Refills

Your dose of drug information in between sessions

What is romosozumab (Evenity™) and what is the evidence for it compared to bisphosphonates?

Conclusion: Romosozumab (Evenity™) is an anabolic medication, approved for the treatment of osteoporosis in postmenopausal females at high risk for fracture. In a direct comparison trial, initiating treatment with romosozumab in postmenopausal females with a previous fracture resulted in fewer symptomatic fractures compared with alendronate.

The BC Provincial Academic Detailing (PAD) service's topic Medications for osteoporosis: an update looks at the evidence for bisphosphonates, denosumab, raloxifene, teriparatide and romosozumab.[1] Click to book a session with an academic detailing pharmacist in your area. We receive this question during PAD sessions: **What is romosozumab and what is the evidence for it compared to bisphosphonates?**

a) **Basics:** Romosozumab is an anabolic medication which stimulates bone formation and is given as a subcutaneous injection once a month for 12 months (dose: 210 mg once a month, given as two 105 mg injections).[2] The cost of a 12-month treatment course is approximately $8500 (excluding markup and professional fees).[3] It is recommended that people transition to a bisphosphonate or denosumab after the initial 12-month course to continue osteoporosis treatment. Romosozumab is contraindicated in people with hypocalcemia.

b) **BC PharmaCare:** Romosozumab was added to the BC PharmaCare Formulary in December 2023 as a Limited Coverage drug for postmenopausal females who have sustained an osteoporotic fracture and are treatment naïve.[4]

c) **Guidelines:** In 2023 Osteoporosis Canada updated their guidelines and included a conditional recommendation for romosozumab in people who have experienced a recent severe vertebral fracture or multiple vertebral fractures.[5] They further suggest seeking advice from a consultant with expertise in osteoporosis.

d) **Comparative evidence:** The ARCH trial compared initiating treatment with romosozumab for 12 months before switching to alendronate versus initiating treatment entirely with alendronate.[6] Participants were treatment-naïve, ambulatory, postmenopausal females with a previous vertebral or hip fracture (ie, secondary prevention). Initiating treatment with romosozumab reduced the risk of symptomatic fractures, including fewer hip and vertebral fractures.

e) **Cardiovascular risk:** In the ARCH trial, major adverse cardiovascular events were increased with romosozumab compared to alendronate (romosozumab: 2%, alendronate 1.1%).[6] Therefore, Health Canada does not recommend its use in people with a history of myocardial infarction or stroke.[2] The manufacturer is required to conduct a postmarketing, cardiovascular risk study to better characterize this risk.[7]

ARCH 2017 trial: romosozumab versus alendronate in postmenopausal females with a previous fracture[6]			
4093 postmenopausal females (aged 55-90) previous hip fracture: 9% previous vertebral fracture: 96%		alendronate (2-3 years of follow up)	romosozumab for 12 months then switch to alendronate (~2-3 years of follow up)
hip fracture	ARR 1.2%	3.2%	2%
symptomatic vertebral fracture	ARR 1.2%	2.1%	0.9%
symptomatic fracture	ARR 3.3%	13%	9.7%
radiographic vertebral fracture	ARR 3.9%	8%	4.1%

[1]BC Provincial Academic Detailing Service 2023 Medications for osteoporosis: an update; [2]Health Canada Drug Product Database Evenity; [3]McKesson Canada PharmaClik (accessed January 12, 2024); [4]BC PharmaCare Special Authority drug list; [5]Osteoporosis Canada CMAJ 2023;39:E1333-1348 (PMID:37816527); [6]ARCH trial N Engl J Med 2017;377:1417-27 (PMID:28892457); [7]Health Canada Regulatory Decision Summary for Evenity

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