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# **Osteoporosis in Menopause**

This clinical practice guideline has been prepared by the Menopause and Osteoporosis Working Group, reviewed by the Clinical Practice Gynaecology and Family Physician Advisory Committees, and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

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**Key Words**: Osteoporosis, prevention, treatment, diagnosis, bone mineral density, dual energy x-ray absorptiometry, bone turnover markers, vertebral fractures, fragility fractures, antiresorptive, hormone therapy, selective estrogen-receptor modulator, bisphosphonates, calcitonin, anabolic, bone forming agent

# Abstract

**Objective:** To provide guidelines for the health care provider on the prevention, diagnosis, and clinical management of postmenopausal osteoporosis.

**Outcomes:** Strategies for identifying and evaluating high-risk individuals, the use of bone mineral density (BMD) and bone turnover markers in assessing diagnosis and response to management, and recommendations regarding nutrition, physical activity, and the selection of pharmacologic therapy to prevent and manage osteoporosis.

Evidence: Published literature was retrieved through searches of PubMed and The Cochrane Library on August 30 and September 18, 2012, respectively. The strategy included the use of appropriate controlled vocabulary (e.g., oteoporosis, bone density, menopause) and key words (e.g., bone health, bone loss, BMD). Results were restricted to systematic reviews, practice guidelines, randomized and controlled clinical trials, and observational studies published in English or French. The search was limited to the publication years 2009 and following, and updates were incorporated into the guideline to March 2013. Grey (unpublished) literature was identified through searching the websites of health technology assessment and health technology assessmentrelated agencies, clinical practice guideline collections, clinical trial registries, and national and international medical specialty societies.

Values: The quality of the evidence was rated using the criteria described by the Canadian Task Force on Preventive Health Care (Table).

Sponsors: The Society of Obstetricians and Gynaecologists of Canada.

#### RECOMMENDATIONS

#### For Postmenopausal Women

- Health care providers should be aware that the goals of osteoporosis management include assessment of fracture risk and prevention of fracture. (I-A)
- 2. Health care providers should understand that a stable or increasing bone mineral density reflects a response to therapy in the absence of low-trauma fracture or height loss due to vertebral-compression fracture. A progressive decrease in bone mineral density, with the magnitude of bone loss being greater than the precision error of the density assessment, indicates a lack of response to current therapy. Management should be reviewed and modified appropriately. (I-A)

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# Key to evidence statements and grading of recommendations, using the ranking of the Canadian Task Force on Preventive Health Care

Quality of evidence assessment*		Classification of recommendations†	
I:	Evidence obtained from at least one properly randomized controlled trial	Α.	There is good evidence to recommend the clinical preventive action
II-1:	Evidence from well-designed controlled trials without randomization	В.	There is fair evidence to recommend the clinical preventive action
II-2:	Evidence from well-designed cohort (prospective or retrospective) or case–control studies, preferably from more than one centre or research group	C.	The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
II-3:	Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in	D.	There is fair evidence to recommend against the clinical preventive action
	uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category	E.	There is good evidence to recommend against the clinical preventive action
III:	Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees	L.	There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

\*The quality of evidence reported in these guidelines has been adapted from The Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

†Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.

Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. CMAJ 2003;169:207–8.

- Health care providers should identify the absolute fracture risk by integrating the key risk factors for fracture; namely, age, bone mineral density, prior fracture, and glucocorticoid use. These risk factors allow estimation of fracture risk using the tool of the Canadian Association of Radiologists and Osteoporosis Canada. (I-A)
- 4. The Fracture Risk Assessment tool of the World Health Organization (FRAX) has now been validated in a Canadian population and may also be used and incorporates additional risk factors; namely, low body mass index, parental history of fracture, smoking status, alcohol intake, and the presence of secondary causes of osteoporosis. (I-A)
- 5. Health care providers should be aware that a fragility fracture markedly increases the risk of a future fracture and confirms the diagnosis of osteoporosis irrespective of the results of the bone density assessment, (I-A) and that the presence of a low-trauma fracture of a vertebra or hip or more than 1 fragility fracture confirms a high fracture risk regardless of the bone mineral density. (I-A)
- 6. Treatment should be initiated according to the results of the 10-year absolute fracture risk assessment. (I-A)

# **Calcium and Vitamin D**

7. Adequate calcium and vitamin D supplementation is key to ensuring prevention of progressive bone loss. For postmenopausal women a total daily intake of 1200 mg of elemental calcium from dietary and supplemental sources and daily supplementation with 800 to 2000 IU of vitamin D are recommended. Calcium and vitamin D supplementation alone is insufficient to prevent fracture in those with osteoporosis; however, it is an important adjunct to pharmacologic intervention with antiresorptive and anabolic therapy. (I-B)

#### Hormone Therapy

 Hormone therapy should be prescribed for symptomatic postmenopausal women as the most effective option for menopausal symptom relief. (I-A) It represents a reasonable choice for the prevention of bone loss and fracture in this patient population. (I-A)  Physicians may recommend low- and ultralow-dosage estrogen therapy to symptomatic women for relief of menopausal symptoms (I-A) but should inform their patients that, despite the fact that such therapy has demonstrated a beneficial effect in osteoporosis prevention, (I-A) no data are yet available on reduction of fracture risk.

### **Bisphosphonates**

- 10. Alendronate, risedronate, and zoledronic acid are valuable first-line agents of choice in the treatment of postmenopausal osteoporosis and should be considered to decrease the risk of vertebral, non-vertebral, and hip fractures. (I-A)
- 11. Etidronate is a weak antiresorptive agent and is not recommended as a first-line agent of choice for the treatment of osteoporosis. (I-D)

# **RANKL** Inhibitor

12. Denosumab is an effective antiresorptive agent, shown to reduce the risk of vertebral, non-vertebral, and hip fractures, (I-A) and should be considered as a first-line agent of choice in the treatment of postmenopausal osteoporosis in women at a high fracture risk. (I-A)

#### Selective Estrogen-Receptor Modulators

 Treatment with raloxifene may be considered to decrease the risk of vertebral fractures, bearing in mind that this agent has not been shown to be effective in reducing the risk of non-vertebral or hip fractures. (I-A)

# Parathyroid Hormone

14. Treatment with teriparatide should be considered to decrease the risk of vertebral and non-vertebral fractures in postmenopausal women with severe osteoporosis (I-A) and should also be considered in postmenopausal women experiencing bone loss or a new fracture despite antiresorptive therapy. (I-A)

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