Diagnosis and Management Of Osteoporosis

EVIDENCE INFORMED PRACTICE TOOLS

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October 2014
# CLINICAL PRACTICE GUIDELINES
## FOR THE DIAGNOSIS AND MANAGEMENT OF OSTEOPOROSIS

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1. Background

I. Purpose of this document:
There has been a paradigm shift in the prevention and treatment of osteoporosis* and related fractures. The focus now is preventing fragility fractures and their negative consequences, rather than simply treating low bone mineral density (which is now considered one of several risks for fracture). It is known that suffering a fragility fracture is a “red flag” for osteoporosis and an indicator of risk for further fractures.

This document, based on the 2010 Clinical Practice Guidelines for the Diagnosis and Management of Osteoporosis in Canada6, is designed to provide an evidence-based process to identify and treat osteoporosis. Recommendations are excerpted from these guidelines.

*Osteoporosis: A systemic skeletal disease characterized by low bone mass and microarchitectural deterioration of bone tissue leading to enhanced bone fragility and a susceptibility to fracture.19

The definition of osteoporosis considers both a reduction in Bone Mineral Density (BMD) and the occurrence of fragility fracture. In the absence of a clinical diagnosis of osteoporosis from fragility fracture, osteoporosis has been operationally defined on the basis of BMD assessment. According to the WHO criteria, osteoporosis is defined as a BMD T-Score 2.5 standard deviations or more below the average value for young healthy women (a T-score of <-2.5 SD).13, 19

Not all people with BMD in the osteoporotic range are at high risk for fracture; conversely, many people at high fracture risk (or who have already sustained a fragility fracture) do not have BMD in the osteoporotic range. This has led to the use of validated tools incorporating multiple independent risk factors to more accurately predict the likelihood of an osteoporotic fracture.

II. Burden of Disease and Impact on Health System (Manitoba Health):
An estimated 1.5 million (10%) Canadians 40 years of age or older report having been diagnosed with osteoporosis.1

In 2006, 12.7% of the Manitoba population age 50 or older had diagnosed osteoporosis, with a greater prevalence among women than men.2 A similar proportion of Canadian women age 50 and older (12.4%) are estimated to be at high fracture risk,22 as defined in the 2010 Clinical Practice Guidelines for Diagnosis and Management of Osteoporosis in Canada.6

Key considerations and costs identified in Manitoba:
- Over 80% of fractures in those over age 50 are low-trauma or fragility fractures**4, 21
- Once an osteoporotic/fragility fracture has occurred, another is more likely to occur in the absence of treatment.4
  - A Canadian study found that 14% of person’s with a wrist fracture suffered a repeat fracture within 3 years.21
  - One in three hip fracture patients re-fracture at one year and more than one in two will suffer another fracture within 5 years.21
  - The risk of suffering a second vertebral fracture in the 12 months following an initial fracture is 20%.21

** Fragility Fracture: A fracture occurring spontaneously or following minor trauma such as a fall from standing height or less.19 Commonly involved sites are the proximal femur (“hip”), vertebral bodies (“spine”), distal forearm (“wrist”) or proximal humerus (“shoulder”) which are collectively referred to as Major Osteoporotic Fractures under the Fracture Risk Assessment (FRAX) system. Other sites (e.g., pelvis, ribs) are still clinically important. Fractures affecting the craniofacial region, cervical spine, ankle, carpal bones, or hands/feet are excluded.

- There are approximately 1000 hip fractures each year in Manitoba in persons age 60 and over. A much larger number of people experience fractures of the spine, wrist, shoulder and pelvis.5
In Manitoba the annual direct costs for management of hip fractures during the first year alone are well in excess of $10 million.\textsuperscript{7,8}

The cost increases to \textbf{over $30 million} when additional osteoporotic fractures are included.\textsuperscript{7,8}

The human cost of osteoporotic fractures is significant. Approximately 28% of women and 37% of men who suffer a hip fracture die within 12 months,\textsuperscript{9,21} often from related complications.\textsuperscript{9} Long-term pain and disability, fear of falling, lifestyle changes, isolation and increased burden on caregivers also follow osteoporotic fractures.\textsuperscript{5,21,22}

Younger people who suffer vertebral or hip fractures incur other significant, indirect costs such as sick leave, loss of job days, employment insurance payments, and loss of productivity.\textsuperscript{5}

A Canadian study showed that among 18 different health conditions, hip and vertebral fractures were among the top three associated with extended hospital stays and substantial health care costs.\textsuperscript{10}

Osteoporotic fractures have been associated with extended hospital stays and increased rates of institutionalization.\textsuperscript{11} The impact on the health care system and the cost to society is substantial.

The implications for long-term care costs are also significant:
- Only 44% of people hospitalized for hip fracture management are discharged to their home.
- 10% go on to another hospital.
- 27% go to rehabilitation care.
- 17% go to long-term care facilities.\textsuperscript{5}
A Manitoba study found that 24% of women and men age 75 years and older who were previously living in the community were transferred to long-term care during the 12 months following a hip fracture.\textsuperscript{11}

Canadian research showed:
- A hip fracture patient who returned home after hospitalization costs the health care system in excess of $21,385 in direct costs.\textsuperscript{5}
- A patient who was institutionalized costs over twice as much at $44,156.\textsuperscript{5,21}

\textbf{Despite the human and economic costs, fewer than 20\% of patients with fragility fractures receive appropriate testing and/or anti-osteoporosis treatment post fracture.}\textsuperscript{4,12,19,21,31}
2. Goals and Objectives of the Guidelines

Goal
The goal of these guidelines is to provide health-care professionals in Manitoba an evidence-based process for the diagnosis and treatment of osteoporosis, based on the Canadian Clinical Practice Guidelines.6

Objectives:
- To consistently identify clients’/patients’ absolute risk of osteoporosis/fragility fractures.
- To ensure prompt, appropriate, and consistent assessment and management of osteoporosis and fracture risk.
- To ensure that patients with fragility fractures receive appropriate treatment to reduce the risk of further fractures.

3. Target Audience
These guidelines are intended for use by health care providers in Manitoba, including direct care staff, policy makers, educators, administrators and members of interprofessional care teams.

4. Target Population
These guidelines target women and men over age 50, the age at which risk of fragility fractures increases.

5. How to Use This Guideline
These guidelines are designed as a foundation that will support, rather than replace, the clinical judgment of health care providers. Use and application of information in these guidelines will depend on situation and populations.

6. Guiding Principles
Recognize practice-specific needs and priorities.
Frame the activities undertaken within a context of excellence in client care, patient safety, and integration.

7. Methodology
“Clinical Practice Guidelines for the Diagnosis and Management of Osteoporosis in Canada (2010)”6 were reviewed and adapted for Manitoba through the collaborative efforts of key stakeholders, Manitoba Health, regional representation and Winnipeg Regional Health Authority.

For details on the methodology used for the national guidelines refer to the Clinical Practice Guidelines for the Diagnosis and Management of Osteoporosis in Canada: Background and Technical Report19 at http://www.osteoporosis.ca/forhealthprofessional/clinical tools and resources.

See Appendix F for established criteria used to grade recommendations and quality of evidence.
8. Clinical Practice Guidelines - Diagnosis and Management of Osteoporosis

Clinical Recommendations

I. Fracture Risk Assessment

Who should be assessed?
Women and men over age 50 who have experienced a fragility fracture are at increased risk of future fracture. Those with hip and vertebral fractures are at highest risk. (See Appendix A)

**Recommendation:** Individuals over age 50 who have experienced a fragility fracture should be assessed. (grade A)⁶

Assessment for osteoporosis & fracture risk
A detailed history and a focused physical examination are recommended to identify risk factors for low bone mineral density (BMD), high risk of falling and fractures, as well as undiagnosed vertebral fractures. In selected individuals, BMD should be measured with dual-energy x-ray absorptiometry (DXA). (See Appendix A Table A₁ with BMD; Table A₂ without BMD) (Also see Appendix B₁ “Anatomy of a Bone Density Report” and B₂ “Explanation of a Bone Density Report”)

**Recommendation:** Annual assessment for osteoporosis should include measurement of height and assessment for the presence of vertebral fractures. (grade A)⁶

**Recommendation:** Perform lateral thoracic and lumbar spine radiographic imaging or vertebral fracture assessment by dual-energy x-ray absorptiometry (DXA) if clinical evidence is suggestive of a vertebral fracture. (grade A)⁶

**Recommendation:** A history of falls in the past year should lead to a multifactorial risk assessment including the ability to get out of a chair without using arms. (grade A)⁶
See section II for 10-Year Fracture Risk.

Also see Falls Prevention and Management: Regional Clinical Practice Guidelines ²⁰ ([http://www.wrha.mb.ca/professionals/ebpt/files/FallsPrev_CPG.pdf](http://www.wrha.mb.ca/professionals/ebpt/files/FallsPrev_CPG.pdf))
### Table 1: When to Order a BMD test (DXA)\(^6\)

<table>
<thead>
<tr>
<th>Older adults (age ≥ 50 yr)</th>
<th>Younger adults (age &lt; 50 yr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥ 65 year (women only)</td>
<td>Fragility fracture</td>
</tr>
<tr>
<td>Fragility fracture after age 40 yr</td>
<td>Prolonged use of glucocorticoids*</td>
</tr>
<tr>
<td>Prolonged use of glucocorticoids*</td>
<td>Use of other high-risk medications†</td>
</tr>
<tr>
<td>Use of other high-risk medications†</td>
<td>Hypogonadism or premature menopause (age &lt; 45 yr)</td>
</tr>
<tr>
<td>Vertebral fracture or osteopenia identified on radiography</td>
<td>Malabsorption syndrome</td>
</tr>
<tr>
<td>Clinical risk factors for fracture</td>
<td>Other disorders strongly associated with rapid bone loss and/or fracture</td>
</tr>
<tr>
<td>Parental hip fracture</td>
<td></td>
</tr>
<tr>
<td>Current smoking</td>
<td></td>
</tr>
<tr>
<td>High alcohol intake</td>
<td></td>
</tr>
<tr>
<td>Low body weight (&lt; 60 kg) or major weight loss (&gt;10% of body weight at age 25 yr)</td>
<td></td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td></td>
</tr>
<tr>
<td>Other disorders strongly associated with osteoporosis</td>
<td></td>
</tr>
</tbody>
</table>

*At least three months cumulative therapy in the previous year at a prednisone-equivalent dose ≥ 7.5 mg daily.
†For example, aromatase inhibitors or androgen deprivation therapy

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### Other Investigations

**Recommendation**: In high risk patients, perform additional biochemical testing to rule out secondary causes of osteoporosis on the basis of clinical assessment. (grade D)\(^6\)

Box 1: The following biochemical tests are recommended in patients being assessed for osteoporosis.
- Calcium, corrected for albumin
- Complete blood count
- Creatinine
- Alkaline phosphatase
- Thyroid-stimulating hormone
- Monoclonal protein investigation (for patients with vertebral fractures)
- 25-Hydroxyvitamin D (measured after three to four months of adequate supplementation and should not be repeated if an optimal level of at least 75nmol/L is achieved)

**Recommendation**: Consider measuring serum level of 25-hydroxyvitamin D in individuals who will receive pharmacologic therapy for osteoporosis, those who have sustained recurrent fractures or have bone loss despite osteoporosis treatment, and those with co morbid conditions that affect absorption or action of vitamin D (grade D)\(^6\)

**Recommendation**: Serum 25-hydroxyvitamin D should be measured after three to four months of adequate supplementation and should not be repeated if an optimal level (≥ 75 nmol/L is achieved. (grade B)\(^6\)

**Recommendation**: Serum 25-hydroxyvitamin D should not be measured in healthy adults at low risk of osteoporosis or conditions affecting the absorption or action of vitamin D. (grade D)\(^6\)
II. Determine 10-Year Fracture Risk

**Recommendation:** Assessment of the absolute risk of fracture should be based on established factors: age, bone mineral density, prior fragility fracture and glucocorticoid use. (grade A)\(^6\)

**Recommendation:** Use the Canadian version of WHO FRAX® tool*** to assess fracture risk (http://www.shef.ac.uk/FRAX/tool.jsp?country=19). (grade A)\(^14, 15, 16\)

**Recommendation:** Use the WHO T-score criteria for reporting BMD diagnostic category and the adapted Canadian version of WHO FRAX® tool for reporting fracture risk. (grade D)\(^6\)

**Recommendation:** Individuals with a T-score for lumbar spine, femoral neck or total hip ≤ -2.5 should be considered to have least moderate risk. (grade D)\(^6\)

**Recommendation:** Multiple fracture episodes confer greater risk than a single fracture. Prior fracture of the hip and spine are associated with greater risk than fractures at other sites. (Grade B)\(^6\)

***FRAX® (Fracture Risk Assessment): A tool developed by WHO to evaluate fracture risk of patients. The output is a 10-year probability of hip fracture and the 10-year probability of a major fracture (spine, forearm, hip or shoulder fracture). FRAX uses gender, age, body mass index, prior fracture, parental hip fracture, prolonged glucocorticoid use, rheumatoid arthritis (or secondary causes of osteoporosis), current smoking, alcohol intake (three or more units daily) and (optionally) bone mineral density of the femoral neck. FRAX www.sheffield.ac.uk/FRAX/tool.jsp?country=19 (Canadian tool) is the system for fracture risk assessment and BMD reporting currently used in Manitoba.

III. Strategies for Fracture Prevention: Lifestyle

a) Exercise

**Recommendation:** Prescribe\(^6\) exercises involving resistance training appropriate for the individual’s age and functional capacity and/or weight bearing aerobic exercises for those with or at risk for osteoporosis. (grade B)\(^6\)

**Recommendation:** For individuals who have had vertebral fractures, prescribe\(^6\) exercises to enhance core stability and help compensate for weakness or postural abnormalities. (grade B)\(^6\)

**Recommendation:** For those at risk of falls, prescribe\(^6\) exercises that focus on balance (e.g. T’ai Chi) or balance and gait training. (grade A)\(^6\)

See Falls Prevention and Management: Regional Clinical Practice Guidelines\(^20\) (http://www.wrha.mb.ca/professional/ebpt)

**Recommendation:** For those living in long term care facilities and who are at high risk of fracture, consider the use of hip protectors. (grade B)\(^6\)

\(^6\) Refer to an exercise professional (Physiotherapist, Kinesiologist, Athletic Therapist) trained for one-on-one instruction in osteoporotic exercises.
b) Nutrition

Calcium

**Recommendation:** For individuals over 50, the total daily intake of elemental calcium (through diet and supplements) should be 1200 mg. (grade B)\(^6,19\)

**Note:** Supplemental calcium should not be taken without concurrent vitamin D supplementation.\(^{18}\)

Vitamin D\(^{17}\)

**Recommendation:** For adults over 50, supplement daily with 800-2000 IU (20-50 ug) vitamin D. To achieve optimal vitamin D status, daily supplementation with more than 800-2000 IU (20-50 μg) may be required. (grade C)\(^6,17,19\) Daily doses up to 4000 IU (100 μg) are safe and do not necessitate monitoring.\(^{32}\)

**Note:** For ease of administration and clarity in recommendations, daily supplementation of 1000IU vitamin D is recommended.

**Recommendation:** For individuals receiving pharmacologic therapy for osteoporosis, measurement of serum 25-hydroxyvitamin D should follow three to four months of adequate supplementation and should not be repeated if an optimal level (≥75 nmol/L) is achieved. (grade D)\(^6\)

IV. Strategies for Fracture Prevention: Pharmacologic

Management of Individuals at Risk of Fractures based on a Fracture Risk Assessment Tool

a) High Risk

**Recommendation:** Individuals at high absolute risk (>20% probability for major osteoporotic fracture over 10 years) should be offered pharmacologic therapy. (grade D)\(^6\)

**Recommendation:** Individuals over age 50 who have had a fragility fracture of the hip or vertebra and those who have had more than one fragility fracture episode, should be offered pharmacologic therapy. (grade B)\(^6\)

**Recommendation:** Individuals at high risk for fracture should continue osteoporosis therapy without a drug holiday. (grade D)\(^6\)

b) Moderate Risk

**Recommendation:** Individual preference and additional risk factors should be used to guide pharmacologic therapy. (grade C)\(^6\) (see Appendix C and D)

Individuals at Moderate Risk who have been prescribed pharmacologic therapy should be reassessed every 3-5 years regarding the need for ongoing medication or consideration of a drug holiday or for drug discontinuation.

c) Low Risk

Individuals at Low Risk of Fracture do not require pharmacologic treatment\(^6\), however they should be reassessed regularly for the presence of new clinical risk factors.
V. Treatment

(See Appendix E for Medication, Dosage and Manitoba Pharmacare Coverage)

Pharmacologic Therapy

**Recommendation:** To support informed decision-making, the potential benefits and risks of the prescribed agents should be discussed before therapy is initiated. (grade D)\(^6\)

**Recommendation:** Initiation of pharmacological treatment for osteoporosis should be predicated on an assessment of absolute fracture risk by means of a validated fracture prediction tool. (grade D)\(^6\)

a) Menopausal Women Requiring Treatment for Osteoporosis

**Recommendation:** For prevention of hip, nonvertebral and vertebral fractures consider alendronate, risedronate, zoledronic acid and denosumab as first-line therapies. (grade A)\(^6\)

**Recommendation:** For prevention of vertebral fractures consider raloxifene as a first-line therapy. (grade A)\(^6\)

**Recommendation:** For osteoporosis in combination with treatment for vasomotor symptoms, consider hormone therapy as first-line therapy for prevention of hip, nonvertebral and vertebral fractures. (grade A)\(^6\)

b) Men

**Recommendation:** For treatment of osteoporosis recommend alendronate, risedronate and zoledronic acid as first-line therapies for prevention of fractures. (grade D)\(^6\)

Testosterone is not recommended for the treatment of osteoporosis in men. (grade B)\(^6\)

c) Special Groups

**Recommendation:** For individuals over age 50 years on long-term glucocorticoids therapy (three or more months cumulative therapy during the preceding year at a prednisone-equivalent dose 7.5 mg or greater daily) a bisphosphonate (alendronate, risedronate, zoledronic acid) should be initiated at the outset and continued for at least the duration of the glucocorticoid therapy. (grade A)\(^6\)

**Recommendation:** For those at high risk for fracture who are taking glucocorticoid therapy (three or more months cumulative therapy during the preceding year at a prednisone-equivalent dose 7.5 mg or greater daily) teriparatide may be considered in selected patients (e.g. those intolerant to oral and IV bisphosphonates or with recurrent fractures on bisphosphonate therapy). (grade A)\(^6\)

(See Appendix E for Medication, Dosage and Manitoba Pharmacare Coverage)

**Recommendation:** Women who are taking aromatase inhibitors and men who are undergoing androgen-deprivation therapy should be assessed for fracture risk, and considered for osteoporosis therapy to prevent fractures. (grade B)\(^6\)
Use of Combination Therapy
Recommendation: Clinicians should avoid simultaneously prescribing more than one antiresorptive agent for fracture reduction. (grade D)\textsuperscript{6}

Knowledge Translation
Recommendation Following a fragility fracture, an educational initiative should be targeted at both the patient/family/caregiver and the primary care physician. (grade B)\textsuperscript{6}

Recommendation: To improve both the diagnosis and the management of osteoporosis, case management is recommended as an effective approach to post fracture care. (grade A)\textsuperscript{6}

Recommendation: Point-of-care tools and other targeted strategies are recommended to support the implementation of osteoporosis guidelines in clinical practice. (grade B)\textsuperscript{6}
Tools and resources can be found on www.osteoporosis.ca and http://www.gov.mb.ca/health/primarycare.bonedensity/index.html.

VI. Monitoring
The subject of “Monitoring” is an evolving area with no clear consensus. The following are a set of recommendations forwarded by the Osteoporosis Steering Committee that are consistent with Bone Mineral Density provincial recommendations.

In treated patients, the major objective of follow-up BMD testing is to identify individuals with continued BMD loss. Significant BMD loss, as described on the Manitoba BMD report, may reflect
- poor adherence to therapy,
- failure to respond to therapy or
- previously unrecognized secondary causes of osteoporosis (e.g., vitamin D insufficiency).
Stable BMD is consistent with successful treatment providing the monitoring interval is sufficiently long (approximately 5 years) to exclude significant loss.
Most osteoporosis therapies do not cause large increases in BMD, and the antifracture effect of treatment is only partly explained by the relatively small changes in BMD.\textsuperscript{15}
In untreated patients, the objective of follow-up testing is to identify those whose fracture risk has increased to the point where treatment initiation would be warranted.

Individuals at Low Risk
For those at low risk and without additional risk factors for rapid BMD loss, a longer testing interval (5-10 years) may be sufficient.\textsuperscript{6, 23, 24} In the absence of new clinical risk factors, healthy individuals over age 65 with normal BMD, transition to osteoporosis is unlikely over the next 15 years and further BMD testing is not required.

Individuals at Moderate Risk Not On Pharmacologic Treatment
BMD monitoring can be used to guide initiation of osteoporosis drug therapy in those at moderate fracture risk undergoing basic care. Some, but not all, studies show that more rapid BMD loss in untreated individuals is an independent risk for fracture.\textsuperscript{19, 25, 26, 27}
Individuals with a T-score of the spine or hip ≤ -2.5 should be considered as having at least moderate risk and a repeat BMD measurement should be obtained after 1-3 years to monitor for rapid bone loss.\(^6\)

- If BMD is stable then less frequent monitoring can be considered.\(^6\)
- An initial 1-year monitoring interval would be reasonable in the setting of high-risk medication use (e.g., daily glucocorticoid therapy, women on aromatase inhibitors or men receiving androgen deprivation therapy).

**Individuals on Pharmacologic Therapy**

Stable or increased BMD is consistent with treatment response, and additional BMD monitoring is not required in the absence of a change in therapeutic regimen or new clinical risk factors.

- If continued follow up is requested then a minimum interval of 5 years would be reasonable in the absence of new clinical risk factors.
- In most cases of post-menopausal osteoporosis, repeat BMD testing should be done 3 years after initiation of pharmacologic therapy.

**Fracture Risk Re-Assessment**

Individuals over age 50 should be re-assessed annually\(^6\) for new risk factors for osteoporotic fractures. This should include:

- a history of falls and fractures since last assessed,
- changes in family history (i.e. parental hip fracture),\(^6\)
- development of intercurrent illness and
- initiation of high-risk medications.
- a physical exam that includes an accurate height measurement.

Significant change (>2 cm measured height loss or >6 cm historical height loss) should prompt imaging for a vertebral compression fracture.

In those with a history of a fall, a multifactorial falls risk assessment, including the ability to rise from a chair without using the arms, should be conducted.\(^6\)

**VII. When to Refer To a Specialist?**

Patients with any of the following factors may benefit from referral to a physician with expertise in osteoporosis:

- fracture or significant ongoing loss of bone mineral density despite good adherence while on first-line therapy
- intolerance of first- and second-line therapies
- any secondary cause of osteoporosis that is outside the expertise of the primary care physician
- extremely low bone mineral density.\(^6,19\)
References

1. Public Health Agency of Canada, what is the impact of Osteoporosis in Canada and what are Canadians doing to maintain healthy bones, 2010


5. Osteoporosis Canada, An Osteoporosis Screening Program for Manitoba: Preventing a Fractured Future


20. Winnipeg Regional Health Authority. Falls Prevention and Management Regional Clinical Practice Guidelines Acute Care, Personal Care Homes, Long Term Care Facilities, Community Services and Programs May 2011


Appendix A1  University of Manitoba Osteoporosis Flowchart (table 1)
With Bone Mineral Density testing

*Other disorders such as (incomplete list)
Malabsorption syndromes
Chronic inflammatory conditions
Primary hyperparathyroidism

Footnote a, b, c, d see page 17
Appendix A2  University of Manitoba Osteoporosis Flowchart (table 2)

Fracture Risk Assessment without BMD Testing

For patients unable or unwilling to undergo BMD testing

Encourage basic bone health for all individuals over age 50, including: regular active weight-bearing exercise, calcium (total from diet and supplements) 1,200 mg daily, vitamin D: 800–2,000 IU daily, and fall prevention strategies

Fracture risk estimation from FRAX without BMD

Assess benefit from pharmacological therapy

Low Risk
10-year Fracture Risk < 10%

Moderate Risk
10-year Fracture Risk 10-20%

High Risk
10-year Fracture Risk > 20% or
Prior fragility hip fracture or
Prior fragility spine fracture or
More than one fragility fracture

Perform spine X-rays and
assess recent glucocorticoid use
Initiate pharmacotherapy if vertebral fracture or major glucocorticoid use

Unlikely to benefit from pharmacotherapy
Reassess risk in 5 years

Consider BMD testing

Pharmacotherapy is recommended
Always consider patient preference

Footnote a, b, c see page 17

Footnotes:

a For patients unable or unwilling to undergo BMD testing, fracture risk assessment without BMD using the Canadian FRAX tool (http://www.shef.ac.uk/FRAX/tool.jsp?country=19) can be helpful in guiding the need for BMD testing or treatment. This tool has been validated for fracture prediction in the Canadian population (Leslie WD, et al. Fracture risk assessment without bone density measurement in routine clinical practice. Osteoporosis International 2011).

b Definite non-traumatic vertebral fractures (>25% height loss with end-plate depression) are associated with a 5-fold increased risk for recurrent vertebral fractures. Equivocal spine fractures are not strong indicators of osteoporosis.

c Major glucocorticoid use is prednisone (or equivalent) at a daily dose of 7.5 mg or greater for at least 90 days in the preceding year. Physiologic use for adrenal replacement is excluded.
Appendix A1 Footnotes:

a BMD testing in individuals younger than age 50 can be considered when there are significant medical conditions or medications associated with osteoporosis. Treatment guidelines are not well defined and requires an individualized approach, bearing in mind that risk of fracture is usually low, while long term safety and efficacy of drug therapy is not well established.

b Other high-risk medication use (e.g., aromatase inhibitors for breast cancer, androgen deprivation for prostate cancer), parental hip fracture, high alcohol intake or current smoking, low body weight (< 60 kg) or major weight loss (>10% of weight at age 25)

c Definite non-traumatic vertebral fractures (>25% height loss with end-plate deformity) are associated with a 5-fold increased risk for recurrent vertebral fractures. Equivocal spine fractures are not strong indicators of osteoporosis.

d The major objective of follow-up testing is to identify individuals with continued BMD loss. The anti-fracture effect of treatment is not explained from the small change in BMD. Stable BMD is consistent with successful treatment.

Appendix A2 Footnotes:

a For patients unable or unwilling to undergo BMD testing, fracture risk assessment without BMD using the Canadian FRAX tool (http://www.shef.ac.uk/FRAX/tood.jsp?country=19) can be helpful in guiding the need for BMD testing or treatment. This tool has been validated for fracture prediction in the Canadian population (Leslie WD, et al. Fracture risk assessment without bone density measurement in routine clinical practice. Osteoporosis International 2011).

b Definite non-traumatic vertebral fractures (>25% height loss with end-plate depression) are associated with 5-fold increased risk for recurrent vertebral fractures. Equivocal spine fractures are not strong indicators of osteoporosis.

c Major glucocorticoid use is prednisone (or equivalent) at a daily dose of 7.5 mg or greater for at least 90 days in the preceding year. Physiologic use for adrenal replacement is excluded.
## Appendix B₁  Anatomy of Bone Density Report

<table>
<thead>
<tr>
<th>INTERPRETATION</th>
<th>Fracture Risk: Moderate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s Risk:</td>
<td>9.3% 10-year risk of osteoporotic fracture</td>
</tr>
<tr>
<td></td>
<td>Risk factors included: age, sex, BMI, femoral neck T-score, spine T-score</td>
</tr>
<tr>
<td>Average Risk:</td>
<td>15% 10-year fracture risk for an average 70 year old female</td>
</tr>
<tr>
<td>BMD Category:</td>
<td>Osteoporotic</td>
</tr>
</tbody>
</table>

## RESULTS

| Femoral Neck Left       | BMD = 0.920 g/cm² |
|                         | T-Score = -0.7 |
| Total Hip Left          | BMD = 0.921 g/cm² |
|                         | T-Score = -0.7 |
|                         | Comparison: No change from previous (BMD 0.904 g/cm² in March 2008) but this remains a significant increase from baseline (BMD 0.890 g/cm² in July 2001). |
| Spine L1-3              | BMD = 0.871 g/cm² |
|                         | T-Score = -2.5 |
|                         | Comparison: No change from previous (BMD 0.834 g/cm² in March 2008) with a significant increase from baseline (BMD 0.764 g/cm² in July 2001). |
| VFA                    | No definite vertebral fractures are identified |

## COMMENTS

This patient's Fracture Risk is "Moderate" based upon an osteoporotic BMD category despite a lower calculated percent risk. Fracture risk reported above is for an untreated patient, and does not reflect the expected reduction in fracture risk from effective anti-resorptive therapy.
### Appendix B2

**Explanation of a Bone Density Report**

| Fracture Risk: | Fracture Risk is based on the patient's 10-year risk of major osteoporotic fracture (low <10%, moderate 10-19%, or high ≥20%) from WHO Fracture Risk Assessment Tool for Canada (FRAX) (see above).

Patient's Risk is estimated from age, sex, body mass index, prolonged glucocorticoid use, current smoking, high alcohol intake, parental hip fracture, rheumatoid arthritis, prior fragility fracture and femoral neck BMD.

Risk factors included is the list of positive risk factors used in the FRAX calculation. (Note: Lumbar spine BMD contributes to the calculation when lumbar spine T-score is 1 SD or more below the femoral neck T-score. If femoral neck BMD cannot be measured then 10-year fracture risk is estimated without BMD from clinical risk factors alone.)

Average Risk is the 10-year osteoporotic fracture risk for an average person of the same age and sex.

Note: Fracture Risk is not estimated in premenopausal women, men younger than age 50, or children.

| BMD Category: | Defined from the BMD and age.

After menopause in women or age ≥50 in men: non-osteoporotic (minimum T-score above -2.5) or osteoporotic (minimum T-score -2.5 or lower).

Premenopausal women, men younger than age 50, and children: normal for age (Z-score above -2.0) or reduced for age (Z-score -2.0 or lower).
Appendix C

### ADDITIONAL RISK FACTORS IN MODERATE RISK PATIENTS

<table>
<thead>
<tr>
<th>Factors that Warrant Consideration for Pharmacologic Therapy in Moderate Risk Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Additional vertebral fracture(s) (&gt;25% height loss with end-plate disruption identified on VFA or lateral spine X-ray)</td>
</tr>
<tr>
<td>• Previous wrist fracture in individuals older than age 65 or those with T-score &lt; -2.5</td>
</tr>
<tr>
<td>• Lumbar spine T-score much lower than femoral neck T-score</td>
</tr>
<tr>
<td>• Rapid bone loss</td>
</tr>
<tr>
<td>• Men on androgen deprivation therapy for prostate cancer</td>
</tr>
<tr>
<td>• Women on aromatase inhibitor therapy for breast cancer</td>
</tr>
<tr>
<td>• Long-term or repeated systemic glucocorticoid use (oral or parenteral) that does not meet the conventional criteria for recent prolonged systemic glucocorticoid use (i.e., ≥ 3 months cumulative treatment during the preceding year at a prednisone equivalent dose ≥ 7.5 mg daily)</td>
</tr>
<tr>
<td>• Recurrent falls defined as falling 2 or more times in the past 12 months</td>
</tr>
<tr>
<td>• Other disorders strongly associated with osteoporosis, rapid bone loss or fractures</td>
</tr>
</tbody>
</table>
Appendix D  Deciding on Pharmacological Treatment Post Fracture

Other fragility fractures after age 50 years

Fragility fracture of the hip or spine or more than one fragility fracture is automatically High Risk

Encourage basic bone health for all individuals over age 50, including: regular active weight-bearing exercise, calcium (diet and supplements) 1,200 mg daily, vitamin D: 800 – 2,000 IU daily, fall prevention strategies and INITIAL BMD TESTING

Fracture Risk Assessment

Low Risk Most patients with fragility fractures should be considered moderate or high risk

Repeat BMD in 1-3 years and reassess risk

No Other Risk Factors

Moderate Risk Further Risk Assessment

Other Factors that Warrant Consideration for Drug Therapy:
- Vertebral fracture(s) identified on VFA or lateral spine X-ray
- Individuals older than age 65
- Individuals with T-score ≤ -2.5
- Lumbar spine T-score much lower than femoral neck T-score
- Falling 2 or more times in the past 12 months
- Other disorders or medications associated with osteoporosis, rapid bone loss or fractures

High Risk

Treat or refer for treatment

Modified from www.osteoporosis.ca
## Appendix E  Medications Indicated for Fracture Prevention


Manitoba Drug Benefits and Interchangeability Formulary

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage Route</th>
<th>Dosage Frequency</th>
<th>Manitoba Formulary Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alendronate</td>
<td>oral</td>
<td>daily or weekly</td>
<td>Part 3 EDS:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Patients with:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>a) Osteoporotic fractures;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>b) Osteoporosis diagnosed with BMD by</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>any approved technology, e.g. a T-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>score of &lt; -2.5; OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>c) X-ray diagnosis of osteoporosis.</td>
</tr>
<tr>
<td>Risedronate</td>
<td>oral</td>
<td>daily or weekly</td>
<td>Part 3 EDS: as for alendronate</td>
</tr>
<tr>
<td>Raloxifene</td>
<td>oral</td>
<td>daily</td>
<td>Part 3 EDS: as for alendronate</td>
</tr>
<tr>
<td>Zoledronic acid</td>
<td>intravenous infusion</td>
<td>yearly</td>
<td>Part 3 EDS:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Female patients with post menopausal osteoporosis (PMO) at high risk for fracture and satisfy at least 2 of the following 3 criteria:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>◦ Age &gt; 75 years;</td>
</tr>
<tr>
<td>Denosumab</td>
<td>subcutaneous</td>
<td>every 6 months</td>
<td>Part 3 EDS: as for zoledronic acid</td>
</tr>
<tr>
<td>Teriparatide</td>
<td>subcutaneous</td>
<td>daily</td>
<td>Not covered</td>
</tr>
</tbody>
</table>


### Appendix F  Criteria used to assign a level of evidence to articles

<table>
<thead>
<tr>
<th>Level</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Studies of diagnosis</strong></td>
<td></td>
</tr>
</tbody>
</table>
| 1     | i. Independent interpretation of test results  
       | ii. Independent interpretation of the diagnostic standard  
       | iii. Selection of people suspected, but not known to have the disorder  
       | iv. Reproducible description of the test and diagnostic standard  
       | v. At least 50 people with and 50 people without the disorder |
| 2     | Meets 4 of the Level 1 criteria |
| 3     | Meets 2 of the Level 1 criteria |
| 4     | Meets 1 or 2 of the Level 1 criteria |
| **Studies of treatment and intervention** | |
| 1+    | Systematic overview of meta-analysis of randomized controlled trials |
| 1     | 1 randomized controlled trial with adequate power |
| 2+    | Systematic overview or meta-analysis of Level 2 randomized controlled trials |
| 2     | Randomized controlled trial that does not meet Level 1 criteria |
| 3     | Non-randomized controlled trial or cohort study |
| 4     | Before-after study, cohort study with non-contemporaneous controls, case-control study |
| 5     | Case series without controls |
| 6     | Case report or case series of < 10 patients |
| **Studies of prognosis** | |
| 1     | i. Inception cohort of patients with the condition of interest, but free of the outcome of interest  
       | ii. Reproducible inclusion and exclusion criteria  
       | iii. Follow-up of at least 80% of participants  
       | iv. Statistical adjustment for confounders  
<pre><code>   | v. Reproducible description of the outcome measures |
</code></pre>
<p>| 2     | Meets criterion i and 3 of the 4 of the Level 1 criteria |
| 3     | Meets criterion i and 2 of the 4 of the Level 1 criteria |
| 4     | Meets criterion i and 1 of the 4 of the Level 1 criteria |
| <strong>Grades of recommendation for clinical practice guidelines</strong> | |</p>
<table>
<thead>
<tr>
<th>Grade</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Need supportive level 1 or 1+ evidence plus consensus*</td>
</tr>
<tr>
<td>B</td>
<td>Need supportive level 2 or 2+ evidence plus consensus*</td>
</tr>
<tr>
<td>C</td>
<td>Need supportive level 3 evidence plus consensus</td>
</tr>
<tr>
<td>D</td>
<td>Any lower level of evidence supported by consensus</td>
</tr>
</tbody>
</table>

2010 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada: summary.  