Clinical Practice Guideline for Osteoporosis Screening and Treatment

Osteoporosis is a condition of decreased bone mass, leading to bone fragility and an increased susceptibility to fractures. While osteoporosis is often thought of as an older person’s disease, it can strike at any age.

Of the 10 million Americans estimated to have osteoporosis, eighty percent of those affected by this bone disease are women, while twenty percent are men. Given its influence on the risk of fracture, osteoporosis may significantly affect life expectancy and quality of life.

**Diagnosis**

The diagnosis of osteoporosis is based upon measurements obtained from densitometry. This measurement is called bone mineral density test or BMD.

The result of this BMD test is reported as a T-score. According to the criteria established by the World Health Organization (WHO), osteoporosis is defined as a BMD that lies 2.5 standard deviations or more below that of a healthy young female. However, the use of the T-score alone is inappropriate in identifying patients at high fracture risk in need of intervention, since age is as great a risk factor as BMD.

BMD test results also includes a Z-score which compares a patients bone density to what is normal in someone of the same age and body size. Z-scores can help identify if there may be an underlying metabolic disorder contributing to osteoporosis.

Practitioners generally do not use a Z-score to diagnose osteoporosis in post-menopausal women and men age 50 or older. Among older adults low bone mineral density is common, so Z-scores can be misleading as this group of people are at greatest risk of breaking a bone.

A new method called **absolute fracture risk** helps healthcare providers and their patients aged 40-90 make better decisions about when to take an osteoporosis medication. Absolute fracture risk estimates a person’s chance of breaking a bone over a period of 10 years, and is most applicable when done prior to starting therapy. Once therapy is initiated, the calculated fracture risk is less applicable. Special web based tools can be utilized to assist in calculating this absolute fracture risk. [http://www.sheffield.ac.uk/FRAX/tool.jsp?country=9](http://www.sheffield.ac.uk/FRAX/tool.jsp?country=9)

The use of BMD measurements together with clinical risk factors provides practitioners with a mechanism for the effective and efficient delivery of health care in the management of osteoporosis.
**Risk factors for Osteoporosis and Osteoporotic Fracture**

- Women aged ≥ 65
- Caucasian or Asian race
- Low body weight; (< 127 lbs or BMI ≤ 20)
- Family history of osteoporosis
- Personal history of fragility fracture and/or fracture as an adult
- History of fragility fracture in a first-degree relative
- Long-term use of glucocorticoids or others *See table 2*
- Current tobacco smoking
- Alcohol in amounts > 2-3 drinks per day
- Estrogen deficiency at an early age (< 45yrs)
- Low calcium intake (lifelong) and/or Vitamin D deficiency
- Sedentary lifestyle
- Testosterone/estrogen depletion in men
- Increased likelihood of falling
  - Dementia
  - Poor health/frailty
  - Recent falls
  - Poor vision

After menopause, all women should be evaluated clinically for osteoporosis risk in order to determine the need for BMD testing. In general, the more risk factors a woman has, the greater her risk of fracture.

**Table 1**

| Medical Conditions that may be associated with an increased risk of osteoporosis |
|-------------------------------|-------------------|------------------|
| AIDS/HIV                     | Hyperparathyroidism | Pernicious anemia |
| Amyloidosis                  | Hypogonadism, primary and secondary (e.g., amenorrhea) | Rheumatoid arthritis |
| Ankylosing spondylitis       | Hypophosphatasia   | Severe liver disease, especially primary biliary cirrhosis |
| Chronic obstructive pulmonary disease | Idiopathic scoliosis | Spinal cord transsection |
| Congenital porphyria          | Inadequate diet    | Sprue            |
| Cushing’s syndrome           | Inflammatory Bowel Disease | Stroke (CVA) |
| Eating disorders (e.g., anorexia nervosa) | Insulin-dependent diabetes mellitus | Thalassemia |
| Female athlete triad         | Lymphoma and leukemia | Thyrotoxicosis |
| Gastrectomy                  | Malabsorption syndromes | Tumor secretion of parathyroid hormone-related peptide |
| Gaucher’s Disease            | Mastocytosis       | Weight loss      |
| Hemochromatosis              | Multiple myeloma   |                  |
| Hemophilia                   | Multiple sclerosis |                  |
### Table 2

<table>
<thead>
<tr>
<th>Drugs that may be associated with reduced bone mass in adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum</td>
</tr>
<tr>
<td>Anticonvulsants (Phenobarbital, phenytoin)</td>
</tr>
<tr>
<td>Cytotoxic drugs</td>
</tr>
<tr>
<td>Glucocorticosteroids and adrenocorticotropic</td>
</tr>
</tbody>
</table>

### Bone mineral density (BMD) is recommended for
- Women aged 65 or older.
- Women age ≥ 60 with risk factors.
- Younger postmenopausal women with one or more risk factors, (other than being female).
- Men aged 70 or older
- May consider screening Men > 50 with risk factors

<table>
<thead>
<tr>
<th>Normal</th>
<th>Osteopenia</th>
<th>Osteopenic + other risk factors</th>
<th>Osteoporosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal BMD (Bone Mineral Density) is a T score greater than −1.0</td>
<td>BMD T score less than or equal to −1.0 but greater than −2.5 is considered to be osteopenic</td>
<td>BMD T score less than −2.0 or less than −1.5 with other risk factors for fracture</td>
<td>Hx of fragility fracture or a BMD T score less than or equal to −2.5 at any site (lumbar spine, femoral neck, greater trochanter, or total hip)</td>
</tr>
</tbody>
</table>

- Discuss eliminating any risk factors possible
- Lifestyle and Dietary changes as listed below should be encouraged for all

### Lifestyle and dietary changes
- Early intervention for individuals under the age of 20 to receive adequate amounts of calcium and vitamin D to promote healthy bone formation.
- Regular exercise program including weight-bearing and muscle-strengthening exercises.
- Avoidance of tobacco use and excessive alcohol intake.
- Adequate intake of elemental calcium (at least 1200 - 1500 mg/day, including supplements if necessary).
- Adequate intake of vitamin D (400-800 IU/day for individuals at risk of deficiency).
- Healthy Diet / Nutritional guidance to reach a healthy BMI.
- Fall Prevention.
Goals / Treatment
The overall health of a person’s bones is determined by many things, ranging from how well the bones were formed as a youth to the person’s physical activity level over the years. During the first 20 years of life the formation of bone is the most important factor. After that point, it is the prevention of bone loss that becomes most important. Anything that causes decreased bone formation early in life, or loss of bone structure later in life, may lead to the disease.

If osteoporosis is diagnosed, medication may be prescribed to stop bone loss, increase bone density, and/or rebuild bone—essentially strengthening them from the inside out. It takes a while for enough minerals to deposit to show a dramatic difference on DEXA testing.

No studies have evaluated the optimal intervals for repeated screening. A minimum of 2 years may be needed to reliably measure a change in bone mineral density; however, longer intervals may be adequate for repeated screening to identify new cases of osteoporosis. Early diagnosis and treatment for osteoporosis is the best defense against broken bones.

Pharmacologic Options
Medication Management for both Prevention and Treatment of osteoporosis should be considered on an individual basis, as determined by the patient’s overall assessment and at the Practitioner’s discretion.

Criteria for use of a medication are driven by formulary status of the drug (subject to step therapy), formulary (open, benefit-driven, closed), and MAC policies. Indication for use shall be evaluated on a case by case basis.

For individuals who are candidates for medication management in addition to therapeutic lifestyle changes, medication options may include but are not limited to:

- Alendromate sodium (oral)
- Actonel (oral)
- Boniva (oral)
- Miacalcin (intranasal)
- Boniva (IV and oral)
- Reclast (IV)
- Forteo (subcutaneous injections)
- Prolia (subcutaneous injections)

Neither Reclast nor Boniva has been shown to be superior to oral alendronate (Fosamax®) in terms of efficacy (fracture reduction).

Forteo is a Formulary medication whose use is reserved for treating women at high risk of fracture, including those with a very low BMD (T-score worse than -3.0 with a prior fragility fracture). Forteo requires prior authorization.

Reclast is available as a generic zoledronate. Treatment course is usually 5 to 7 years.

Prolia may be useful for post-menopausal osteoporosis. Length of treatment is more open-ended.
Reasons for DEXA Scan prior to the recommended two (2) years

1. Monitoring of patients with long term (> than three months) steroid therapy of 7.5 mg or greater per day, for more than three months or a patient taking an approved osteoporosis drug. *Drugs such as calcium, vitamin D and estrogen replacement therapy would not support the necessity of more frequent testing.

2. A confirmatory baseline bone mass measurement to permit monitoring may be allowed if the initial test was performed with a technique that is different from the proposed monitoring method. Thus, if the initial test was performed using bone sonometry and monitoring using bone densitometry is anticipated, coverage would be allowed for baseline measuring using bone densitometry.

References:

National Institutes of Health, Osteoporosis and Related Bone Diseases National Resource Center webpage at http://www.osteo.org

National Osteoporosis Foundation webpage at http://www.nof.org

EndocrineWeb; Making the Diagnosis of Osteoporosis found at www.endocrineweb.com/osteoporosis/diagnosis.html

World Health Organization: Diagnosis Criteria for Osteoporosis


Medical Review Criteria - Apollo
Chief Medical Officer  
Medical Associates Clinic & Health Plans

<table>
<thead>
<tr>
<th>Original:</th>
<th>Revised:</th>
<th>Reviewed:</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/99</td>
<td>10/03</td>
<td>07/08</td>
</tr>
<tr>
<td>11/99</td>
<td>09/04</td>
<td>11/09</td>
</tr>
<tr>
<td>02/00</td>
<td>01/05</td>
<td>01/10</td>
</tr>
<tr>
<td>03/01</td>
<td>01/06</td>
<td>06/11</td>
</tr>
<tr>
<td>03/02</td>
<td>06/07</td>
<td>06/12</td>
</tr>
</tbody>
</table>

Reviewed: 05/14  
Reviewed: 12/15