

EVIDENCE-STATEMENT:

OSTEOPOROSIS (Screening and Treatment)

Why This Chapter is Important for Employers: An Overview

- Approximately 44 million Americans — 55% of the adult population over the age 50 — have either osteoporosis or osteopenia. Many of the 10 million Americans who have osteoporosis are undiagnosed.¹
- Approximately 50% of postmenopausal women will suffer a fracture as a result of osteoporosis at some point during their lifetime.² Twenty-five percent (25%) of these women will suffer a deformity in their spines and 15% will fracture their hips.³
- Fractures are a costly and common events associated with osteoporosis. Approximately 1.5 million osteoporotic fractures occur in the United States each year, which result in more than 500,000 hospitalizations, over 800,000 emergency room visits, more than 2,600,000 physician office visits, and nearly 180,000 nursing home admissions.⁴
- The estimated annual direct-care expenditure for osteoporotic fractures ranges from \$12 billion to \$18 billion (in year 2002 dollars).⁴ In 2001, the cost of osteoporotic care delivered in hospitals and nursing homes totaled \$17 billion.⁵
- Osteoporosis will continue to grow as a major public health problem for both women and men as the population ages.¹ By the year 2020 experts predict that, combined, osteoporosis and osteopenia will affect 61 million Americans over the age of 50 and by the year 2040 the number of hip fractures is estimated to triple or quadruple.⁴
- Screening offers the opportunity to intervene early in the course of disease and prevent further weakening of the bones, thus reducing an individual's risk of fracture.
- Osteoporosis can be effectively treated with medication to improve bone density and reduce the risk of fractures.

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians screen all women over the age of 65 for osteoporosis. The USPSTF also recommends that clinicians screen women at high risk of osteoporosis beginning at age 60. Age and lower body weight (less than 70 kg) are the best predictors of low bone density. There is some evidence to support other risk factors, such as white race, smoking, weight loss, family history, decreased physical activity, alcohol or caffeine use, or low calcium and vitamin D intake.⁶

Evidence Rating: B (Recommended / At Least evidence)

The USPSTF found good evidence that the risk for osteoporosis and fracture increases with age and other factors, that bone density measurements accurately predict the risk for fractures in the short-term, and that treating asymptomatic women with osteoporosis reduces their risk for fracture. The USPSTF concluded that the benefits of screening and treatment are of at least moderate magnitude for women at increased risk by virtue of age or presence of other risk factors.⁶

Other Evidence-Based Research Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) has approved the following classes of medications for the treatment of osteoporosis^{4,7}:

- Bisphosphonates such as alendronate (Fosomax[®]), risedronate (Actonel[®]), and ibandronate (Boniva[®]).

- Selective Estrogen Receptor Modulators (SERMs) such as raloxifene (Evista®).
- Calcitonin (Miacalcin®)
- Parathyroid hormone (Forteo®)

Evidence Rating:

FDA-approved drug therapies have been shown through clinical trials to effectively reduce osteoporotic or fragility fractures at various sites in the body.

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Agency for Healthcare Research and Quality (AHRQ)
- Food and Drug Administration (FDA)
- National Osteoporosis Foundation (NOF)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)
- U.S. Surgeon General

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information**Epidemiology of Condition/Disease**

Osteoporosis is a common and serious disease associated with aging; it is a skeletal disorder characterized by compromised bone strength.⁴ Osteoporosis weakens the bones through a thinning of the bone mass, thereby increasing an individual's chance of experiencing a fracture.² Fractures occur at different and often multiple sites including the hip, vertebrae, wrist, and forearm. Osteoporosis can also cause chronic pain and loss of height due to compression of the spine. Osteoporosis is defined as a bone mineral density (BMD) 2.5 standard deviations or more below the mean BMD of healthy adult women. Authoritative diagnostic criteria for men are not established, but a BMD value 2.0 to 2.5 below normal for men with an appropriate clinical history has been proposed as a threshold for intervention.⁸ Osteopenia is a milder reduction in bone mass (BMD 1- 2.5 SD's below mean of healthy persons), which results in some increased risk of fracture, but not as great as the increased risk associated with osteoporosis. Because osteopenia covers a wide range of BMD values, not everyone with osteopenia is at the same risk of fracture, and therefore the best approach to minimize fracture risk in this group will vary.

Approximately 44 million Americans — 55% of the adult population over the age 50 — have either osteoporosis or osteopenia. Many of the 10 million Americans who have osteoporosis are undiagnosed.¹ Although women have a higher risk of developing osteoporosis than do men, osteoporosis is not only a disease of women and many men experience osteoporotic fractures.

Osteoporosis will continue to grow as a major public health problem for both women and men as the population ages.¹ By the year 2020 experts predict that, combined, osteoporosis and osteopenia will affect 61 million Americans over the age of 50.⁴ With such a rise in prevalence, the number of osteoporotic fractures — particularly hip fractures — is likely to increase. In fact, by the year 2040 the number of hip fractures is estimated to triple or quadruple.⁴

There is a strong and direct relationship between declining bone density and increasing risk of fracture. According to a recent research study, women diagnosed with osteoporosis are 4 times as likely to suffer a fracture in the year after they are diagnosed with osteoporosis compared to their peers without osteoporosis.³ Approximately 50% of postmenopausal women will suffer a fracture as a result of osteoporosis at some point during their lifetime.² Twenty-five percent (25%) of these women will suffer a deformity in their spines and 15% will fracture their hips.³

Each year, 1.5 million Americans suffer a fracture as a result of bone diseases such as osteoporosis and osteopenia including^{1,4}:

- 700,000 vertebral fractures
- 300,000 hip fractures
- 250,000 wrist fractures
- 300,000 fractures at other sites

Vertebral fractures range in severity and can cause severe pain and disfigurement. Vertebral fractures cause 150,000 hospitalizations each year for adults over the age of 65, require approximately 161,000 physician office visits, and lead to over 5 million days of restricted activity.⁹

Hip fractures are one of the most serious complications of osteoporosis. Approximately 10 million men and women over the age of 50 suffer from osteoporosis of the hip, and an additional 33.6 million Americans suffer from osteopenia of the hip.⁴ Hip fractures are associated with high mortality rates and are a major cause of disability. Individuals who suffer hip fractures have a 2.8 to 4 greater risk of dying during the first 3 months after the fracture than do fracture-free individuals of similar age, gender, and health status. Individuals who survive a hip fracture often suffer pain, loss of independence, and a reduced quality of life. For example, only 15% of patients are able to walk across a room without assistance six months after a hip fracture.¹ It is estimated that 1 in 5 individuals who suffer a hip fracture is forced to enter a nursing home.⁴ Further, hip fractures often initiate a downward spiral in health; 24% of individuals who suffer a hip fracture die within a year of the fracture.¹

Condition/Disease Risk Factors

Two major risk factors for the presence and severity of osteoporosis are gender and increasing age. Eighty-percent (80%) of those affected by osteoporosis are women.¹ Osteoporosis strikes mainly postmenopausal women in their 60s, 70s, and 80s and the percentage of women with osteoporosis increases markedly with age. Nearly 70% of white women age 80 and older have osteoporosis.¹

Another major risk factor for osteoporosis is personal history. Individuals who

experienced a fracture in adulthood are at high risk of experiencing a subsequent fracture. Because of this relationship, it is recommended that any individual with a history of a low-trauma fracture should be assessed for osteoporosis if they have not been previously evaluated.⁴ Unfortunately, many of those at risk for subsequent fractures fail to be evaluated and treated for osteoporosis.

Other major risk factors for osteoporosis include low body weight, no current use of estrogen, and Caucasian descent. Physical inactivity, tobacco use, weight loss, a family history of osteoporosis and osteoporotic fractures, alcohol and caffeine use, and insufficient calcium or vitamin D intake are also risk factors.⁴

Certain medications, particularly glucocorticoids and other steroids, can induce osteoporosis. Other medications such as those used to treat rheumatoid arthritis, endocrine disorders, and seizure disorders may also increase an individual's risk of osteoporosis.

Rates of osteoporosis vary by ethnicity. The prevalence of osteoporosis is highest in elderly white women. African-American women experience osteoporosis at half the rate of white women, but other ethnic minorities such as Mexican-Americans experience rates similar to whites.³

Value of Prevention

Economic Burden of Condition/Disease

The economic burden of fractures resulting from osteoporosis is substantial. Each year there are approximately 1.5 million osteoporotic fractures in the United States, which result in more than 500,000 hospitalizations, over 800,000 emergency room visits, more than 2,600,000 physician office visits and nearly 180,000 nursing home admissions. Hip fractures are the most severe osteoporotic fracture, accounting for 60% of all osteoporotic hospitalizations each year.⁴ A recent study that analyzed a private insurance claims database and the Medicare Supplemental and Coordination of Benefits (COB) database, found that osteoporosis patients with concurrent fractures represent just 7% of all osteoporosis patients but are responsible for 61% of the costs attributable to the disease.¹⁰ The estimated annual direct-care expenditure for osteoporotic fractures ranges from \$12 billion to \$18 billion (in year 2002 dollars).⁴ In 2001, the cost of osteoporotic care delivered in hospitals and nursing homes totaled \$17 billion.⁵ The indirect costs associated with osteoporosis have not been well-studied but would likely raise the direct cost estimates by several billion dollars.¹

Workplace Burden of Condition/Disease

Osteoporosis dramatically reduces an individual's functional status. Many individuals who suffer fractures are unable to care for themselves during their recuperation, and some are unable to care for themselves ever again. The burden of care often falls on family members who must take time off work to care for affected parents or spouses. Osteoporosis can thus be a direct or indirect cause of lost productivity and absenteeism. While it is rare for working-age adults to suffer severe fractures as a result of osteoporosis, it can — and does — happen, resulting in lost work time and possibly long-term disability. As the workforce ages, the workplace burden of osteoporosis is certain to increase unless preventive measures are implemented.

<p>Economic Benefit of Preventive Intervention</p>	<p>The economic benefits of screening for osteoporosis mainly result from decreases in treatment and rehabilitation costs associated with a reduction in osteoporotic fractures. A full analysis of the economic benefits of screening and early treatment should also include averted mortality and morbidity costs.</p>																
<p>Estimated Cost of Preventive Intervention</p>	<p>The cost of screening for osteoporosis varies depending on locality, provider type, and measurement tool used. In 2004, the private-sector cost of the initial health risk assessment averaged \$23 and approximately 95% of all paid claims fell within the range of \$0 to \$81.¹¹ In 2004, the private-sector cost of osteoporosis screening, bone density scans, and ultrasonography averaged \$55 and approximately 95% of all paid claims fell within the range of \$0 to \$132.¹¹</p>																
<p>Estimated Cost of Treatment</p>	<p>The cost of treatment varies substantially depending on the type of medication used and its dosage. Average wholesale price (AWP) figures are noted below for a 1-month supply of FDA-approved medications for the treatment of osteoporosis.¹²</p> <table border="1" data-bbox="516 793 1477 1113"> <thead> <tr> <th>Drug Name</th> <th>2006 Average Wholesale Price (AWP)</th> </tr> </thead> <tbody> <tr> <td>alendronate (Fosomax®)</td> <td>\$72.23</td> </tr> <tr> <td>calcitonin (Miacalcin®)</td> <td>\$47.08</td> </tr> <tr> <td>ibandronate (Boniva®)</td> <td>\$80.90</td> </tr> <tr> <td>parathyroid hormone (Forteo®)</td> <td>\$608.72</td> </tr> <tr> <td>raloxifene (Evista®)</td> <td>\$80.64</td> </tr> <tr> <td>risedronate (Actonel®)</td> <td>\$64.28 (dose pack)</td> </tr> <tr> <td>risedronate (Actonel®)</td> <td>\$68.86 (daily)</td> </tr> </tbody> </table>	Drug Name	2006 Average Wholesale Price (AWP)	alendronate (Fosomax®)	\$72.23	calcitonin (Miacalcin®)	\$47.08	ibandronate (Boniva®)	\$80.90	parathyroid hormone (Forteo®)	\$608.72	raloxifene (Evista®)	\$80.64	risedronate (Actonel®)	\$64.28 (dose pack)	risedronate (Actonel®)	\$68.86 (daily)
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<p>Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention</p>	<p>A recent study found that, compared to no intervention, universal screening with bone densitometry combined with alendronate therapy for those diagnosed with osteoporosis is highly cost-effective for women aged 65 years and older and may be cost-saving for ambulatory women age 85 and older.⁵</p>																

Preventive Intervention Information

<p>Preventive Intervention: Purpose of Screening and Treatment</p>	<p>Screening for osteoporosis allows clinicians to identify affected patients and begin treatment early in the course of disease. Established treatments can reduce bone loss and improve bone density, thereby reducing the risk of fractures and their associated complications.</p>
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<p>Benefits and Risks of Intervention</p>	<p>While no controlled studies have specifically evaluated the effect of screening for osteoporosis on fracture-related mortality, screening does offer the opportunity to intervene early in the course of disease and prevent further weakening of the bones, thus reducing an individual's risk of fracture.</p> <p>Screening for and treating osteoporosis does carry risks. Women who are diagnosed with osteoporosis report increased fear and anxiety in their daily lives. As with all screening tests, false-positive results can precipitate unnecessary treatment.⁷ In the past, women who were screened for osteoporosis were more likely to begin hormone replacement therapy than women who were not screened.</p>
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Hormone replacement therapy (HT) carries additional risks. Some of the medications used to treat osteoporosis increase the risk of other serious medical complications such as gastrointestinal disorders, ulcer disease, thromboembolic events, endometrial cancer, and cholecystitis.³ Despite these risks, experts agree that the benefits of screening for osteoporosis and treating osteoporosis in its earliest stages have substantial benefits that outweigh the risks involved.

Initiation, Cessation,
and Interval
Screening

Screening for osteoporosis should begin for normal-risk women at age 65 and for high-risk women at age 60. The benefits of screening increase with age because osteoporosis affects older women more frequently than younger women and because osteoporosis is more likely to result in fractures in older women.³ The age at which screening no longer offers substantial benefit is not known and there is little information on screening or treating women over the age of 85 for osteoporosis. Clinicians should cease screening for osteoporosis when a woman and her physician agree that the risks of screening outweigh the benefits of screening. Although there is not yet wide consensus regarding screening in men, some groups have recommended screening healthy men starting at age 70, with earlier testing of men with risk factors such as fracture, primary hyperparathyroidism, or use of GnRH agonists or glucocorticoids.⁴

Treatment

The optimal interval for screening has not been established. Evidence suggests that screening intervals of no less than 2 years is reasonable because the bone density tests are not precise enough to measure a change in bone density reliably in a shorter period of time. Evidence suggests that less frequent screening may be reasonable in younger women.⁷

Intervention Process
Screening

Medications used to treat osteoporosis should be used — and covered — as prescribed by a clinician.

Several methods of screening for osteoporosis are currently used. The best predictor of hip fracture is the dual-energy x-ray absorptiometry of the hip (DXA). Other bone density tests include DXA of the spine, whole body or forearm, ultrasound, radiographic absorptiometry, single-energy absorptiometry, peripheral dual-energy x-ray absorptiometry, and peripheral quantitative computed tomography.³ The likelihood of a diagnosis of osteoporosis depends on the type of measurement tool used, the site of the measurement, the number of sites tested, the brand of the measurement tool, and the relevance of the reference range.³

Physician- or self-administered verbal or written screening instruments used to detect and assess the risk of low bone density generally have high sensitivity but low specificity; therefore false-positive results are a greater problem than false-negative results. One validated instrument is the Osteoporosis Risk Assessment Instrument (ORAI), a 3-item tool that uses an individual's age, weight, and hormone replacement therapy history to quantify the risk of osteoporosis. Another instrument is the Simple Calculated Osteoporosis Risk Estimation tool (SCORE), a similar 6-item measure of risk based on age, weight, ethnicity, estrogen use, presence of rheumatoid arthritis, and history of fractures.³

Treatment

Health benefits should include provisions for treatment services.

Osteoporosis can be effectively treated with medication to improve bone density and reduce the risk of fractures. The Food and Drug Administration (FDA) has approved the following classes of medications for the treatment of osteoporosis^{4,7}:

- Bisphosphonates such as alendronate (Fosomax[®]), risedronate (Actonel[®]), and ibandronate (Boniva[®])
- Selective estrogen receptor modulators (SERMs) such as raloxifene (Evista[®])
- Calcitonin (Miacalcin[®])
- Parathyroid hormone (Forteo[®])

Any decision to use hormone therapy (HT) must take into consideration its impact on overall health outcomes, including its potential to reduce the risk of fractures and its potential to increase the risk of other health problems. The FDA has advised that postmenopausal women who use, or are considering using, estrogen or estrogen with progestin discuss the therapy's benefits and risks with their physicians. These products are approved therapies for relief from moderate to severe hot flashes and symptoms of vulvar and vaginal atrophy. Although HT is effective for the prevention of postmenopausal osteoporosis, it should only be considered for women at significant risk of osteoporosis who cannot take non-estrogen medications. The FDA recommends that estrogens and progestins should be used at the lowest possible doses for the shortest amount of time needed to achieve treatment goals. It is not yet clear whether following this advice will lead to long-term benefits for bone health.⁴

Note: The USPSTF recommends against (“D” rating) routine use of HT to prevent chronic diseases in postmenopausal women because the harmful effects of unopposed estrogen are likely to exceed the chronic disease prevention benefits in most women.¹³

Treatment Information

Because the purpose of treating osteoporosis is to *prevent* the poor health outcomes associated with fractures, treatment is considered a preventive intervention. Please refer to “Intervention Process” for information on treatment services.

In addition to medications, physical activity, in general, and resistance-weight-training, in particular, is very helpful in preventing fractures. Resistance training helps retard bone loss. Moreover, physical activity reduces the risks of falls by a variety of mechanisms (e.g., increased agility, increased strength, etc), thereby indirectly influencing fracture rates. While there is no direct mechanism for purchasers to cover the promotion of physical activity through health plan benefits, purchasers should encourage their at-risk beneficiaries to partake in physical activity.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)

Strength of Evidence: B (Recommended/At Least Fair Evidence)

- The USPSTF found good evidence to support screening all women over the age of 65 for osteoporosis. The Task Force also recommends that clinicians screen women at high-risk of osteoporosis beginning at age 60. Age and lower body weight (less than 70 kg) are the best predictors of low bone density. There is some evidence to support other risk factors, such as: white race, smoking, weight loss, family history, decreased physical activity, alcohol or caffeine use, or low calcium and vitamin D intake.⁶

Food and Drug Administration (FDA)

Strength of Evidence: FDA approved drug therapies have been shown through clinical trials to effectively reduce osteoporotic or fragility fractures at various sites in the body.

- The Food and Drug Administration (FDA) has approved the following classes of medications for the treatment of osteoporosis^{4,7}:
 - Bisphosphonates such as alendronate (Fosomax[®]), risedronate (Actonel[®]), and ibandronate (Boniva[®])
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Authored by:

Campbell KP, Lanza A, Looker A. Osteoporosis evidence-statement: screening and treatment. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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