

## HEALTH EVIDENCE REVIEW COMMISSION (HERC)

### COVERAGE GUIDANCE: OSTEOPOROSIS SCREENING AND MONITORING BY DUAL-ENERGY X-RAY ABSORPTIOMETRY (DXA)

Approved June 12, 2014

#### HERC COVERAGE GUIDANCE

Osteoporosis screening by dual-energy X-ray absorptiometry (DXA) is recommended for coverage only for women aged 65 or older, and for men or younger women whose 10-year risk of major osteoporotic fracture is equal to or greater than 9.3 percent. Fracture risk should be assessed by the World Health Organization's FRAX tool (*strong recommendation*).

**Routine** osteoporosis screening by DXA is not recommended for coverage in men (*weak recommendation*).

The frequency of subsequent monitoring for development of osteoporosis should not be based on DXA scores alone. If rapid change in bone density is expected, more frequent DXA scanning is appropriate (for example, in patients taking glucocorticoids, those with a history of rapid weight loss, those with medical conditions that could result in secondary osteoporosis, etc.).

If there has been no significant change in an individual's risk factors, monitoring of individuals with low bone density by repeat DXA scanning is recommended for coverage (*weak recommendation*) only at the following frequencies:

- once every two years for those with osteoporosis or advanced osteopenia (T-score of -2.00 or lower)
- once every four years for moderate osteopenia (T-score between -1.50 and -1.99)
- once every ten years for mild osteopenia (T-score between -1.01 and -1.49).
- once every fifteen years for those with normal bone density

Repeat testing should only be covered if the results will influence clinical management. For purposes of monitoring osteoporosis medication therapy, testing at intervals of less than two years is not recommended for coverage (*weak recommendation*).

Note: Definitions for strength of recommendation are provided in Appendix A GRADE Element Description

#### RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care

- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

## EVIDENCE SOURCE

### *Trusted Sources*

Gourlay, M.L., Fine, J.P., Preisser, J.S., May, R.C., Li, C., Lui, L., et al. (2012). Bone-density testing interval and transition to osteoporosis in older women. *New England Journal of Medicine*, 366(3), 225-233.

National Clinical Guideline Center. (2012). *Osteoporosis: Assessing the risk of fragility fracture*. London: National Clinical Guideline Center. Retrieved May 10, 2013, from <http://guidance.nice.org.uk/CG146/Guidance>

Nelson, H.D., Haney, E.M., Chou, R., Dana, T., Fu, R., & Bougatsos, C. (2010). *Screening for osteoporosis: Systematic review to update the 2002 U.S. Preventive Services Task Force recommendation*. Evidence Synthesis No. 77. AHRQ Publication No. 10-05145-EF-1. Rockville, Maryland: Agency for Healthcare Research and Quality. Retrieved May 10, 2013, from <http://www.ncbi.nlm.nih.gov/books/NBK45201/>

U.S. Preventive Services Task Force. (2011). Screening for osteoporosis: U.S. Preventive Services Task Force recommendation statement. *Annals of Internal Medicine*, 154(5), 356-364. Retrieved May 10, 2013, from <http://www.uspreventiveservicestaskforce.org/uspstf/uspsoste.htm>

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

### *Additional Sources*

Berry, S.D., Samelson, E.J., Pencina, M.J., McClean, R.R, Cupples, L.A., Broe, K.E, et al (2013). Repeat Bone Mineral Density Screening and Prediction of Hip and Major Osteoporotic Fracture. *JAMA*, 310(12):1256-1262.

Jiang, X., Westermann, L.B., Galleo, G.V., Marakovits, K.A., & Schnatz, P.F. (2013). Age as a predictor of osteoporotic fracture compared with current risk-prediction models. *Obstetrics & Gynecology*, 122(5), 1040-1046.

Reid, I.R., & Gamble, G.D. (2014). Intervals between bone density testing. *Journal of Bone and Mineral Research*, 29(2), 389-391.

## SUMMARY OF EVIDENCE

### **Clinical Background**

Osteoporosis is characterized by low bone mineral density (BMD) and a resultant increased risk for fractures. It is estimated that as many as 1 in 2 women and 1 in 5 men are at risk for an osteoporosis-related fracture during their lifetime. Osteoporosis is more common in women than men and is more common in white persons than in any other racial group. For all demographic groups, the rates of osteoporosis increase with age. Elderly patients have increased susceptibility to fractures because they commonly have additional risk factors for fractures, such as poor bone quality and an increased tendency to fall. Hip fractures in particular can result in significant morbidity and mortality. Fractures at other sites also can lead to significant illness, causing chronic pain or disability and negatively affecting functional ability and quality of life. Direct medical care costs of osteoporotic fractures were estimated to be \$12.2 to \$17.9 billion per year in 2002 U.S. dollars; these estimates do not include indirect costs associated with lost productivity of patients and caregivers.

Many different risk assessment instruments have been developed to predict risk for low BMD or fractures. Multiple studies have validated these tools; however, few of these studies have included men. Despite various risk factors and variables included in the different risk assessment tools, none of the tools has consistently superior performance. The FRAX tool, developed by the World Health Organization and the National Osteoporosis Foundation, is one of the most widely used instruments to predict risk for fractures. This tool was derived from data on 9 cohorts in Europe, Canada, the United States, and Japan. Seven of these cohorts included men. The FRAX tool was validated in 11 cohorts, but only 1 of these cohorts included men. Because a large and diverse sample was used to develop and validate the FRAX tool and this instrument includes a publicly available risk calculator, the USPSTF used the FRAX tool to determine which individuals would exceed the baseline risk threshold for fractures on the basis of their age or other risk factors (such as low BMI, parental history of hip fracture, smoking status, and daily alcohol use). Considering a 65-year-old white woman who has no other risk factors to be the baseline risk case (a 10-year risk for any osteoporotic fracture of 9.3%), women as young as 50 years may have a 10-year risk for any osteoporotic fracture of 9.3% or greater, depending on the type and number of risk factors present.

Bone mineral density (BMD) criteria were developed by the World Health Organization (WHO) from epidemiologic data that describe the normal distribution of BMD in a young

healthy reference population. Osteoporosis is diagnosed when the BMD at the spine, hip, or wrist is 2.5 or more standard deviations (SD) below the reference mean. Low bone density or mass (sometimes referred to as osteopenia) is diagnosed when BMD is between 1.0–2.5 SD below the reference mean. The number of standard deviation units above or below the young healthy mean is called the T-score. Although intended for epidemiologic purposes, T-scores have been used as selection criteria for trials of therapies. They are now used to identify individuals with low BMD and to make treatment decisions.

## **Evidence Review**

### **USPSTF**

#### **Detection**

The USPSTF found convincing evidence that bone measurement tests predict short-term risk for osteoporotic fractures in women and men. The most commonly used tests are dual-energy x-ray absorptiometry (DXA) of the hip and lumbar spine and quantitative ultrasonography of the calcaneus. Adequate evidence indicates that clinical risk assessment instruments have only modest predictive value for low bone density or fractures.

#### **Benefits of Detection and Early Intervention**

No controlled studies have evaluated the effect of screening for osteoporosis on fracture rates or fracture related morbidity or mortality. In postmenopausal women who have no previous osteoporotic fractures, the USPSTF found convincing evidence that drug therapies reduce the risk for fractures. In women aged 65 years or older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors, the USPSTF judged that the benefit of treating screening-detected osteoporosis is at least moderate. Because of the lack of relevant studies, the USPSTF found inadequate evidence that drug therapies reduce the risk for fractures in men who have no previous osteoporotic fractures.

#### **Accuracy of Screening Tests**

##### *DXA*

Measurement of bone density using DXA has become the gold standard for the diagnosis of osteoporosis and for guiding decisions about which patients to treat. Although it is not a perfect predictor of fractures, DXA of the femoral neck is considered the best predictor of hip fracture and is comparable with DXA measurements of the forearm for predicting fractures at other sites. Previous studies evaluating the accuracy of DXA for predicting fractures have focused mainly on women; studies have only recently assessed the predictive ability of DXA in men. A large prospective cohort study

in the Netherlands that included men and women older than 55 years reported the incidence of vertebral and nonvertebral fractures approximately 6 years after baseline DXA measurements of the femoral neck were obtained. For each SD reduction in BMD at the femoral neck, the hazard ratio for vertebral and non-vertebral fractures increased to a similar degree in both men and women. Other studies of the performance of DXA in men have reported similar findings.

### *Quantitative Ultrasonography*

The most commonly used test in the United States after DXA is quantitative ultrasonography (US) of the calcaneus. Quantitative US is less expensive than DXA, does not involve radiation, and can feasibly be implemented in primary care settings. Recent studies demonstrate that quantitative US of the calcaneus can predict fractures as effectively as DXA in postmenopausal women and in men. Quantitative US seems to be equivalent to DXA for predicting fractures and has other potential advantages, but also a few distinct disadvantages. The current diagnostic criteria for osteoporosis use DXA measurements as cutoffs, and the measurements obtained from quantitative US are not interchangeable with those obtained from DXA. Also, all trials evaluating drug therapies for osteoporosis use DXA measurements as inclusion criteria. Thus, for quantitative US to be relevant and clinically useful, a method for converting or adapting results of quantitative US to the DXA scale will need to be developed.

One meta-analysis examined 25 studies to assess the accuracy of quantitative US compared with DXA in identifying patients with osteoporosis. When various quantitative US index parameter cutoffs were used, the results varied widely in sensitivity and specificity for identifying individuals with a T-score of -2.5 or less on DXA. No quantitative US cutoff existed at which sensitivity and specificity were both high.

### **Frequency of Monitoring**

The USPSTF did not make any specific recommendations regarding screening interval or frequency. The systematic review conducted to support the recommendation reported on only one study that addressed this question, a large good-quality prospective cohort study of 4,124 women age  $\geq 65$  years from the Study of Osteoporotic Fractures. This study found that repeating a BMD measurement up to 8 years after an initial measurement did not significantly change estimates for non-vertebral, hip, or vertebral fractures. No studies of screening intervals have been conducted in men or other groups of women.

Because of the limited evidence supporting frequency of monitoring, an additional search of the literature was undertaken from the end date of the Nelson review (December 2009). One study was identified that addressed frequency of monitoring (Gourlay et al. 2012). This NIH funded study evaluated women with normal or osteopenic BMD who were older than 66 years of age and had no history of hip or

vertebral fracture. Osteopenia was categorized as mild (T-score -1.01 to -1.49), moderate (T-score -1.50 to -1.99) or advanced (T-score -2.0 to -2.49). They were followed prospectively for 15 years and the BMD testing interval, defined as the estimated time for 10% of women to make the transition to osteoporosis, was calculated. The estimated BMD testing interval was 16.8 years (95% CI, 11.5 to 24.6) for women with normal BMD, 17.3 years (95% CI, 13.9 to 21.5) for women with mild osteopenia, 4.7 years (95% CI, 4.2 to 5.2) for women with moderate osteopenia, and 1.1 years (95% CI, 1.0 to 1.3) for women with advanced osteopenia.

### **Effectiveness of Early Detection and Treatment**

No controlled studies have evaluated the effect of screening for osteoporosis on rates of fractures or fracture related morbidity or mortality. Drug therapies for osteoporosis can be for primary prevention (prevention of an osteoporotic fracture in patients with low BMD who have no previous fractures) or secondary prevention (prevention of an osteoporotic fracture in patients who have a known previous osteoporotic fracture). Primary prevention trials are more applicable to the screening population addressed in this recommendation. Drug therapies include bisphosphonates, parathyroid hormone, raloxifene, estrogen, and calcitonin. For primary prevention in postmenopausal women, bisphosphonates, parathyroid hormone, raloxifene, and estrogen have been shown to reduce vertebral fractures. The evidence is strongest and most consistent for bisphosphonates and raloxifene.

In a meta-analysis of 7 trials, the relative risk (RR) for vertebral fractures for bisphosphonates compared with placebo was 0.66 (95% CI, 0.50 to 0.89). Two large placebo controlled trials of raloxifene reported reduced vertebral fractures, with a combined RR for raloxifene of 0.61 compared with placebo (CI, 0.55 to 0.69). A pooled analysis of 9 trials demonstrated a non-statistically significant trend toward a reduction in non-vertebral fractures with bisphosphonates compared with placebo (RR, 0.83 [CI, 0.64 to 1.08]). In the largest trial of bisphosphonates, the Fracture Intervention Trial of alendronate, fractures were significantly reduced only in women with baseline femoral neck T-scores less than -2.5. Evidence of the effectiveness of treatment of osteoporosis in men is limited. There are no primary prevention trials of bisphosphonates in men and only 2 secondary prevention trials of alendronate. When the 2 trials were pooled, alendronate was associated with a reduced risk for vertebral fractures (odds ratio [OR], 0.35 [CI, 0.17 to 0.77]), and the effect on non-vertebral fractures was not statistically significant (OR, 0.73 [CI, 0.32 to 1.67]). A single primary prevention trial of parathyroid hormone in men reported a non-statistically significant trend toward a reduction in vertebral and non-vertebral fractures. None of the other therapies for osteoporosis in men has been evaluated in randomized trials.

## **Potential Harms of Screening and Treatment**

Potential harms of screening for osteoporosis include false-positive test results causing unnecessary treatment, false-negative test results, and patient anxiety about positive test results. No studies that addressed the potential harms of screening were identified during this review. The harms of drug therapy for osteoporosis have been studied most extensively for bisphosphonates, raloxifene, and estrogen. For bisphosphonates, the evidence demonstrates no definitive increase in the risk for serious gastrointestinal adverse events (for example, perforations, ulcers, bleeding, esophagitis, or esophageal ulceration) in persons who use these medications appropriately. The evidence on the risk for atrial fibrillation with bisphosphonates is conflicting. One large case-control study in Denmark showed an increased risk for atrial fibrillation with any use of alendronate compared with no use of this agent (OR, 1.86 [CI, 1.09 to 3.15]), but a smaller case-control study in Washington showed no increased risk for atrial fibrillation with any use of etidronate (RR, 0.95 [CI, 0.84 to 1.07]) or any use of alendronate (RR, 1.04 [CI, 0.90 to 1.21]) compared with no use of either agent.

Osteonecrosis of the jaw has been associated with bisphosphonates in case reports, but this condition typically develops in patients with cancer who receive higher doses than those normally used for osteoporosis treatment or prevention. Case reports also have described severe musculoskeletal symptoms associated with all of the bisphosphonates. In October 2010, the U.S. Food and Drug Administration issued a warning about a possible elevated risk for midfemur fractures in patients receiving bisphosphonates, especially for patients who have received them for more than 5 years.

Raloxifene and estrogen are associated with higher rates of thromboembolic events than placebo. Estrogen increases the risk for stroke, and estrogen with progestin increases the risk for coronary heart disease and breast cancer. Evidence is limited on the harms associated with use of calcitonin and parathyroid hormone for osteoporosis.

Overall, the USPSTF found no new studies that described harms of screening for osteoporosis in men or women. Screening with DXA is associated with opportunity costs (time and effort required by patients and the health care system). Harms of drug therapies for osteoporosis depend on the specific medication used. The USPSTF found adequate evidence that the harms of bisphosphonates, the most commonly prescribed therapies, are no greater than small. Convincing evidence indicates that the harms of estrogen and selective estrogen receptor modulators are small to moderate.

## **Estimate of Magnitude of Net Benefit**

The USPSTF found convincing evidence that drug therapies reduce subsequent fracture rates in postmenopausal women. For women aged 65 years or older and younger women who have similar estimates of fracture risk, the benefit of treating screening-detected osteoporosis is at least moderate. The harms of treatment were

found to range from no greater than small for bisphosphonates and parathyroid hormone to small to moderate for raloxifene and estrogen. Therefore, the USPSTF concludes with moderate certainty that the net benefit of screening for osteoporosis in this group of women is at least moderate. For men, the USPSTF concludes that evidence is inadequate to assess the effectiveness of drug therapies in reducing subsequent fracture rates in men who have no previous fractures. Treatments that have been proven effective in women cannot necessarily be presumed to have similar effectiveness in men. Thus, the USPSTF could not assess the balance of benefits and harms of screening for osteoporosis in men.

### **Overall USPSTF Assessment**

The USPSTF concludes that for women aged 65 years or older and younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors, there is moderate certainty that the net benefit of screening for osteoporosis by using DXA is at least moderate. The USPSTF concludes that for men, evidence of the benefits of screening for osteoporosis is lacking and the balance of benefits and harms cannot be determined.

[\[Evidence Source\]](#)

### **NICE GUIDELINE**

The NICE guideline makes the follow recommendations pertaining to assessing the risk of fragility fractures:

#### *Targeting risk assessment*

##### 1. Consider assessment of fracture risk:

- in all women aged 65 years and over and all men aged 75 years and over
- in women aged under 65 years and men aged under 75 years in the presence of risk factors, for example:
  - previous fragility fracture,
  - current use or frequent recent use of oral or systemic glucocorticoids,
  - history of falls,
  - family history of hip fracture,
  - other causes of secondary osteoporosis<sup>1</sup>,

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<sup>1</sup> Causes of secondary osteoporosis include endocrine (hypogonadism in either sex including untreated premature menopause and treatment with aromatase inhibitors or androgen deprivation therapy; hyperthyroidism; hyperparathyroidism; hyperprolactinaemia; Cushing's disease; diabetes), gastrointestinal (coeliac disease; inflammatory bowel disease; chronic liver disease; chronic pancreatitis; other causes of malabsorption), rheumatological (rheumatoid arthritis; other inflammatory arthropathies), haematological (multiple myeloma; haemoglobinopathies; systemic mastocytosis), respiratory (cystic

- low body mass index (BMI) (less than 18.5 kg/m<sup>2</sup>),
- smoking,
- alcohol intake of more than 14 units per week for women and more than 21 units per week for men.

2. Do not routinely assess fracture risk in people aged under 50 years unless they have major risk factors (for example, current or frequent recent use of oral or systemic glucocorticoids, untreated premature menopause or previous fragility fracture), because they are unlikely to be at high risk.

3. Estimate absolute risk when assessing risk of fracture (for example, the predicted risk of major osteoporotic or hip fracture over 10 years, expressed as a percentage).

4. Use either FRAX<sup>2</sup> (without a bone mineral density [BMD] value, if a dual-energy X-ray absorptiometry [DXA] scan has not previously been undertaken) or QFracture<sup>3</sup>, within their allowed age ranges, to estimate 10-year predicted absolute fracture risk when assessing risk of fracture. Above the upper age limits defined by the tools, consider people to be at high risk.

5. Interpret the estimated absolute risk of fracture in people aged over 80 years with caution, because predicted 10-year fracture risk may underestimate their short-term fracture risk.

6. Do not routinely measure BMD to assess fracture risk without prior assessment using FRAX (without a BMD value) or QFracture.

7. Following risk assessment with FRAX (without a BMD value) or QFracture, consider measuring BMD with DXA in people whose fracture risk is in the region of an intervention threshold<sup>4</sup> for a proposed treatment, and recalculate absolute risk using FRAX with the BMD value.

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fibrosis; chronic obstructive pulmonary disease), metabolic (homocystinuria), chronic renal disease and immobility (due for example to neurological injury or disease).

<sup>2</sup> FRAX, the WHO fracture risk assessment tool, is available from [www.shef.ac.uk/FRAX](http://www.shef.ac.uk/FRAX). It can be used for people aged between 40 and 90 years, either with or without BMD values, as specified.

<sup>3</sup> QFracture is available from [www.qfracture.org](http://www.qfracture.org). It can be used for people aged between 30 and 84 years. BMD values cannot be incorporated into the risk algorithm.

<sup>4</sup> An intervention threshold is the level of risk at which an intervention is recommended. People whose risk is in the region from just below to just above the threshold may be reclassified if BMD is added to assessment. It is out of the scope of this guideline to recommend intervention thresholds. Healthcare professionals should follow local protocols or other national guidelines for advice on intervention thresholds.

8. Consider measuring BMD with DXA before starting treatments that may have a rapid adverse effect on bone density (for example, sex hormone deprivation for treatment for breast or prostate cancer).

9. Measure BMD to assess fracture risk in people aged under 40 years who have a major risk factor, such as history of multiple fragility fracture, major osteoporotic fracture, or current or recent use of high-dose oral or systemic glucocorticoids (more than 7.5 mg prednisolone or equivalent per day for 3 months or longer).

10. Consider recalculating fracture risk in the future:

- if the original calculated risk was in the region of the intervention threshold<sup>5</sup> for a proposed treatment and only after a minimum of 2 years, or
- when there has been a change in the person's risk factors.

11. Take into account that risk assessment tools may underestimate fracture risk in certain circumstances, for example if a person:

- has a history of multiple fractures
- has had previous vertebral fracture(s)
- has a high alcohol intake
- is taking high-dose oral or high-dose systemic glucocorticoids (more than 7.5 mg prednisolone or equivalent per day for 3 months or longer)
- has other causes of secondary osteoporosis.<sup>6</sup>

12. Take into account that fracture risk can be affected by factors that may not be included in the risk tool, for example living in a care home or taking drugs that may impair bone metabolism (such as anti-convulsants, selective serotonin reuptake inhibitors, thiazolidinediones, proton pump inhibitors and anti-retroviral drugs).

#### [\[Evidence Source\]](#)

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<sup>5</sup> An intervention threshold is the level of risk at which an intervention is recommended. It is out of the scope of this guideline to recommend intervention thresholds. Healthcare professionals should follow local protocols or other national guidelines for advice on intervention thresholds.

<sup>6</sup> Causes of secondary osteoporosis include: endocrine (hypogonadism in either sex including untreated premature menopause and treatment with aromatase inhibitors or androgen deprivation therapy; hyperthyroidism; hyperparathyroidism; hyperprolactinaemia; Cushing's disease; diabetes), gastrointestinal (coeliac disease; inflammatory bowel disease; chronic liver disease; chronic pancreatitis; other causes of malabsorption), rheumatological (rheumatoid arthritis; other inflammatory arthropathies), haematological (multiple myeloma; haemoglobinopathies; systemic mastocytosis), respiratory (cystic fibrosis; chronic obstructive pulmonary disease), metabolic (homocystinuria), chronic renal disease and immobility (due for example to neurological injury or disease).

## Evidence Summary

Bone measurement tests predict short-term risk for osteoporotic fractures in women and men. The most appropriate interval for screening has not been identified, but repeating a BMD measurement up to 8 years after an initial measurement does not significantly change fracture estimates, and transition to osteoporosis occurs for most women with normal BMD no sooner than 17 years. In postmenopausal women who have no previous osteoporotic fractures, drug therapies reduce the risk for fractures (primary prevention). Bisphosphonates, parathyroid hormone, raloxifene, and estrogen have all been shown to reduce vertebral fractures in this population. Potential harms of screening for osteoporosis include false-positive test results causing unnecessary treatment, false-negative test results, and patient anxiety about positive test results.

For women aged 65 years or older and younger women who have similar estimates of fracture risk, the benefit of treating screening-detected osteoporosis is at least moderate, while the harms range from small to moderate. Therefore, the net benefit of screening for osteoporosis in this group of women is at least moderate. For men, the evidence is inadequate to assess the effectiveness of drug therapies in reducing subsequent fracture rates in men who have no previous fractures.

## GRADE-INFORMED FRAMEWORK

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are four elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Balance between desirable and undesirable effects, and quality of evidence, are derived from the evidence presented in this document, while estimated relative costs, values and preferences are assessments of the HERC members.

Indication	Balance between desirable and undesirable effects	Quality of evidence*	Resource Allocation	Values and preferences	Coverage Recommendation
Screening for osteoporosis in women aged 65 or over, or with equivalent risks	Small to moderate net benefit	High	Moderately high on a population-wide basis, but with significant offsets if effective fracture prevention	Low variability (most people would prefer screening and fracture prevention)	Recommended for coverage (strong recommendation)
Screening for osteoporosis in men aged 70 or over	Unknown	Very low	Moderately high	Moderate variability (some would prefer availability of screening even if benefit not established)	Not recommended for coverage (weak recommendation)
Repeat DXA < 2 years for monitoring osteoporosis or advanced osteopenia	Likely no net benefit	Very low	Moderately significant cost associated with more frequent monitoring	Low variability	Not recommended for coverage (weak recommendation)

Indication	Balance between desirable and undesirable effects	Quality of evidence*	Resource Allocation	Values and preferences	Coverage Recommendation
Repeat DXA < 4 years for monitoring moderate osteopenia	Likely no net benefit	Very low	Moderately significant cost associated with more frequent monitoring	Low variability	Not recommended for coverage (weak recommendation)
Repeat screening DXA < 15 years in women with normal BMD or mild osteopenia	Likely no net benefit	Very low	Moderately significant cost associated with more frequent monitoring	Low variability	Not recommended for coverage (weak recommendation)

\*The Quality of Evidence rating was assigned by the primary evidence source, not the HERC Subcommittee

Note: GRADE framework elements are described in Appendix A

## POLICY LANDSCAPE

*Choosing Wisely*<sup>®</sup> is part of a multi-year effort of the ABIM Foundation to help physicians be better stewards of finite health care resources. Originally conceived and piloted by the [National Physicians Alliance](#) through a [Putting the Charter into Practice grant](#), nine medical specialty organizations, along with Consumer Reports, have identified five tests or procedures commonly used in their field, whose necessity should be questioned and discussed. The American College of Rheumatology makes the following recommendation:

**Don't routinely repeat DXA scans more often than once every two years.**

Initial screening for osteoporosis should be performed according to National Osteoporosis Foundation recommendations. The optimal interval for repeating Dual-energy X-ray Absorptiometry (DXA) scans is uncertain, but because changes in bone density over short intervals are often smaller than the measurement error of most DXA scanners, frequent testing (e.g., <2 years) is unnecessary in most patients. Even in high-risk patients receiving drug therapy for osteoporosis, DXA changes do not always correlate with probability of fracture. Therefore, DXAs should only be repeated if the result will influence clinical management or if rapid changes in bone density are expected. Recent evidence also suggests that healthy women age 67 and older with normal bone mass may not need additional DXA testing for up to ten years provided osteoporosis risk factors do not significantly change.

Five quality measures were identified pertaining to BMD testing when searching the [National Quality Measures Clearinghouse](#). All five were developed by the National Committee for Quality Assurance, and four of the five are endorsed by the NQF:

- Osteoporosis management in women who had a fracture: percentage of women 67 years of age and older who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat or prevent osteoporosis in the six months after the fracture.
- Osteoporosis testing in older women: the percentage of Medicare women 65 years of age and over who report ever having received a bone density test to check for osteoporosis.
- Osteoporosis: percentage of patients aged 50 years and older with a fracture of the hip, spine or distal radius who had a central DXA measurement ordered or performed or pharmacologic therapy prescribed.
- Osteoporosis: percentage of female patients aged 65 years and older who have a central DXA measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months.

The fifth measure has not been endorsed by the NQF:

- Osteoporosis: percentage of patients aged 18 years and older with one of the following conditions or therapies: receiving oral glucocorticosteroid therapy for greater than 3 months OR hypogonadism OR fracture history OR transplant history OR obesity surgery OR malabsorption disease OR receiving aromatase therapy for breast cancer who had a central dual-energy X-ray absorptiometry ordered or performed or pharmacologic therapy prescribed within 12 months.

#### COMMITTEE DELIBERATIONS – HTAS

At its meeting 11/25/2013, the HTAS reviewed public comments. After brief discussion, the subcommittee referred the draft coverage guidance to VbBS and HERC for implementation and approval.

#### COMMITTEE DELIBERATIONS – VBBS

At its meeting 1/9/2013, the VbBS reviewed the draft coverage guidance and an associated diagnostic guideline for implementation in the Oregon Health Plan. The diagnostic guideline was approved for review by the HERC.

#### HERC DELIBERATIONS

At its meeting March 13, 2014, the HERC reviewed the draft coverage guidance and asked for additional staff research regarding a modeling study referenced by Dr. E. Michael Lewiecki, the appointed ad hoc expert for this coverage guidance. At its June 12, 2014 meeting the HERC reviewed the additional information. After discussion, they decided to remove the language about risk equivalent to a 65-year-old white woman and replace it with a 9.3% 10 year risk of major osteoporotic fracture, to address concerns that primary care providers would have a difficult time interpreting the prior language. They also changed the rescreening interval to 10 years from 15 for those whose initial test shows normal bone density.

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

## Appendix A. GRADE Element Descriptions

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted

### Strong recommendation

***In Favor:*** The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

***Against:*** The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

### Weak recommendation

***In Favor:*** the subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

***Against:*** the subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

### Quality of evidence across studies for the treatment/outcome

***High*** = Further research is very unlikely to change our confidence in the estimate of effect.

***Moderate*** = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

***Low*** = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

***Very low*** = Any estimate of effect is very uncertain.

## Appendix B. Applicable Codes

<b>CODES</b>	<b>DESCRIPTION</b>
<b>ICD-9 Diagnosis Codes</b>	
733.0	Osteoporosis
733.90	Disorder of bone and cartilage, unspecified
V82.81	Special screening for osteoporosis
<b>ICD-9 Volume 3 (Procedure Codes)</b>	
None	
<b>CPT Codes</b>	
76977	Ultrasound bone density measurement and interpretation, peripheral sites, any method
77080	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)
77081	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)
<b>HCPCS Level II Codes</b>	
None	

Note: Inclusion on this list does not guarantee coverage



# Screening for osteoporosis in men without additional risk factors

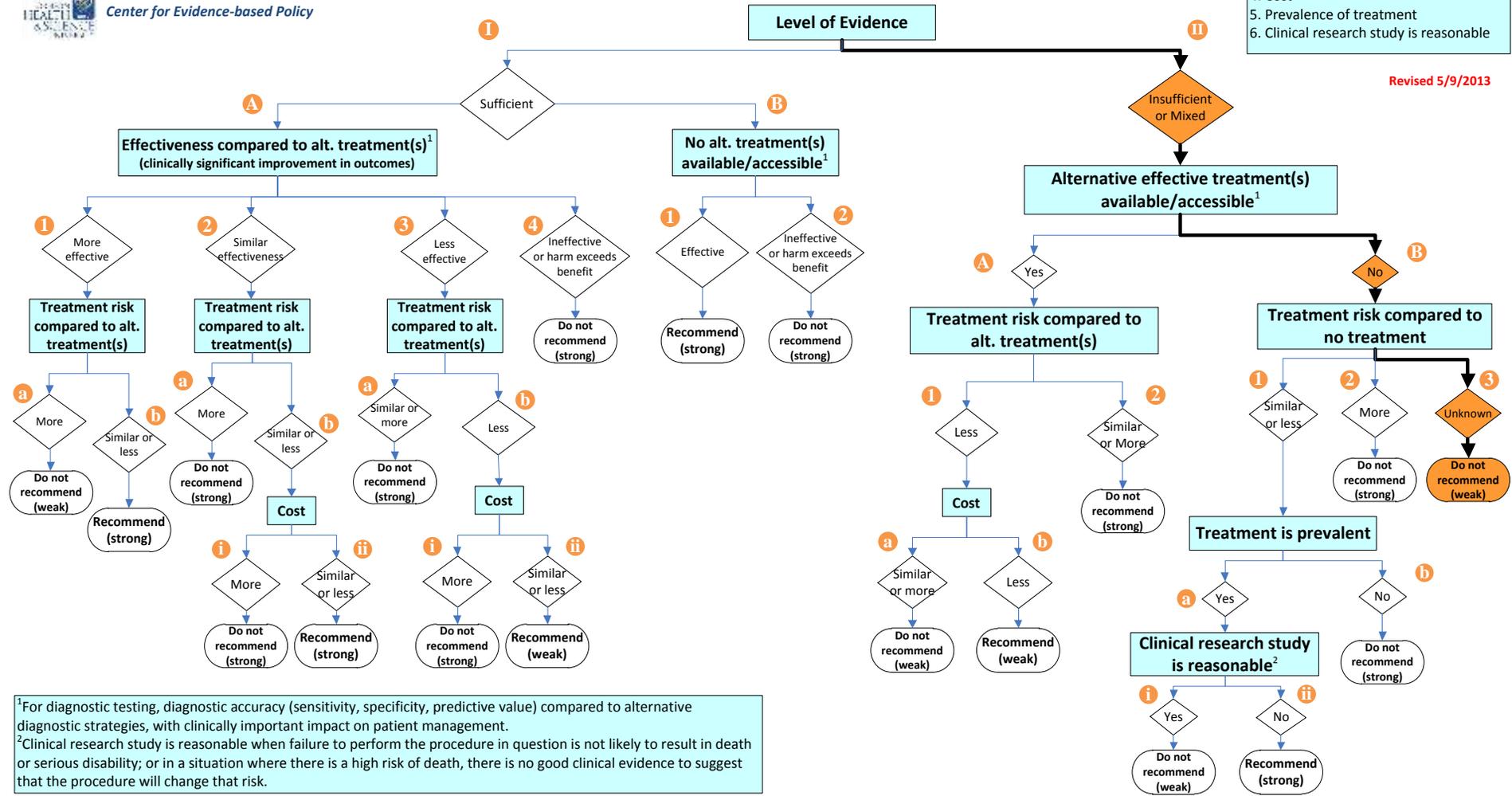


## HERC Guidance Development Framework

Refer to HERC Guidance Development Framework Principles for additional considerations

- Decision Point Priorities**
1. Level of evidence
  2. Effectiveness & alternative treatments
  3. Harms and risk
  4. Cost
  5. Prevalence of treatment
  6. Clinical research study is reasonable

Revised 5/9/2013



<sup>1</sup>For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.  
<sup>2</sup>Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

Repeat DXA for monitoring osteoporosis or advanced osteopenia < 2 years; Repeat screening <4 years for moderate, Repeat screening DXA < 15 years in women with normal BMD or mild osteopenia



## HERC Guidance Development Framework

Refer to HERC Guidance Development Framework Principles for additional considerations

- Decision Point Priorities**

  1. Level of evidence
  2. Effectiveness & alternative treatments
  3. Harms and risk
  4. Cost
  5. Prevalence of treatment
  6. Clinical research study is reasonable

Revised 5/9/2013

