



Osteoporosis Information

Bone Mineral Density testing (BMD)

BMD measurement can be used to establish or confirm a diagnosis of osteoporosis and predict future fracture risk. BMD has a continuous, graded, inverse relationship to the risk of fracture: the lower the BMD, the greater the fracture risk. Many individuals have slight builds, and their BMD will generally be lower.

Measurements of BMD at any skeletal site have value in predicting fracture risk. A variety of densitometers are in clinical use and provide reliable assessment of fracture risk. However, hip BMD is the best predictor of hip fractures, and it predicts fractures at other skeletal sites. Thus, the recommendations made here are based on measurements of the hip.

BMD is expressed as a relationship to two norms: the expected BMD for the patient's age and sex (Z-score), or for "young normal" adults of the same sex (T-score). The difference between the patient's score and the norm is expressed in standard deviations (SD) above or below the mean. (Usually, 1 SD equals 10 to 20% of the bone density value.) T-scores decline in parallel with the steady drop in bone mass that occurs with aging. DEXA T-scores are usually used for clinical decision making.

Defining Osteoporosis by BMD

The World Health Organization has established the following definitions based on bone mass measurement at the spine, hip, or wrist in white postmenopausal women:

- Normal: BMD is within 1 SD of a "young normal" adult (T-score at -1.0 and above)
- Osteopenia: BMD is between 1 and 2.5 SD below that of a "young normal" adult (T-score between -1 and -2.5)
- Osteoporosis: BMD is 2.5 SD or more below that of a "young normal" adult (T-score at or below -2.5). Women in this group who have already experienced one or more fractures are deemed to have severe or "established" osteoporosis.

Although these definitions are necessary to establish the prevalence of osteoporosis, they should not be used as the sole determinant of treatment decisions.

Who should be tested?

The decision to test for BMD should be based on an individual's risk profile, and testing is never indicated unless the results could influence a treatment decision.

BMD testing should be performed on:

- All women aged 65 and older regardless of risk factors. Medicare covers BMD
- Younger postmenopausal women with one or more risk factors (other than being white, postmenopausal, and female).
- Postmenopausal women who present with fractures (to confirm diagnosis and determine disease severity). Estrogen deficient women at clinical risk for osteoporosis
- Individuals with vertebral abnormalities
- Individuals receiving, or planning to receive, long-term glucocorticoid (steroid) therapy
- Individuals with primary hyperparathyroidism
- Individuals being monitored to assess the response or efficacy of an approved osteoporosis drug therapy

BMD testing techniques

All of the tests described below are good predictors of future fracture.

- Dual x-ray absorptiometry (DEXA). DEXA can be used to measure BMD in the spine, hip, or wrist, the most common sites for osteoporotic fractures. A DEXA measurement can be completed in a few minutes with radiation exposure that is approximately one tenth that of a standard chest x-ray. Hip BMD is the best predictor of hip fracture risk. Central DEXA of the hip and/or spine is the preferred measurement for definitive diagnosis.
- Peripheral dual x-ray absorptiometry (PIXI) and single-energy x-ray absorptiometry (SXA). These techniques measure bone density in the forearm, finger, and sometimes the heel.
- Quantitative computed tomography (QCT). QCT measures trabecular and cortical bone density at several skeletal sites, but is most commonly used to measure trabecular bone density in the spine. It is also possible to measure trabecular and cortical bone density in the periphery by pQCT (peripheral QCT).
- Ultrasound densitometry. Ultrasound assesses bone in the heel, tibia, patella, or other peripheral sites where the bones are relatively superficial. Ultrasound measurements are generally not as precise as DEXA or SXA, but appear to predict fracture risk as well as other measures of bone density.

Biochemical markers

Markers of bone turnover in the serum or urine are sometimes used to help assess risk of fracture, predict bone loss, or assess response to antiresorptive therapy. However, biochemical marker tests cannot replace BMD testing.

How can osteoporosis and fractures be prevented?

- Calcium: Increasing dietary calcium is the first-line approach, but calcium supplements should be used when an adequate dietary intake cannot be achieved. Postmenopausal American women typically consume about 600 mg per day of calcium in their diets.
- Vitamin D: Vitamin D plays a major role in calcium absorption and bone health. Chief dietary sources of vitamin D include vitamin-D-fortified milk (400 IU per quart) and cereals (40 to 50 IU per serving), egg yolks, salt-water fish, and liver.
- Regular weight-bearing exercise: Exercise reduces the risk of falls and fractures. Among its many health benefits, weight-bearing and muscle-strengthening exercise can improve agility, strength, and balance, which may reduce the risk of falls. In addition, exercise may increase bone density modestly.
- Fall prevention: In addition to exercise as described above, strategies to reduce risk of falling include, but are not limited to, checking and correcting vision and hearing, evaluating any neurological problems, reviewing prescription medications for side effects that may affect balance and stability and providing a check list for improving safety at home. Wearing undergarments with hip protectors (brands: Safehip®, HIPS®, HipGuard®, ImpactWear®) may protect an individual from injuring the hip in the event of a fall.
- Restriction of alcohol and tobacco: The use of tobacco products is detrimental to the skeleton as well as to overall health. Moderate alcohol intake has no known negative effect on bone and may even be associated with slightly higher bone density and lower risk of fracture in postmenopausal women. However, excessive alcohol intake is detrimental to bone health and requires treatment when identified.

Who should be treated?

Initiate therapy to reduce fracture risk in women with

- BMD T-scores below -2.0 by central DEXA with no risk factors
- BMD T-scores below -1.5 by central DEXA with one or more risk factors
- A prior vertebral or hip fracture

Osteoporosis medications

U.S. Food and Drug Administration-approved pharmacologic options for the prevention and/or treatment of postmenopausal osteoporosis include, in alphabetical order: bisphosphonates (alendronate, risedronate), calcitonin, estrogens (estrogen and/or hormone therapy), parathyroid hormone [PTH(1-34)], and selective estrogen receptor modulators or SERMs (raloxifene). Please see the Physicians Desk Reference for more detailed information about these drugs and for their other indications (e.g., bisphosphonate indications for male osteoporosis and for glucocorticoid-induced osteoporosis).

- Bisphosphonates (alendronate or Foxamax, risedronate or Actonel),
Alendronate is approved by the FDA for the prevention (5 mg daily and 35 mg weekly) and treatment (10 mg daily and 70 mg weekly) of osteoporosis in postmenopausal women. Controlled clinical trials indicate that over a 3 to 4 year period alendronate increases bone mass and reduces the incidence of vertebral, hip and all non-vertebral fractures by 50%.
Risedronate (5 mg daily dose and 35 mg weekly) is approved by the FDA for the prevention and treatment of postmenopausal osteoporosis. Controlled clinical trials indicate that risedronate increases bone mass and reduces the risk of vertebral fractures by 40% and all non-vertebral fractures by 30% over a 3-year period.
Side Effects and Administration of Bisphosphonates
Clinical trials have found the incidence of side effects in patients taking alendronate and risedronate to be no different than the incidence in the placebo groups. However, clinical experience suggests that some patients may experience upper gastrointestinal disorders such as dysphagia, esophagitis, and esophageal or gastric ulcer. Alendronate and risedronate must be taken after a prolonged fast with 8 ounces of water (no other liquid), at least 30 minutes before eating or drinking. Patients should remain upright (sitting or standing) during this interval as well.
- Calcitonin (Miacalcin®)
Salmon calcitonin is FDA-approved for the treatment of osteoporosis in women who are at least 5 years postmenopausal. It is delivered as a single daily intranasal spray that provides 200 international units (IU) of the drug. Subcutaneous administration by injection also is available. Controlled clinical trials indicate that calcitonin decreases the vertebral fracture rate by 54%. In the single large trial, however, it lowered vertebral fracture risk by 21%. It did not alter the non-vertebral fracture rate in any of the studies. Calcitonin is generally safe and well tolerated, although some patients experience rhinitis and, rarely, epistaxis.
- Estrogen/Hormone Therapy (HRT)
HRT is approved by the FDA for the prevention of osteoporosis, relief of vasomotor symptoms and vulvovaginal atrophy associated with menopause. Women who have not had a hysterectomy require progesterone added to the estrogen to protect the uterine lining. The Woman's Health Initiative (WHI) found that 5 years of Prempro® reduced the risk of clinical vertebral fractures and hip fractures by 34%. However, the FDA recommends that when their use is considered solely for prevention of osteoporosis, approved non-estrogen treatments should first be carefully considered. HRT should not be used for the prevention of cardiovascular disease. The WHI reported increased risks of

myocardial infarction, stroke, invasive breast cancer, pulmonary emboli and deep vein phlebitis during 5 years of treatment with Prempro®. Other doses and combinations of estrogen and progestins were not studied and, in the absence of comparable data, their risks should be assumed to be comparable. Because of the risks, HRT should be used in the lowest possible doses for the shortest duration to meet treatment goals.

- Parathyroid hormone (Forteo®)
PTH (1-34) is approved by the FDA for the treatment of osteoporosis in postmenopausal women. PTH (1-34) is an anabolic (bone-building) agent when administered by daily subcutaneous injection. PTH (1-34) was recently shown to decrease the risk of vertebral fractures by 65% and non-vertebral fractures by 54% after an average of 18 months of therapy. PTH (1-34) is well tolerated although some patients experience leg cramps and dizziness. Because PTH (1-34) caused an increase in the incidence of osteosarcoma in rats, patients with an increased risk of osteosarcoma (e.g., patients with Paget's disease of bone, prior radiation therapy of the skeleton, bone metastases, hypercalcemia, or a history of skeletal malignancy) should not receive PTH (1-34) therapy. The safety and efficacy of PTH (1-34) has not been demonstrated beyond 2 years of treatment.
- Raloxifene (Evista®)
Raloxifene is approved by the FDA for both prevention and treatment of osteoporosis in postmenopausal women. Raloxifene increases vertebral bone mass modestly and reduces the risk of vertebral fracture by 40 %. Currently, there is no evidence that it significantly reduces risk of non-vertebral fractures. Raloxifene increases the risk of deep vein thrombosis to a degree similar to that observed with estrogen. It also increases hot flashes (~6% over placebo).
Raloxifene appears to decrease the risk of estrogen-dependent breast cancer. Its effect on coronary heart disease is under investigation.

Combination therapy (usually a bisphosphonate with a non-bisphosphonate) can provide additional small increases in BMD when compared with monotherapy; however, the impact of combination therapy on fracture rates is unknown. The added cost and potential side effects should be weighed against potential gains.

For more information:
www.nof.org/patientinfo/medications.htm