652 Stn Prov Govt, Victoria, BC V8W 9P4

This facsimile is Doctor-Patient privileged and contains confidential information intended only for PharmaCare. Any other distribution, copying or disclosure is strictly prohibited. If you have received this fax in error, please write "MIS-DIRECTED" across the front of the form and fax toll-free to 1 800 609-4884, then destroy the pages received in error.

If PharmaCare approves this Special Authority request, approval is granted solely for the purpose of covering prescription costs. PharmaCare approval does not indicate that the requested medication is, or is not, suitable for any specific patient or condition.

Forms with information missing will be returned for completion. If no prescriber fax or mailing address is provided, PharmaCare will be unable to return a response.

SECTION 1 – PRESCRIBER INFORMATION

PRESCRIBER'S NAME AND MAILING ADDRESS — ☐ MAIL CONFIRMATION

☐ COLLEGE ID **OR** ☐ MSP NUMBER | PHONE NUMBER (INCLUDE AREA CODE)

CRITICAL FOR A TIMELY RESPONSE → | PRESCRIBER'S FAX NUMBER

SECTION 2 – PATIENT INFORMATION

PATIENT (FAMILY) NAME

PATIENT (GIVEN) NAME(S)

DATE OF BIRTH (YYYY / MM / DD) | DATE OF APPLICATION (YYYY / MM / DD)

CRITICAL FOR PROCESSING → | PERSONAL HEALTH NUMBER (PHN)

SECTION 3 – MEDICATION DETAIL INFORMATION

☐ NEW REQUEST
☐ RENEWAL

MEDICATION REQUESTED | DOSE AND REGIMEN

INDICATION(S) FOR SPECIAL AUTHORITY (PLEASE CHECK ALL THAT APPLY, AND SPECIFY WITH SUPPORTING DETAILS)

☐ Diagnosis requiring use ☐ Previously tried therapies, and response

☐ Patient-specific contraindications to alternatives (if applicable)

Personal information on this form is collected, used and disclosed under the authority of, and in accordance with, the *British Columbia Pharmaceutical Services Act* and *Freedom of Information and Protection of Privacy Act*. It will not be disclosed to any persons without the patient's consent.The information you provide will be relevant to and used solely to (a) provide PharmaCare benefits for the medication requested, (b) to implement, monitor and evaluate this and other Ministry programs, and (c) to manage and plan for the health system generally. If you have any questions about the collection or use of this information, call Health Insurance BC from Vancouver at 1-604-683-7151 or from elsewhere in BC toll free at 1-800-663-7100 and ask to consult a pharmacist concerning the Special Authority process.

I have discussed with the patient that the purpose of releasing their information to PharmaCare is to obtain Special Authority for prescription coverage and for the purposes set out here.

Prescriber's Signature (Mandatory)

PharmaCare may request additional documentation to support this Special Authority request.
Actual reimbursement is subject to the rules of a patient's PharmaCare plan, including any annual deductible requirement, and to any other applicable PharmaCare pricing policy.

PHARMACARE USE ONLY

STATUS | EFFECTIVE DATE (YYYY / MM / DD) | DURATION OF APPROVAL

For use in women with postmenopausal osteoporosis or men with osteoporosis with clinical or radiographically-documented fracture due to osteoporosis

Form **MUST** indicate that bisphosphonate use is contraindicated due to hypersensitivity or patient has abnormalities of the esophagus

Pr prolia® denosumab

REVIEWED BY PAAB