



## 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, 80% of those affected by this bone disease are women, while 20% are men. Although the number of men with Osteoporosis is lower than the number of women with the disease, the incidence of fractures in males is higher than the risk of fracture in women, at least partially owing to gender inequalities in testing and treatment. Given its influence on the risk of fracture, Osteoporosis may significantly affect life expectancy and quality of life.

Recommendations are to screen women over age 65 and men over age 70. The National Osteoporosis Foundation (NOF) guideline recommends screening men and women age 50 and older who are affected by 1 of the 90 predisposing conditions, diseases, or medications identified in the guideline (<https://my.nof.org/bone-source/education/clinicians-guide-to-the-prevention-and-treatment-of-osteoporosis>).

### **Risk Factors For Osteoporosis And Osteoporotic Fractures:**

- Women aged  $\geq 65$
- Caucasian or Asian race
- Low body weight; ( $< 127$  lbs or  $BMI \leq 20$ )
- 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 ( $< 45$  yrs)
- Low calcium intake (lifelong) and/or Vitamin D deficiency
- Sedentary lifestyle
- Testosterone/Estrogen depletion in men
- Increased risk of falling due to:
  - 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**

<b>Medical Conditions That May Be Associated With An Increased Risk Of Osteoporosis</b>		
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 transection
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	Multiple Sclerosis
Hemophilia		

**Table 2**

<b>Drugs That May Be Associated With Reduced Bone Mass In Adults</b>		
Cytotoxic drugs (chemotherapy)	Gonadotropin-releasing hormone agonists/antagonists	Aromatase inhibitors (tamoxifen)
Anticonvulsants (phenobarbital, phenytoin)	Immunosuppressants (cyclosporine)	Glucocorticosteroids
Long-term Heparin use		

## Diagnosis:

A dual-energy X-Ray absorptiometry (DXA) measures bone mineral density (BMD) which aids in the diagnosis of Osteoporosis. The result of this BMD test is reported as a **T-score**. A BMD-defined T-score alone of less than or equal to -2.5 calculated at the lumbar spine, femoral neck, or hip is a threshold for treatment and diagnosis. However, it is important to note additional screening and treatment of Osteoporosis should not be withheld on the basis of T-score alone because DXA measurements assess the density of bone, not the quality nor strength of bone. BMD test results also includes a **Z-score** which compares a patient's 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. 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 (FRAX)** 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. A FRAX derived 10-year hip fracture risk estimate of  $>$  or  $=$  to 3% or a major osteoporotic fracture (hip, spine, shoulder, forearm) risk of  $>$  or  $=$  to 20% and/or history of a hip or spine fracture supports the diagnosis of Osteoporosis. **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>

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.

## Bone Mineral Density (BMD) Is Recommended For:

- Men aged 70 or older
- Women aged 65 or older
- Men or women age 50 or older with one or more risk factors, (**other than being female for women**).
- Men who will be receiving androgen deprivation therapy, typically associated with the diagnosis of metastatic prostate cancer, should have a baseline measurement of bone mineral density

Normal	Osteopenia	Osteopenic + other risk factors	Osteoporosis
Normal BMD (Bone Mineral Density) is a T score greater than -1.0	BMD T score less than or equal to -1.0 but greater than -2.5 is considered to be Osteopenic	BMD T score less than -2.0 or less than -1.5 with other risk factors for fracture	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)

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

### **Reasons For DEXA Scan Prior To The Recommended 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.

### **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 for men age 50-70 (1000mg per day)
  - ◆ Of note, the body can only absorb 500 mg of calcium at a time, so splitting the dose as twice daily offers maximal benefit
- ◆ Adequate intake of elemental Calcium for women age 51 and older and men age 71 and older (1200mg per day)
- ◆ Adequate intake of Vitamin D (400-800 IU/day for individuals at risk of deficiency).
- ◆ Adequate intake of Vitamin D in both men and women over age 50 (800-1000IU per day)
- ◆ Certain patients may require more Vitamin D and dosing should be individualized based on health history and laboratory monitoring.
- ◆ All patients are screened for baseline Calcium and Vitamin D levels before initiation of treatment, at the initial follow-up visit post start of therapy, and yearly thereafter.
- ◆ Deficiencies or excesses are treated on an as-needed basis.
- ◆ Healthy Diet / Nutritional guidance to reach a healthy BMI.
- ◆ Fall Prevention.
- ◆ Care should be taken in patients with bone loss to maintain a neutral position of the spine and avoid activities that involve bending, lifting, and twisting because this has been shown to induce vertebral body compression fractures.

### **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, in some cases subject to step therapy) 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:

- **Bisphosphonates: decrease osteoclastic activity; increasing bone mass and reducing incidence of fractures**
  - The most improvement in BMD is seen in the first 3-5 years following initiation
  - The duration of treatment ranges from 3-10 years depending on severity of disease, patient risk profile, and expert opinion.
  - **Types of Bisphosphonates include:**
    - Fosamax (alendronate,oral)
    - Actonel (risedronate, oral)
    - Boniva (ibandronate, oral & IV)
    - Reclast (zoledronic acid IV):
      - Treatment typically given once every 5 years
  - Neither **Reclast** nor **Boniva** has been shown to be superior to oral **alendronate (Fosamax)** in terms of efficacy (fracture reduction).
- **Monoclonal Antibody: prevents bone breakdown by blocking osteoclastic activity**
  - Severe osteoclastic rebound effect is seen with abrupt cessation of these medications leading to subsequent increase in vertebral compression fracture risk
  - The rebound increase in bone resorption rate lasts for 24 months after cessation of therapy.
  - Given to patients at higher risk of fracture or in patients who can't take or tolerate bisphosphonates.

- Must be administered by a healthcare professional
- **Type of Monoclonal Antibody-Bone Modifying agent:**
  - Prolia (denosumab, subcutaneous injections):
    - May be useful for post-menopausal Osteoporosis.
    - Length of treatment is more open-ended. If treatment is discontinued, patient will need to use another medication to prevent bone loss and vertebral fracture.
- **Type of Monoclonal Antibody-Sclerostin Inhibitor: stimulates bone formation and to a lesser degree decreases bone resorption**
- Approved by the FDA 2019 and is indicated in higher risk individuals; not indicated for first-line treatment. Patients appropriate for this medication include those with multiple fragility fractures, high risk patients who cannot tolerate any other Osteoporosis therapies, and those with failure of other medications (i.e. fracture with loss of BMD in spite of compliance with medication)
- **Type of Sclerostin Inhibitor:**
  - Evenity (romosozumab, subcutaneous injection)
- **Selective Estrogen Receptor Modulator (SERM): inhibits osteoclastic activity, resulting in decreased bone resorption, resulting in a reduced spinal fracture risk**
  - **Type of SERM:**
    - Evista (raloxifene, oral)
- **Anabolic Agents: stimulate osteoblastic activity inducing bone formation**
  - Forms of human PTH given to patients at higher risk of fracture
  - Reserved for women at high risk of fracture, including those with a very low BMD (T-score worse than -3.5 or T-score worse than -2.5 with a prior fragility fracture)
  - Self-administered daily for a maximum of 2 years
  - Benefits of this medication are quickly lost once therapy has been discontinued; patients should start bisphosphonate or another medication to maintain the bone density gained while on one of these medications
  - **Types of Anabolic Agents:**
    - Forteo (teriparatide) and Tymlos (abaloparatide) both subcutaneous injections:

**References:**

U.S. Department of Health & Human Services: AHRQ, Agency for Healthcare Research and Quality, U.S. Preventive Services Task Force (USPSTF); Screening for Osteoporosis in Postmenopausal Women.

National Institutes of Health, Osteoporosis and Related Bone Diseases National Resource Center webpage at <http://www.osteoporosis.gov>

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

EndocrineWeb; Making the Diagnosis of Osteoporosis found at [www.endocrineweb.com/osteoporosis/diagnosis.html](http://www.endocrineweb.com/osteoporosis/diagnosis.html)

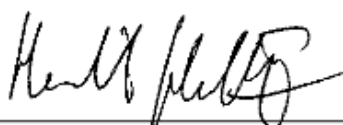
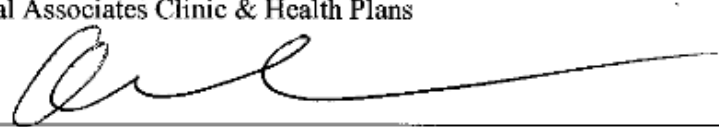
World Health Organization: Diagnosis Criteria for Osteoporosis

North American Menopause Society (NAMS) 2006 position statement.

Physician’s Guide to Prevention and Treatment of Osteoporosis developed by the National Osteoporosis Foundation in collaboration with the American Academy of Orthopaedic Surgeons, Physical Medicine and Rehabilitation, Obstetricians and Gynecologists, American College of Radiology and Rheumatology, American Geriatrics Society, American Medical Association, International Society for Physical Medicine and Rehabilitation and the Endocrine Society. 2003.

Medical Review Criteria – Apollo

“Osteoporosis Screening and Treatment: A Collaborative Approach”; The Journal for Nurse Practitioners (JNP) Volume 16, Issue 1, P60-63, January 01, 2020

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