



Refills

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Denosumab for osteoporosis: two important updates

Updates: 1. The rate of multiple vertebral fractures after denosumab discontinuation is estimated to increase with duration of therapy. 2. BC PharmaCare coverage for denosumab has transitioned to a biosimilar product.

The BC Provincial Academic Detailing (PAD) service is providing the topic [Medications for osteoporosis: an update](#).¹ This topic looks at the evidence for bisphosphonates, denosumab, raloxifene, teriparatide and romosozumab. Visit www.bcpad.ca to [book a session](#) with an academic detailing pharmacist in your area. Since launching this topic in June 2023, there have been important updates to the clinical evidence and BC PharmaCare coverage of denosumab.

1. Discontinuing denosumab is associated with an increased risk of multiple vertebral fractures. Revised estimates on the rate of multiple vertebral fractures and the relationship to duration of therapy have been provided in a posthoc analysis sponsored by the manufacturer.² The rate of multiple vertebral fractures in postmenopausal females, beginning 7 months after stopping denosumab, are now reported as:
 - After stopping placebo (the comparator in the pivotal trial): 3.6 per 100 patient years
 - After stopping denosumab: 5.1 per 100 patient years
 - After having taken denosumab shorter term (1-3 years): 3.0 per 100 patient years
 - After having taken denosumab longer term (> 3 years): 7.5 per 100 patient years

Osteoporosis Canada suggests (suggests = conditional recommendations due to limited evidence):³

- a) that denosumab treatment should be long-term and uninterrupted, including consistency with the 6-month dosing schedule (doses should not be delayed by more than 1 month)
- b) if discontinuing denosumab after ≤ 4 doses: transition to a bisphosphonate for 1 year then reassess
- c) if discontinuing denosumab after ≥ 5 doses: seek advice from a consultant with osteoporosis expertise on how to transition to an alternative therapy

Osteoporosis Canada's updated 2023 guideline is [publicly accessible](#). We could not identify ongoing trials evaluating the optimal exit strategy to mitigate the risk of multiple vertebral fractures after discontinuing denosumab.

2. Biosimilars Initiative - BC PharmaCare coverage of denosumab: In July 2024, Health Canada approved Jubbonti[®], a biosimilar biologic drug to Prolia[®].⁴ The annual drug cost of Prolia is \$950; Jubbonti is \$420 (without markup or professional fee).⁵ Patients currently receiving coverage through PharmaCare for Prolia will need to switch to Jubbonti to maintain coverage.⁶ As of August 29, 2024, all new Special Authority requests, including renewals, for denosumab will only be approved for Jubbonti. On March 4, 2025, Prolia will no longer be an eligible PharmaCare benefit. During this six-month transition period, prescribers must write a new prescription for their patients indicating the transition to Jubbonti for PharmaCare coverage to continue. This is particularly important given the increased risk of multiple vertebral fractures if denosumab doses are delayed.

Prescribers may [request a list](#) of their patients receiving PharmaCare coverage for Prolia so they can contact them to discuss switching to Jubbonti. There is a patient support fee prescribers can claim for having the biosimilar transition discussion with their patients. For more information, visit [Biosimilars Initiative for health professionals](#).

¹BC Provincial Academic Detailing Service 2023: Medications for osteoporosis: an update; ²COSMAN J Bone Miner Res 2022;37:2112-120 (PMID:36088628); ³Osteoporosis Canada CMAJ 2023;39:E1333-1348 (PMID:37816527); ⁴Health Canada Drug Product Database; ⁵McKesson PharmaClik (accessed Dec 6, 2024); ⁶BC PharmaCare Limited coverage drugs – denosumab