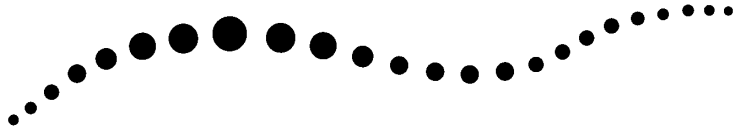


Osteoporosis  
Society  
of Canada

La Société  
de l'Ostéoporose  
du Canada



FINAL

**Osteoporosis:**  
**Preventing A Fractured Future<sup>©</sup>**  
**A Summary Policy Statement**  
**by the**  
**Osteoporosis Society of Canada**  
**2004**

**The Osteoporosis Society of Canada would like to thank the following individuals for their work in the writing and review of the policy paper:**

**Dr. Rick Adachi**

**Joan Barltrop**

**Patricia Bayne**

**Shawn Chirrey**

**Joyce Gordon**

**Heather Hase**

**Sylvia Kowal**

**Dr. Robert Josse**

**Judy Lynn**

**Karen Ormerod**

**Ellen Overton**

**Dr. Alexandra Papaioannou**

**Donna Spafford**

**Dr. Diane Thériault**

**Osteoporosis: Preventing A Fractured Future**  
**A Summary Policy Statement by the Osteoporosis Society of Canada**

**Executive Summary**

Osteoporosis is a widespread disease where bones become thin and brittle, leading to disabling bone fracture. It currently affects more than 1.4 million Canadians and causes 70 to 90 percent of the almost 30,000 hip fractures in Canada each year.<sup>1-4</sup> Morbidity and mortality from osteoporosis fractures is strikingly high.<sup>5-9</sup> Yet the disease remains severely under-diagnosed in even the most high-risk patients – those who have already fractured. Canadian data indicates that for hip fracture patients, the risk of death within one year is five times greater in patients who are not treated with an osteoporosis therapy after that fracture.<sup>10</sup>

Scientists worldwide cite osteoporosis as a costly global epidemic which, left unchecked, will reach crisis proportions as the population ages. In many countries, it currently consumes more bed days than stroke, heart attack or diabetes.<sup>11</sup> The majority of all osteoporotic fractures – more than 50 percent - could be prevented with appropriate nutrition, lifestyle and/or pharmacological management.

The Osteoporosis Society of Canada is renowned worldwide for its evidence-based Clinical Practice Guidelines.<sup>12</sup> Based on these guidelines and the current gap of care for osteoporosis in Canada, the Society supports the following as immediate priorities for Government action:

**Recommendation I:**

**All citizens must have access (both geographically and in a timely manner) to appropriate use of bone mineral density testing for the identification of those with osteoporosis, as well as those at risk of fracture. The identification of who should be tested is clearly defined in the Osteoporosis Society of Canada's Clinical Practice Guidelines. Evidence does not support the use of bone mineral density testing for mass screening of the population prior to the age of sixty-five years. The best available form of BMD measurement is Dual-Energy X-ray Absorptiometry (DXA).**

**Recommendation II**

**Coverage of osteoporosis therapies on provincial drug formularies should be in accordance with the strength of evidence for fracture prevention and in recognition of the striking impact of untreated osteoporosis on global health care and social costs. New therapies designed to reduce fracture risk should receive due and expeditious review.**

**Recommendation III**

**Provinces must act swiftly to undertake the development of a coordinated approach for the prevention, early identification, management and follow up of osteoporosis and osteoporosis-related fracture. This requires the commitment of appropriate human and financial resources to develop the appropriate infrastructure and identify appropriate strategies to address current gaps in care. The identification of these strategies must involve recognized experts in osteoporosis care.**

## **A POLICY FRAMEWORK FOR MANAGING OSTEOPOROSIS**

### **Canada's Clinical Practice Guidelines: An Evidence-Based Approach**

In November 2002, the Osteoporosis Society of Canada published the first and only evidence-based clinical practice guidelines for osteoporosis in the world.<sup>12</sup> The guidelines are intended to provide Canadian physicians and policy makers with the information they need to effectively manage this debilitating disease. The approach in formulating the guidelines involved the retrieval of almost 90,000 abstracts and the review, evaluation and grading of 6,941 full citations according to strength of evidence. The review was conducted by the Society's Scientific Advisory Council, comprised of many of the leading osteoporosis experts in Canada and in the world. These guidelines put the Osteoporosis Society of Canada on the international forefront of the battle to end the pain, deformity, disability and death associated with the disease.

### **What is Osteoporosis?**

Osteoporosis is a disease where bones become thin and brittle and bone strength declines. This leads to an increased risk of fracture, particularly of the hip, spine and wrist. Forty percent of women over the age of 50 will suffer an osteoporotic fracture of the wrist, spine or hip.<sup>12</sup> Osteoporosis is often known as "the silent thief" because, until fracture occurs, bone loss happens without symptom.<sup>12, 13</sup> Osteoporosis affects 1 in 4 Canadian women and more than 1 in 8 men over the age of fifty with 1 in 4 men and women having evidence of vertebral fracture.<sup>1, 14</sup>

- **More than 1.4 million Canadians currently have osteoporosis.<sup>1</sup> That number is staggering when you consider it is equal to or greater than: the combined population of Nova Scotia, Prince Edward Island and Newfoundland; the entire population of Manitoba; or the population of Greater Vancouver**
- **In Canada, almost 30,000 hip fractures occur each year.<sup>1</sup> Seventy-to-ninety percent of these are caused by osteoporosis.<sup>4</sup> That means a Canadian suffers an osteoporosis-related hip fracture every 18 minutes. By the year 2030, the number of hip fractures is expected to quadruple.<sup>3, 15</sup>**
- **Complications from osteoporotic fractures kill more women each year than cancer of the breast, uterus and ovaries combined.<sup>8a, 8b, 8c</sup>**
- **More men will suffer an osteoporotic hip fracture than will have prostate cancer.<sup>8b</sup>**
- **80 percent of women over 75 who were surveyed said they would rather be dead than suffer the loss of independence and quality of life that results from hip fracture and transfer to a nursing home.<sup>16</sup> Nearly all of them would trade their entire life expectancy to avoid being admitted to a nursing home.**
- **Osteoporosis is one of the leading causes of loss of independence in the elderly.<sup>17</sup>**

Osteoporosis is not a normal part of aging any more so than heart disease, cancer or stroke. It is critical to remember that the majority of osteoporotic fractures can be prevented through appropriate pharmacological, diet and lifestyle management.

### **The Burden of the Disease**

Left untreated, osteoporosis has a devastating impact on patient, morbidity, mortality and quality of life.<sup>5-9</sup> Those afflicted can suffer loss of mobility and function, and unrelenting pain. In a health system already struggling to manage the impact of chronic diseases in Canada's aging population, osteoporosis has grave consequences.

At more than \$1.9 billion<sup>18</sup>, the direct costs of osteoporosis are similar to the direct costs of treating diabetes, stroke, or obesity-related illnesses and more than the combined direct *and* indirect costs of treating asthma.<sup>11, 19-22</sup> Without effective action on osteoporosis prevention and treatment strategies, it is estimated that by 2018 Canada will spend at least \$32.5 billion treating osteoporotic fractures.<sup>23</sup>

- Osteoporotic fractures consume more hospital bed days than stroke, diabetes, or heart attack.<sup>11</sup>
- The average hip fracture patient costs four times more than the average acute care hospital patient.<sup>24</sup>
- Of those who fracture a hip, 20-25 percent will die within six months.<sup>24</sup> The mortality rate is even higher for men.<sup>25</sup> Of those who survive a hip fracture, 50 percent never regain their previous functioning; another 25 percent require institutional care.<sup>26</sup>
- A hip fracture patient costs the health care system \$21,385 in the first year after hospitalization; \$44,156 if the patient is institutionalized.<sup>27</sup>
- Mortality from vertebral fractures is the same as for hip – though over a longer period... of five years.<sup>28, 29</sup> Death occurs primarily from respiratory complications.
- Almost 20 percent of patients with a vertebral fracture will go on to have another fracture within one year, and so begins the deadly fracture cascade.<sup>28-33</sup> The risk of fracture rises dramatically with each additional fracture.

**The lesson is clear: it is imperative to prevent, or at the very least, treat the first fracture.**

### **Moving Toward Improved Diagnosis, Treatment and Prevention**

#### **The Overarching Issue: A Gap in Care**

**Given the evidence of the serious social, personal and economic costs associated with osteoporosis, it is disquieting that it remains severely under-diagnosed and under-treated in the Canadian population, even in patients who experience a hip or other fragility fracture and are treated for that fracture in an acute care hospital.**

The World Health Organization warns that policy makers must act quickly to stem the “impending epidemic” of fracture that will occur if appropriate diagnostic, prevention and treatment practices are not implemented.<sup>16</sup>

## **The Issue: Inadequate Diagnosis**

Canadian studies suggest that up to 50 percent of post-menopausal women who presently *have* osteoporosis have not been diagnosed with the disease.<sup>34</sup> The figure is even higher for men. This means that a significant number of patients with osteoporosis are not treated before the deadly fracture cascade begins. Even in patients who present with low trauma fracture - an almost certain indicator of osteoporosis in patients over 50 - appropriate diagnostic intervention does not occur:

- Currently, even when a patient over 50 is seen in the emergency room or in an acute care hospital for fracture, only 10-20% are referred for assessment of osteoporosis. Almost 2/3 do not receive therapy for osteoporosis within one year after fracture; only 4.5 percent of men receive any follow up (yet, the mortality rate for men after fracture is nearly twice that of women).<sup>35-38</sup>
- Canadian data indicates that for hip fracture patients, the risk of death within one year is five times greater in patients who are not treated with an osteoporosis therapy after that fracture.
- Despite the fact that 20 percent of patients with a first vertebral fracture will go on to suffer an additional fracture within one year, 2/3 of vertebral fractures are still undiagnosed.<sup>30, 39</sup>
- New research clearly shows the efficacy of deliberate interventions with physicians in improving diagnosis and treatment in patients who present with fracture at treatment facilities.<sup>38, 40</sup>
- Although all provinces fund diagnostic assessment of osteoporosis, access to appropriate diagnostic technology is not uniformly available.

## **The Strategy: Improved Access to Bone Densitometry**

**The Osteoporosis Society of Canada believes that all citizens, regardless of age, race, gender, culture, language or socio-economic status must have access to appropriate use of diagnostic technology, as supported by the current best available evidence, to confirm who has osteoporosis, as well as who is at risk of fracture. The definition of who is at risk for osteoporosis and osteoporotic fracture and who should receive diagnostic assessment are clearly defined in current clinical practice guidelines<sup>12</sup> (also Appendix A - Clinical Quick Reference Card). The OSC does *not* recommend the use of BMD for mass screening of the population.**

Bone mineral density (BMD) testing is considered to be the “gold standard” for diagnosing osteoporosis. Currently, the best available form of BMD measurement is Dual-Energy X-ray Absorptiometry (DXA), which is used most commonly to measure bone mineral density in the spine and hip. High-risk individuals presenting with one major or two minor risk factors (Appendix A), along with all individuals over 65, even if they do not have other risk factors (i.e., age over 65 is a major risk factor), should be tested. Appropriate use of standards established in the Clinical Practice Guidelines for both diagnosis and follow up will help to ensure appropriate use of technology, while eliminating unnecessary testing in individuals without significant risk.

## **The Issue: Inequitable Access to Effective Treatment Therapies**

In Canada, when a new drug is brought to the market, Health Canada ascertains its efficacy and safety before it is made available to patients. Once Health Canada issues an approval, each province reviews the therapy to decide whether or not it will be covered by the provincial drug benefit plan. This is the plan that seniors and many low-income individuals rely on for coverage. The drugs covered by the provincial plan are listed on what is called the provincial drug formulary. If seniors, low-income, or other individuals want access to drugs not available to them through the provincial formulary, they must pay for these drugs out-of-pocket.

At present, very few osteoporosis medications are covered without restrictions on provincial drug plans, and the time for reviewing and listing these medications is increasing. This means that the newest, and most effective, medications may be restricted on an ability-to-pay basis, effectively creating a two-tier system.

Presently, under most provincial drug plans, patient access to osteoporosis medications is not aligned with the evidence-based treatment recommendations contained within the Clinical Practice Guidelines, which clearly rate and distinguish amongst therapies according to the level of evidence that exists to support their use for fracture prevention:

- The guidelines assign the designation “first line”, or Grade “A” evidence to therapies where the highest level of evidence exists for fragility fracture prevention.<sup>12</sup>
- A designation of second line, or Grade “B”, is reserved for therapies that demonstrate evidence for the prevention of bone mineral density loss, but insufficient or lower quality of evidence for fracture prevention<sup>12</sup>.

**In many provinces, patients must suffer a fracture, continued rapid bone loss, or intolerance before they are granted coverage for the most effective therapies – and the ones with the best science behind them.** Since the risk of fracture rises sharply once fracture has already occurred, it seems at definite odds with good science and economical management of the disease to require that patients reach a severe state before the best treatment is provided.

Osteoporosis patients are not permitted the same degree of choice in therapy afforded to sufferers of other conditions, such as depression, high blood pressure or asthma. This suggests that Governments have failed to heed the warning of the World Health Organization that fracture management will become a worldwide crisis if policymakers fail to grasp the severity of the disease.

It would not be rational to spend money on BMD tests to diagnose a patient with osteoporosis and not treat the disease with effective drugs.

**See Appendix B for information regarding provincial formulary access.**

## The Strategy: Improved Access To Effective Treatments

**The Osteoporosis Society of Canada believes that coverage of osteoporosis therapies on provincial drug formularies should be in accordance with the designations of first-line therapy and grade of evidence contained within the Clinical Practice Guidelines. Moreover, the range of options covered should meet the diversity in need within the population. Some drugs will be more appropriate for certain individuals than others. New therapies designed to reduce fracture risk should receive due and expeditious review by therapeutic review committees.**

## **The Issue: The Need for a Prevention Strategy Across the Life Cycle**

At root, osteoporosis is a paediatric disease with geriatric consequences, since almost ninety percent of bone growth occurs between the ages of 10 and 20. That means that any strategy to prevent osteoporosis and osteoporosis-related fracture must surely target children, adolescents and adults across the entire life cycle. The most important contributors to the development of healthy bones for children are nutrition, physical activity and pubertal development. In addition, the preservation of bone, through attention to calcium, vitamin D and exercise, is critical for women in their peri-menopausal years, when all women lose bone mass at an accelerated rate because of declining estrogen levels. Fully one-quarter of women *lose up to 3 to 5 percent* of bone mass during each of the five to ten years around menopause.

Though far less study of osteoporosis in men has occurred, evidence does confirm that the disease is not gender-specific to women. Strikingly, almost one-third of osteoporotic hip fractures occur in men. In addition, men have a higher mortality rate from hip fracture than women: 34 percent of men will die within a year of fracture. The fact that osteoporosis seems to occur about ten years later in men than in women may account for the greater complications men experience. What is clear for both men and women is that the risk of falling and fracture increases with age and so fall risk assessment must be an essential component of managing the disease.

The Osteoporosis Society of Canada recommends that provinces act swiftly to undertake the development of a coordinated approach for the prevention, early identification, management and follow up of osteoporosis and osteoporosis-related fracture. This requires the commitment of appropriate human and financial resources to develop the appropriate infrastructure and strategies and must involve recognized experts in osteoporosis care.

In summary, osteoporosis is a disease with devastating consequences for the individual and for the health care system. International scientists are calling hip fractures a global epidemic that is likely to reach crisis proportions as the population ages. Policy makers must act decisively to stem the tide of impending fracture. The cost of anything else is just too high.

## **Appendix A – Osteoporosis Quick Reference Guide**



## Appendix B – Provincial Formulary Access

	<b>Actonel 5 mg, 35 mg Fosamax 10 mg, 70 mg Novo-Alendronate 10 mg</b>	<b>Fosamax 5 mg</b>	<b>Evista 60 mg</b>	<b>Miacalcin 200 IU Nasal Spray<sup>(1)</sup> Apo-Calcitonin<sup>(2)</sup></b>
BC	<p><b><u>Special Authority Criteria</u></b></p> <p>Radiographically documented fractures due to osteoporosis  <b>PLUS</b>  an adequate trial of etidronate that has failed to prevent clinically significant fractures (i.e. those that are painful, produce disability, or both)</p> <p><b>Special Notes</b></p> <ul style="list-style-type: none"> <li>Adequate trial for osteoporosis is defined as at least one year of etidronate therapy</li> </ul>	Not Listed	<p><b><u>Special Authority Criteria</u></b></p> <p>Radiographically documented fractures due to osteoporosis  <b>PLUS</b>  An adequate trial of etidronate that has failed to prevent clinically significant fractures (i.e., those that are painful, produce disability, or both).</p> <p><b>Special Notes</b></p> <ul style="list-style-type: none"> <li>Adequate trial for osteoporosis is defined as at least one year of etidronate therapy</li> </ul>	Not Listed
AB	<p><b><u>Special Authority Criteria</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of osteoporosis in patients who have documented hip, vertebral or other fractures. Special authorization may be granted for 24 months.</li> <li>For the treatment of osteoporosis in patients with documented evidence of intolerance or lack of response to etidronate (i.e. demonstrated as a &gt; 2% loss in bone mineral density in one year). Special authorization for this criteria may be granted for 24 months.</li> </ul> <p>Coverage cannot be provided for two or more osteoporosis medications (Actonel, Didrocal, Evista, Fosamax, Miacalcin) when these medications are intended for use as combination therapy.</p>		<p><b><u>Special Authority Criteria</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of osteoporosis in patients who have documented hip, vertebral or other fractures. Special authorization may be granted for 24 months.</li> <li>For the treatment of osteoporosis in patients with documented evidence of intolerance or lack of response to etidronate (i.e. demonstrated as a &gt; 2% loss in bone mineral density in one year). Special authorization for this criteria may be granted for 24 months.</li> </ul> <p>Coverage cannot be provided for two or more osteoporosis medications (Actonel, Didrocal, Evista, Fosamax, Miacalcin) when these medications are intended for use as combination therapy.</p>	<p><b><u>Special Authority Criteria<sup>(1)</sup></u></b></p> <ul style="list-style-type: none"> <li>For the treatment of osteoporosis in patients with documented evidence of intolerance or lack of response to etidronate (i.e. demonstrated as a &gt; 2% loss in bone mineral density in one year). Special authorization for this criteria may be granted for 24 months.</li> </ul> <p>Coverage cannot be provided for two or more osteoporosis medications (Actonel, Didrocal, Evista, Fosamax, Miacalcin) when these medications are intended for use as combination therapy.</p>

	<b>Actonel 5 mg, 35 mg Fosamax 10 mg, 70 mg Novo-Alendronate 10 mg</b>	<b>Fosamax 5 mg</b>	<b>Evista 60 mg</b>	<b>Miacalcin 200 IU Nasal Spray<sup>(1)</sup> Apo-Calcitonin<sup>(2)</sup></b>
SK	<p><b><u>Exception Drug Status</u></b></p> <p>a) For treatment of osteoporosis in patients who do not respond to etidronate disodium/calcium (Didrocal) after receiving it for one year.</p> <p>b) For treatment of osteoporosis in patients unable to tolerate etidronate disodium/calcium (Didrocal).</p> <p>c) For treatment of osteoporosis in patients who have pre-existing and/or recent fractures.</p> <p>d) For treatment of glucocorticoid-induced osteoporosis in patients who have received systemic glucocorticoid treatment for at least 3 months.</p>	Not Listed	<p><b><u>Exception Drug Status</u></b></p> <p>a) For treatment of osteoporosis in patients who do not respond to etidronate disodium/calcium (Didrocal) after receiving it for 1 year.</p> <p>b) For treatment of osteoporosis in patients unable to tolerate etidronate disodium/calcium (Didrocal).</p>	<p><b><u>Exception Drug Status<sup>(1), (2)</sup></u></b></p> <p>a) For treatment of osteoporosis in patients unable to tolerate listed bisphosphonates.</p> <p>b) For treatment of osteoporosis in patients not responding to listed bisphosphonates after treatment for one year.</p> <p>c) (c) For treatment of crush fracture with bone pain. <i>Coverage will be provided for a maximum of 3 months as an alternative to the subcutaneous dosage form.</i></p>
MN	<p><b><u>Exception Drug Status (Part II)</u></b></p> <p>For the treatment of patients with:</p> <p>(a) osteoporotic fractures;</p> <p>(b) osteoporosis diagnosed with bone mineral density measurements by any approved technology, i.e., a T-score of &lt;- 2.5; and</p> <p>(c) x-ray diagnosis of osteoporosis.</p> <p>NOTE: Concurrent calcium and vitamin D supplementation is recommended.</p>	Not Listed	<p><b><u>Exception Drug Status (Part III)</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of documented osteoporosis in post-menopausal women.</li> <li>Details of criteria may be obtained from the EDS office at Manitoba Health</li> </ul>	<p><b><u>Exception Drug Status (Part III)<sup>(1), (2)</sup></u></b></p> <p>a) Short-term management of pain associated with acute spinal fracture (maximum coverage - 12 weeks).</p> <p>b) For the treatment of osteoporosis in patients who are intolerant or have contraindications to bisphosphonates.</p>

	<b>Actonel 5 mg, 35 mg Fosamax 10 mg, 70 mg Novo-Alendronate 10 mg</b>	<b>Fosamax 5 mg</b>	<b>Evista 60 mg</b>	<b>Miacalcin 200 IU Nasal Spray<sup>(1)</sup> Apo-Calcitonin<sup>(2)</sup></b>
ON	<p><u>Limited Use Criteria</u></p> <p>For the treatment of osteoporosis in patients who have:</p> <p>369 Two out of the following three criteria: BMD at least 3.0 standard deviations below the young adult mean, age of 75 or greater, prior osteoporosis-related fracture; or</p> <p>370 Failed* or, experienced intractable side effects, or have a contraindication to, cyclical etidronate (Didrocal) therapy.</p> <p>*Failure is defined as: continued loss of bone mineral density (loss of more than 3%) after two years of therapy; or a new osteoporosis related fracture after one year of therapy.</p>	Not Listed	<p><u>Limited Use Criteria</u></p> <p>For the treatment of osteoporosis in postmenopausal women who have:</p> <p>373 Failed or, experienced intractable side effects, or have a contraindication to, alendronate OR risedronate.</p> <p>Failure is defined as: continued loss of bone mineral density (loss of more than 3%) after two years of therapy; or a new osteoporosis related fracture after one year of therapy.</p>	Not Listed
QC	Open	Open	Open	Open

	<b>Actonel 5 mg, 35 mg Fosamax 10 mg, 70 mg Novo-Alendronate 10 mg</b>	<b>Fosamax 5 mg</b>	<b>Evista 60 mg</b>	<b>Miacalcin 200 IU Nasal Spray<sup>(1)</sup> Apo-Calcitonin<sup>(2)</sup></b>
NS	<p><b><u>Exception Status Drug</u></b></p> <ul style="list-style-type: none"> <li>• for the treatment of diagnosed osteoporosis associated with documented fragility fracture (with low impact) even in the absence of bone mineral density (BMD) measurements</li> <li>• for the treatment of diagnosed osteoporosis without documented fractures when patients have BMD measurements of -2.5 or lower at the spine (L2-L4) or at the hip (excluding Ward's area)</li> <li>• for the treatment of conventional x-ray documented osteopenia/demineralization only in patients without access to BMD measurements. (Ideally, radiologist's comment of osteopenia or demineralization on any x-ray report warrants further assessment with BMD measurement. However, since there is evidence to show that once osteopenia is visible on conventional x-ray that bone is usually decidedly osteoporotic (BMD of -2.5 or lower), conventional x-ray can be used to recommend treatment if BMD is not accessible.)</li> <li>• as prophylaxis of corticosteroid induced osteoporosis in patients expected to receive oral corticosteroid therapy for 3 months or more</li> <li>• other requests reviewed on case by case basis</li> </ul>	Not Listed	<p><b><u>Exception Status Drug</u></b></p> <ul style="list-style-type: none"> <li>• for the treatment of diagnosed post-menopausal osteoporosis associated with documented fragility fracture (with low impact) even in the absence of bone mineral density (BMD) measurements</li> <li>• for the treatment of diagnosed post-menopausal osteoporosis without documented fractures when patients have BMD measurements of -2.5 or lower at the spine (L2-L4) or at the hip (excluding Ward's area)</li> <li>• for the treatment of conventional x-ray documented osteopenia/demineralization only in women without access to BMD measurements. (Ideally, radiologist's comment of osteopenia or demineralization on any x-ray report warrants further assessment with BMD measurement. However, since there is evidence to show that once osteopenia is visible on conventional x-ray that bone is usually decidedly osteoporotic (BMD of -2.5 or lower), conventional x-ray can be used to recommend treatment if BMD is not accessible.)</li> <li>• other requests reviewed on case by case basis</li> </ul>	<p><b><u>Exception Status Drug</u></b> <sup>(1), (2)</sup></p> <ul style="list-style-type: none"> <li>• for the treatment of diagnosed osteoporosis associated with documented fragility fracture (with low impact) even in the absence of bone mineral density (BMD) measurements and alendronate, risedronate and raloxifene are not tolerated or contraindicated</li> <li>• for the treatment of diagnosed osteoporosis without documented fractures when patients have BMD measurements of -2.5 or lower at the spine (L2-L4) or at the hip (excluding Ward's area) and alendronate, risedronate and raloxifene are not tolerated or contraindicated</li> <li>• for the treatment of conventional x-ray documented osteopenia/demineralization only in patients without access to BMD measurements** and alendronate, risedronate and raloxifene are not tolerated or contraindicated</li> <li>• as prophylaxis of corticosteroid induced osteoporosis in patients expected to receive oral corticosteroid therapy for 3 months or more and alendronate and risedronate are not tolerated or contraindicated</li> <li>• for the treatment of pain associated with osteoporotic fragility fractures, bone metastases, pathological fractures (short term up to 3 months)</li> <li>• other requests reviewed on case by case basis</li> </ul> <p>**Ideally, radiologist's comment of osteopenia or demineralization on any x-ray report warrants further assessment with BMD measurement. However, since there is evidence to show that once osteopenia is visible on conventional x-ray that bone is usually</p>

	<b>Actonel 5 mg, 35 mg Fosamax 10 mg, 70 mg Novo-Alendronate 10 mg</b>	<b>Fosamax 5 mg</b>	<b>Evista 60 mg</b>	<b>Miacalcin 200 IU Nasal Spray<sup>(1)</sup> Apo-Calcitonin<sup>(2)</sup></b>
NB	<p><b><u>Special Authorization Drug</u></b></p> <p>For the treatment of osteoporosis when hormone replacement therapy (HRT) is declined, not tolerated or contraindicated.</p> <p>For the prevention of corticosteroid induced osteoporosis in patients expected to receive oral corticosteroid therapy for 3 months or more.</p> <p>Osteoporosis is defined as a bone mineral density (BMD) at least 2.5 standard deviations below the young adult mean (T score <math>\leq</math> -2.5) and/or the presence of osteoporotic fractures. (World Health Organization definition).</p>	Not Listed	<p><b><u>Special Authorization Drug</u></b></p> <p>For the treatment of post-menopausal osteoporosis when hormone replacement therapy (HRT) is declined, not tolerated or contraindicated.</p> <p>Osteoporosis is defined as a bone mineral density (BMD) at least 2.5 standard deviations below the young adult mean (T score <math>\leq</math> -2.5) and/or the presence of osteoporotic fractures. (World Health Organization definition).</p>	<p><b><u>Special Authorization Drug</u></b> <sup>(1), (2)</sup></p> <p>1) For the treatment of osteoporosis when hormone replacement therapy (HRT) is declined, not tolerated or contraindicated, and alendronate, risedronate and raloxifene have failed, are not tolerated or are contraindicated.</p> <p>Osteoporosis is defined as a bone mineral density (BMD) at least 2.5 standard deviations below the young adult mean (T score <math>\leq</math> -2.5) and/or the presence of osteoporotic fractures. (World Health Organization definition).</p> <p>2) For pain associated with osteoporotic fragility fractures, bone metastases, pathological fractures (short-term coverage of up to 12 weeks).</p>

	<b>Actonel 5 mg, 35 mg Fosamax 10 mg, 70 mg Novo-Alendronate 10 mg</b>	<b>Fosamax 5 mg</b>	<b>Evista 60 mg</b>	<b>Miacalcin 200 IU Nasal Spray<sup>(1)</sup> Apo-Calcitonin<sup>(2)</sup></b>
NF	<p><b><u>Special Authorization Drug</u></b></p> <p>For the treatment of osteoporosis under one of the following circumstances:</p> <p>a) as a first-line agent for patients whose BMD is <math>\geq 3.5</math> SD below young adult level or hip fracture has occurred:</p> <p>b) following failure of and/or intolerance to etidronate (failure defined as a decrease in BMD after one year of treatment or a new fracture following a minimum of 2 cycles)</p>	Not Listed	<p><b><u>Special Authorization Drug</u></b></p> <p>For the treatment of osteoporosis in postmenopausal females under the following circumstances:</p> <p>a) following failure of/contraindication/intolerance to etidronate</p> <p>For the prevention of osteoporosis in postmenopausal females who:</p> <p>a) are osteopenic (BMD = 1 SD below young adult level) OR</p> <p>b) have significant risk factors for the development of osteoporosis ( e.g. family history of osteoporosis, low body mass index, early menopause)</p> <p>AND have failed an adequate trial of calcium and vitamin D supplementation and other non-pharmacological interventions are in place.</p>	<p><b><u>Special Authorization Drug<sup>(1)</sup></u></b></p> <p>For the treatment of osteoporosis under the following circumstances:</p> <p>a) following failure of and/or intolerance or contraindication to etidronate</p> <p>b) for short-term treatment (2 to 6 weeks) of pain when required following a vertebral compression fracture</p> <p>c) for the short-term (4 to 6 weeks) treatment of pain of bone metastases and pathological fractures</p>
PEI	Not Listed	Not Listed	Not Listed	Not Listed
NIHB	<p><b><u>Limited Use Benefit</u></b></p> <p>For treatment of:</p> <p>a) osteoporosis in patients who have documented hip, vertebral or other fractures.</p> <p>b) osteoporosis in patients who are intolerant of or do not respond to etidronate or etidronate/calcium.</p>	<p><b><u>Limited Use Benefit</u></b></p> <p>For treatment of:</p> <p>a) osteoporosis in patients who have documented hip, vertebral or other fractures.</p> <p>b) osteoporosis in patients who are intolerant of or do not respond to etidronate or etidronate/calcium.</p>	<p><b><u>Limited Use Benefit</u></b></p> <p>For:</p> <p>a) secondary prevention of osteoporosis in women who experience failure on hormone replacement therapy or bisphosphonates.</p> <p>b) secondary prevention of osteoporosis in women who have a personal history or a first-degree relative with a history of breast cancer.</p>	<p><b><u>Limited Use Benefit<sup>(1)</sup></u></b></p> <p>For treatment of patients with postmenopausal osteoporosis who have failed therapy, are intolerant to, or who have contraindications to both bisphosphonates and raloxifene.</p>

---

## REFERENCES

- <sup>1</sup> Goeree R, O'Brien B, Pettitt D, Cuddy L, Ferraz M, Adachi J. (1996) An assessment of the burden of illness due to osteoporosis in Canada. *J Soc Obstet Gynaecol Can* 18(suppl July):15-24.
- <sup>2</sup> Lorrain J, Paiemont G, Chevalier N, et al. (2003) Population demographics and socioeconomic impact of osteoporosis in Canada. *Menopause* 10: 228-34.
- <sup>3</sup> Papaidmitropouos EA, Coyte PC, Josse RG, Greenwood CE (1997) Current and projected rates of hip fracture in Canada. *Can Med Assoc J* 158:870-71.
- <sup>4</sup> Melton LJ, Thamer M, Ray NF, et al. (1997) Fractures attributable to osteoporosis: report from the national osteoporosis foundation. *J Bone Min research.* 112: 16-23.
- <sup>5</sup> Cauley JA, Thompson DE, Ensrud KC, Scott JC, Black DM. (2000) Risk of mortality following clinical fractures. *Osteoporos Int* 11:556-561.
- <sup>6</sup> Center JR, Nguyen TV, Schneider D et al. (1999) Mortality after all major types of osteoporotic fracture in men and women: an observational study. *Lancet* 353: 878-82.
- <sup>7</sup> Kado DM, Browner WS, Palermo L, et al. (1999) Vertebral fractures and mortality in older women. *Arch Intern Med* 1215-20.
- <sup>8a</sup> Cummings, SR, Black, DM, Rubin, SM (1989). Lifetime Risk of Hip, Colles', or Vertebral Fracture and Coronary Heart Disease Among Postmenopausal Women. *Arch Intern Med* - Vol 149: 2445-2448.
- <sup>8b</sup> Melton LJ. Epidemiology of fractures. *Osteoporosis: Etiology, Diagnosis and Management*, Second Edition. pp. 225-247, BL Biggs and LJ Melton (Eds). Lippincott-Raven Publishers, Philadelphia, 1995.
- <sup>8c</sup> Charney, P, Walsh, ME, Nattinger, AB, (1998). update in Women's Health. *Ann Intern Med*; Vol 129: 551-558.
- <sup>9</sup> Nevitt, MC, Thompson, DE, Black, DM, *et al.* (2000) Effect of alendronate on limited-activity days and bed-disability days caused by back pain in postmenopausal women with existing vertebral fractures. *Arch Intern Med* 160:77-85.
- <sup>10</sup> Saskatchewan Health Quality Council. (2003). Saskatchewan Seniors Experiencing Hip Fracture: Characteristics and Health Outcomes. Saskatoon: HQC.
- <sup>11</sup> International Osteoporosis Foundation (2000) *The Osteoporosis Paradox: The Neglected Disease. Satellite Symposium, 2<sup>nd</sup> International Meeting on Social and Economic Aspects of Osteoporosis.* Belgium: IOF.
- <sup>12</sup> Brown J and Josse R. (2002) Clinical practice guidelines for the diagnosis and management of osteoporosis in Canada.

- 
- 13 National Institutes of Health (2000) Osteoporosis Diagnosis and Therapy: NIH Consensus Statement Mar 27-29, 2000; 17:1-45.
  - 14 S. A. Jackson, A. Tenenhouse, L. Robertson and the CaMos Study Group (2000) Vertebral Fracture Definition from Population-Based Data: Preliminary Results from the Canadian Multicenter Osteoporosis Study (CaMos), *Osteoporosis Int.* Volume 11 Issue 8 (2000) pp 680-687.
  - 15 Ontario Women's Health Council. 2000. *A Framework and Strategy for the Prevention and Management of Osteoporosis.* Ontario Ministry of Health: Toronto.
  - 16 Salkeld G, Cameron ID, Cumming RG, et al. (2000). Quality of life related to fear of falling and hip fracture in older women: a time trade-off study. *BMJ*; 320: 241-46.
  - 17 Bone and Joint Decade Canada. (2002). *Promoting Bone and Joint Health.* National Action Network of the Bone and Joint Network: Ottawa.
  - 18 IOF (2003). *Osteoporosis in the Workplace: the social, economic and human costs of osteoporosis on employees, employers and governments.* WHO Collaborating Center: Belgium.
  - 19 Heart and Stroke Foundation of Canada (1997) *Heart and Stroke in Canada.* Ottawa: Heart and Stroke in Canada.
  - 20 Health Canada. 1997 *Economic Burden of Illness in Canada (1993)* Ottawa: Minister of Public Works and Government Services Canada.
  - 21 Krahn D, Berka C, Langlois P and Detsky A. (1996) Direct and indirect costs of asthma in Canada. *CMAJ*; 154: 821-31.
  - 22 Birmingham C, Muller L, Palepu A, et al. (1999) The cost of obesity in Canada. *CMAJ*; 160: 483-8.
  - 23 Melton LJ, Chrischilles A, Cooper C, et al. (1992) Perspective; how many women have osteoporosis? (1992). *J Bone Miner Research* 7: 1005-1010.
  - 24 Jagal S. (1998) Osteoporotic fractures: incidence and impact. In Williams JI, Badley EM, eds. *Patterns in Health Care in Ontario: Arthritis and Related Conditions.* Toronto: ICES: 143-56
  - 25 Josse RG. (2001) Osteoporosis in men. *Endocrinology Rounds*; 1:1-6.
  - 26 Melton LJ, Chrischilles A, Cooper C, et al. (1992) Perspective; how many women have osteoporosis? (1992). *J Bone Miner Research* 7: 1005-1010.
  - 27 Wiktorowicz ME, Goeree R, Papaioannou A. et al. (2001) Economic implications of hip fracture: health service use, institutional care and cost in Canada. *Osteoporosis Int.* 12: 271-78.
  - 28 Cauley JA, Thompson DE, Ensrud KC, Scott JC, Black DM. (2000) Risk of mortality following clinical fractures. *Osteoporosis Int*; 11:556-561.
  - 29 Cooper C, Atkinson EJ, Jacobsen SJ, O'Fallon WM, Melton LJ. (1993) Population-based study of survival after osteoporotic fractures. *Am J Epidemiol*; 137:1001-1005.

- 
- <sup>30</sup> Lindsay R, Silverman SL, Cooper C, Hanley DA, Barton I, Broy SB et al. (2001) Risk of new vertebral fracture in the year following a fracture. *JAMA*; 285:320-323.
- <sup>31</sup> Ettinger B, Black DM, Mitlak BH, Knickerbocker RK, Nickelsen T, Genant HK et al. (1999) Reduction of vertebral fracture risk in postmenopausal women with osteoporosis treated with raloxifene: results from a 3-year randomized clinical trial. Multiple Outcomes of Raloxifene Evaluation (MORE) Investigators. *JAMA* ;282:637-645.
- <sup>32</sup> Ross PD, Genant HK, Davis JW, Miller PD, Wasnich RD. (1993) Predicting vertebral fracture incidence from prevalent vertebral fractures and bone density among non-black, osteoporotic women. *Osteoporos Int*;3:120-126.
- <sup>33</sup> Black DM, Arden NK, Palermo L, Pearson J, Cummings SR. (1999) Prevalent vertebral deformities predict hip fractures and new vertebral deformities but not wrist fractures. *J Bone Miner Res*;14:821-828.
- <sup>34</sup> Canadian Multicentre Osteoporosis Study. 2000.
- <sup>35</sup> Juby AG, De Geus-Wenceslau CM. (2002). Evaluation of osteoporosis treatment in seniors after hip fracture. *Osteoporos Int*;13(3):205-10.
- <sup>36</sup> Port L, Center J, Briffa NK et al. (2003). Osteoporotic fracture: missed opportunity for intervention. *Osteoporosis Int*; 14: 780-4.
- <sup>37</sup> Hajcsar EE, Hawker G, Bogoch ER. (2000). Investigation and treatment of osteoporosis with fragility fractures. *CMAJ*; 163: 819-22.
- <sup>38</sup> Gardener MJ, Kyle R, Flik MD, et al. (2002) Improvement in the under-treatment of osteoporosis following hip fracture. (2002). *Journal of Bone and Joint Surgery*; 84: 1342-48.
- <sup>39</sup> Nevitt C, Ettinger B, Black D, et al. (1998). The association of radiographically detected vertebral fractures with back pain and function. *Ann Intern Med*; 128: 793-800.
- <sup>40</sup> Cuddihy MT, Sherine E, Gabriel MD, et al. (2002). Osteoporosis intervention following distal forearm fractures. *Arch Intern Med*; 162: 421-26.