Screening Bone Mineral Density (Average Risk)

RECOMMENDATIONS:

Postmenopausal women:

A. A bone mineral density (BMD) test by dual energy x-ray absorptiometry (DXA) is recommended for postmenopausal women age 65 and older who are not on drug treatment for osteoporosis. (Evidence based: B)

Please note: Those with clinically diagnosed osteoporosis (i.e., prior fragility fracture of the hip or spine) and those at very high risk of fracture (i.e., oral glucocorticoid users and other secondary causes of low BMD) are excluded from this problem formulation.

B. A bone mineral density (BMD) test by dual energy x-ray absorptiometry (DXA) is recommended for postmenopausal women under the age of 65 whose fracture risk is equal to that of a 65 year-old white woman with no additional risk factors (i.e., 10-yr hip fracture risk of 1.2% or a 10-yr major osteoporotic fracture risk of 9.3%).
This risk can be assessed by calculating a FRAX score prior to obtaining a BMD (http://www.shef.ac.uk/FRAX/). (Consensus based)

**Risk Factors for osteoporosis include:**

*Evidence-based: A*
- Fragility fracture after age 50
- History of frequent falling in the past year
- Smoking
- Weight < 127 lbs, or BMI < 21
- 1st degree relative with hip fracture

*Consensus-based:*
- 15 years of menopause or estrogen deficiency for women

Note that 60% of fracture risk can be accounted for by bone density and the remaining 40% is due to other factors (i.e., bone strength).

**Men:**

C. Screening is an option for men over age 70 with risk factors. (Consensus based)

**Optimal screening frequency:**

D. Consider the following time frames for follow up BMD based on T-score if patient risk factors do not change (Consensus based)

<table>
<thead>
<tr>
<th>T-score</th>
<th>Screening Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal to -1.49</td>
<td>10-15 years</td>
</tr>
<tr>
<td>-1.5 to -2.0</td>
<td>5 years</td>
</tr>
<tr>
<td>-2.0 to -2.49</td>
<td>2 years</td>
</tr>
</tbody>
</table>

**Testing for Women and Men at Very High Risk of Fracture**

**RECOMMENDATIONS:**

**Women and Men with prior fragility fracture**

* after the age of 50:

A. For women and men with a fragility fracture of the hip or spine (i.e., clinical osteoporosis) after the age of 50: Initiating treatment directly without undergoing testing with BMD is recommended. (Consensus based)

For women and men with other fragility fractures (e.g., wrist or humerus) after the age of 50: Initiating treatment directly without undergoing testing with BMD is an option. (Consensus based)

*A fragility fracture is a low-trauma fracture resulting from a fall from standing height or less.*

**Women and Men on oral glucocorticoid therapy***:

B. For women and men on oral glucocorticoid therapy: Initiating treatment with bisphosphonates directly without undergoing testing with BMD is an option (Evidence based: B)
* >5 mg/day prednisone or equivalent for >3 months duration

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### Bone Mineral Density Screening Measurement Sites

**RECOMMENDATIONS:**

A. The hip and lumbar spines are recommended measurement sites for BMD to predict risk of osteoporotic fracture in women and men. (Evidence-based: B)

B. BMD of the forearm is an option for patients in whom hip and spine BMD cannot be measured or interpreted. (Evidence-based: B)

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### Lifestyle Changes

**RECOMMENDATIONS:**

A. The following lifestyle changes are recommended for all women and men to reduce the risk of osteoporosis:
   - Exercise – regular weight-bearing and muscle-building exercise
   - Smoking cessation
   (Consensus-based)

B. Home safety proofing is recommended for postmenopausal women and men at risk of falling.* (Consensus-based)

C. The routine use of hip protectors is not recommended as an intervention for reducing the risk of hip fractures in postmenopausal women and men aged 50 and older. (Evidence-based D)

*Home safety proofing includes removing rugs, adding grab bars, establishing adequate lighting (i.e. nightlights), and securing electrical cord placement.

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### Preventive Measures

<table>
<thead>
<tr>
<th>Population</th>
<th>Recommendations</th>
</tr>
</thead>
</table>
| **Women or Men with and without Osteoporosis** | A. Total daily dietary intake of 900 mg calcium is recommended for all pre- or post-menopausal women and older men (Consensus-based)  
B. Total daily intake of at least 1000 IU/day vitamin D is recommended for all pre- or postmenopausal women and men over age 50. (Evidence based: B) |
| **Women and Men Without Osteoporosis**         | Hormone therapies solely for the prevention of osteoporosis is not recommended. (Consensus-based) |
| **Postmenopausal Women and Men**               | Diagnosis by:                                                        |
| Diagnosed with Osteoporosis | Women aged 65 or older with a diagnosis of osteoporosis (T-score < −2.5). (Evidence–based: A)  
Osteopenia with 10 year risk of hip fracture >3% or a 10 year major osteoporotic fx risk >20% per FRAX calculation (Consensus-based)  
Consider checking VitD level and treat deficiencies if present  
Pharmacological Treatment  
Bisphosphonates are 1st line treatment options  
- Alendronate 70mg once weekly is preferred  
- If alendronate is NOT tolerated:  
  - risedronate (Actonel) 35 mg weekly (NF review required for commercial members), OR  
  - zoledronic acid (Reclast) 5mg IV once yearly can be considered if contraindications/intolerances to oral bisphosphonates  
The following are treatment options if the above bisphosphonates are contraindicated or not tolerated. It is recommended treatment be discussed with endocrinology before ordering any of the below agents.)  
- Once monthly oral ibandronate (Boniva) -- Unlike other bisphosphonates, evidence has NOT demonstrated a statistically significant decrease in the incidence of hip fractures.  
- Teriparatide (Forteo)  
- Raloxifene (Evista) – Should only be considered if low risk of thrombotic complications. Evidence has NOT demonstrated a statistically significant decrease in the incidence of hip fractures.  
- Calcitonin (Fortical) has NOT demonstrated a statistically significant decrease in the incidence of hip fractures.  
- Denosumab (Prolia)  

| Premenopausal Women with a T-score at or below -2.5 | There is insufficient evidence to recommend for or against treatment with any prescribed pharmacological therapy for premenopausal women.* (Evidence based: I)  
*Bisphosphonates are not recommended in women of childbearing age without adequate contraception.  

| Women and Men taking Corticosteroid Therapy | Bisphosphonates: Alendronate 70 mg once weekly is recommended as first-line therapy for women and men taking oral corticosteroid medication (>5 mg/day prednisone or equivalent, for >3 months duration). If alendronate is not tolerated, consider risedronate (Actonel) 35 mg once weekly (Non-Formulary).*† (Evidence based: B)  
*Bisphosphonates are not recommended in women of childbearing age without adequate contraception.  
†Bisphosphonates should be used with caution in patients with chronic kidney disease and reduced GFR.  

Treatment Durations (consensus based)

Clinical considerations:
For patients who have taken bisphosphonates for >5 years, the decision to continue or discontinue treatment may take the following issues into account:

- For patients at lower risk of fragility fracture, the risk of rare but serious atypical femur fractures may outweigh the relatively small additional reduction in fragility fracture risk conferred by continuing treatment.
- For patients at higher risk of fragility fracture, the benefit of reduced fragility fracture risk may outweigh the potential harms of long term therapy.
- Based on one small study (the FLEX trial), continuous use of alendronate for 10 years reduced the risk for clinical vertebral fracture from ~1 in 20 to ~1 in 40, compared to stopping after 5 years of treatment.¹
- There is an association between increased duration of bisphosphonate use and increased risk for atypical femur fracture. The risk ranges from ~1 per 50,000 for < 2 years of treatment to ~1 per 1,000 for 8-10 years of treatment.

For further consensus based guidance, Drug Holiday Considerations

Monitoring Treatment

RECOMMENDATIONS:
A. There is insufficient evidence to recommend assessing bone density while on treatment
B. There is insufficient evidence on routine bone turnover testing with biochemical markers [N-telopeptide (NTx) and C-telopeptide (CTx)] for monitoring women and men taking antiresorptive therapy for osteoporosis. (Evidence based: I)
C. There is insufficient evidence for routine bone turnover testing with biochemical markers [N-telopeptide (NTx) or C-telopeptide (CTx)] to assess a patient’s risk for developing osteonecrosis of the jaw (ONJ) while on bisphosphonate therapy. (Consensus-based)

Evaluation of secondary causes

A. History and physical are critical in evaluation of secondary causes
B. The following lab tests may also be considered (consensus based):
   - CBC
   - Comprehensive metabolic profile
   - TSH with reflex T4
   - PTH panel
   - 25 hydroxy Vit D level
   - For males- testosterone level
   - Consider 24 hr urine calcium

For all patients with secondary causes, consider endocrinology/other appropriate consult using “p advice endo”.

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## Supplemental Information on Secondary Causes of Bone Loss


(note that these are not listed in order of frequency or clinical importance)

| Medications | • Oral or intramuscular use of glucocorticoids for > 3 months  
|            | • Aromatase inhibitors: anastrozole (Arimidex), letrozole (Femara), exemestane (Aromasin)  
|            | • Long-term use of certain anticonvulsants (carbamazepine, phenobarbital, phenytoin, primidone, valproic acid)  
|            | • Heparin  
|            | • Cytotoxic agents  
|            | • Gonadotropin-releasing hormone agonists or analogues  
|            | • Intramuscular medroxyprogesterone contraceptive  
|            | • Immunosuppressives (eg, cyclosporine, tacrolimus)  
|            | • Excessive thyroxine doses |
| Genetic Disorders | • Osteogenesis imperfecta  
|                  | • Thalassemia  
|                  | • Hypophosphatasia  
|                  | • Hemochromatosis |
| Disorders of calcium balance | • Hypercalciuria  
|                  | • Vitamin D deficiency |
| Endocrinopathies | • Cortisol excess  
|                  | • Cushing’s syndrome  
|                  | • Gonadal insufficiency (primary and secondary)  
|                  | • Hyperthyroidism  
|                  | • Type 1 diabetes mellitus  
|                  | • Primary hyperparathyroidism |
| Gastrointestinal disease | • Chronic liver disease (eg, primary biliary cirrhosis)  
|                  | • Malabsorption syndromes (eg, celiac disease, Crohn’s disease)  
|                  | • Total gastrectomy  
|                  | • Billroth I gastroenterostomy |
| Other disorders and conditions | • Multiple myeloma  
|                  | • Lymphoma and leukemia  
|                  | • Systemic mastocytosis  
|                  | • Nutritional disorders (eg, anorexia nervosa)  
|                  | • Rheumatoid arthritis |
For all patients with secondary causes, consider endocrinology/other appropriate consult using “p advice endo”.

Guideline Metadata

Target Population

Women over age 65 years and women age 50 and over with risk factors for osteoporosis.
Men over age 70 with risk factors or men age 50 and over at high risk due to other conditions (e.g., chronic glucocorticoid use).

Rationale for Guideline

This is a consensus-based guideline. Although many studies have been published about osteoporosis treatment in postmenopausal women, only 1 trial in early postmenopausal women has evaluated the effectiveness of osteoporosis screening on fracture outcome (Barr RJ Osteoporos Int (2010) 21:561–568). Therefore, direct evidence that screening improves outcomes is limited. Recommendation for screening is based on the following three points:

1. The risk of osteoporosis increases with advancing age particularly for postmenopausal women
2. Accurate screening tests for osteoporosis exist and decreased BMD does strongly predict fracture risk
3. High quality trials have demonstrated the efficacy of bisphosphonates in preventing hip fractures and selective estrogen-receptor modulator medications in preventing vertebral fractures in women with osteoporosis.

The average mortality rate in the first year following a hip fracture is approximately 25% and ~25% of previously ambulatory hip fracture survivors require subsequent long-term care. Despite this impact on premature morbidity and mortality and recommendations by many organizations including the USPSTF, assessment of fracture risk and screening for osteoporosis is not routine.

Definition

Osteoporosis is defined as a skeletal disorder characterized by compromised bone strength predisposing to an increased risk of fracture. Bone strength reflects both bone density and bone quality.

Source of Evidence

- See National Osteoporosis Guideline Nov 2010 for problem formulations, evidence discussion and evidence tables. This guideline has been modified to align with formulary and operational issues in KPCO.
Settings for Application

Internal Medicine, Family Practice, Ob/Gyn, Radiology, Endocrinology, Nephrology, Rheumatology and other specialties as appropriate

These procedures are informational only and are not intended or designed to substitute the reasonable exercise of independent clinical judgment by the practitioner in any particular set of circumstances for each patient encounter. The guidelines are flexible and are intended for use as a resource for integration with a sound exercise of clinical judgment. They can be used to create an approach to care that is unique to the needs of each individual patient.