Washington State Health Care Authority

Health Technology Assessment

Screening and Monitoring Tests for Osteopenia/Osteoporosis

Draft Report Public Comment & Response

October 20, 2014

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Screening and Monitoring Tests for Osteopenia/Osteoporosis

Response to Topic and Public Comments on Key Questions

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Response to Public Comments, Draft Report

Screening and Monitoring Tests for Osteopenia/Osteoporosis

Hayes, Inc. is an independent vendor contracted to produce evidence assessment reports for the WA HTA program. For transparency, all comments received during the comments process are included in this response document.

Comments related to program decisions, processes, or other matters not pertaining to the evidence report are acknowledged through inclusion only. When comments cite evidence, the information is forwarded to the vendor for consideration in the evidence report.

This document responds to comments from the following parties:

- Christopher Shuhart, MD; Medical Director, Bone Health and Osteoporosis Institute, Swedish Hospital, Seattle, WA
- Jointly from the American Association of Clinical Endocrinologists (AACE), American Society for Bone and Mineral Research (ASBMR), International Society for Clinical Densitometry (ISCD), and National Bone Health Alliance (NBHA)

Table 1 provides a summary of the comments with corresponding responses.

Table 1. Public Comments on Draft Report, Screening and Monitoring Tests for Osteopenia/Osteoporosis

Key: AHRQ, Agency for Healthcare Research and Quality; BMD, bone mineral density; ISCD, International Society for Clinical Densitometry

Comment and Source	Response
October 5, 2014, email from Dr. Christopher Shuhart (Swedish Hospital)	
SUMMARY OF BACKGROUND "Comment: Low bone mass is multifactorial: contributing factors to level of bone mass are largely genetic, but aging in women creates loss of ovarian estrogen, which escalates bone loss. If you are going to use the word "steroids" more precision is warranted."	Thank you for this comment. Based on re-review of references used for the **BACKGROUND** section, a statement has been added that peak bone mass is largely determined by genetics. The statement about steroidal changes and bone loss has been modified.
SUMMARY OF CLINICAL BACKGROUND **Osteoporosis and Fracture** "Comment: Osteoporotic fractures in men attend worse mortality compared to women. This may be important to point out."	Thank you for your comment. This information, with reference, has been added to the **BACKGROUND** section.
SUMMARY OF CLINICAL BACKGROUND **Tools For Assessing Risk Of Osteoporosis and Risk of Fracture** "Comment: A number of tools have been validated to predict risk of osteoporosis and risk of fracture. Those predicting risk of fracture are clinically more useful. Only FRAX has the epidemiological power to include competing mortality for older individuals. Other models like QFracture and Garvan tend to overestimate fracture risk above age 75 because they do not take into account the risk of dying during the ten-year risk interval. See: Osteoporos Int. 2013 Feb;24(2):681-8. The take home point is that the preceding paragraphs make it appear that there are a plethora of tools, and perhaps the abundance creates confusion and imprecision, calling into question the validity of any of the tools."	Thank you for this comment. The report describes all fracture-risk tools identified by the 2010 AHRQ evidence review as being "externally validated." The cited study has been added to the discussion with a comment that the FRAX tool may have an advantage over other tools in that it takes into account the competing risk of death due to other causes. However, estimates of the accuracy of FRAX are similar to estimates of the accuracy of other tools, according to data presented in the AHRQ review. These findings are now also acknowledged in the discussion.
SUMMARY OF CLINICAL BACKGROUND **Treatment** "Comment: NOF's 2013 Clinicians Manual considers the presence of any low-energy vertebral fracture (clinical or x-ray determined) as an indication for treatment."	Thank you for this comment. The descriptions of guideline recommendations for treatment have been changed accordingly.

Comment and Source	Response
SUMMARY OF CLINICAL BACKGROUND **Treatment** "Comment: In paragraph 4, it is stated that little is known about treatment to prevent osteoporosis in those with osteopenia. The Women's Health Initiative Trial (estrogen/progestin and estrogen only arms) clearly shows reduction in fracture risk in postmenopausal women who on average at baseline did not have osteoporosis."	Thank you for this comment. The descriptions of treatment efficacy have been modified.
SUMMARY OF TECHNICAL ASPECTS OF DXA **How DXA Scanning Works** "Comment: Beyond the concordance of hip/spine BMD and fractures at those sites, in the USA the femoral neck region at the proximal femur is the only region with a harmonized reference database between all three major manufacturers of DXA machines in USA."	Thank you for your comment. Relevant recommendations from the ISCD have been added.
POLICY CONTEXT "Comment: In paragraph seven, the results of the State of Oregon's HERC are restated. The advice on rescreening relies heavily on the article now commonly referred to in bone health as the "Gourlay Article." Oregon HERC made an ill-advised cognitive leap from the specific findings of the study (in women 67+), recommending that the rescreening intervals be applied to all postmenopausal women, denying the clear fact of accelerated and unpredictable bone loss in the perimenopause and post menopause."	Thank you for your comment. This study is discussed as part of the evidence for Key Question #2c. A statement has been added to clarify that this study did not evaluate whether testing intervals should shorten with advancing age beyond 67 years. A more explicit acknowledgement of the lack of evidence pertaining to perimenopausal women has been added.
October 6, 2014, letter from Donna Fiorentino, Legislative Counsel for ISCD, on behalf of AACE, ASBMR, ISCD, and NBHA. The following quoted comments are taken from an accompanying Executive Summary.	
"Despite US costs estimated at $25 billion in 2025, and despite the capability to reduce fractures once discovered, osteoporosis evaluation with DXA remains underutilized: fewer scans are performed and fewer providers offer DXA services—18% fewer in Washington State in 2012 than in 2008."	Thank you for your comment. The **BACKGROUND** sections of the report include information on economic burden of osteoporotic fractures and cite published concerns about the underdiagnosis and undertreatment of DXA scanning.
"A National Coverage Determination does exist through CMS for bone densitometry, validating the importance of DXA in the eyes of CMS, and	Thank you for this information. Appropriate edits have been made in the report.

Comment and Source	Response
creating a level national playing field: see Chapter 15, Section 80.5 of Pub. 100-02. Medicare Benefit Policy Manual. Effective date 01/01/2007. Implementation date 07/02/2007."	
"Important research regarding Key Question #1 was not included: population-based studies from large Health Maintenance Organizations Kaiser Permanente of Southern California and The Geisinger Health Plan showed significant reductions in fracture rates and cost-of-care when formal systems to increase DXA screenings were implemented."	Thank you for identifying these programs. The 2 articles cited by the commenters (Newman et al., 2003; Dell et al., 2011) were reviewed. Both articles described multifaceted programs, of which DXA scanning was only 1 of several simultaneously implemented program elements. Thus, the impact of DXA scanning per se could not be evaluated. The article by Dell et al. did not report outcomes. However, a short description of the Geisinger study (Newman et al.) was added as *Additional Potentially Policy-Relevant Information* to the Literature Review.
"Regarding Key Question #2, the reliance on the "Gourlay" article ("Bone Density Testing Interval and Transition to Osteoporosis in Older Women" Gourlay et al., NEJM, Jan 19, 2012) for the majority of evidence addressing the question is misguided at best. The study suffers from: 1) lowest-risk sub-selection, 2) exclusion of only a minority of patients with clinically important vertebral fractures, 3) arbitrary and un-recognized sub-classification of patients with low bone mass, 4) insufficient capture of patients at risk when utilizing hip bone density only, 5) allowing limited applicability without understanding of rapid bone loss in the menopausal transition, and 6) an antiquated understanding of notion of fracture risk based in T-score only. Similarly the "Frost" article (Frost SW, Nguyen DN. Timing of Repeat BMD Measurements: Development of an Absolute Risk-Based Prognostic Model, Journal of Bone and Mineral Research, Volume 24, Number 11, 2009, Published online on May 4, 2009; doi: 10.1359/JBMR.090514 Ó 2009.) also calculates screening intervals based on T-score based thresholds, which just do not represent actual risks to patients since most patients who fracture do not have T-scores less than –2.5."	Thank you for these comments. Regarding the Gourlay study: (1) The report clarifies that neither the Gourlay nor Frost estimates apply to individuals with risk factors other than age. (2) We also interpret the study to have included women with radiographic but asymptomatic vertebral fracture (women with prior clinical fracture were excluded), and we agree that this means some women who were already eligible for treatment and at higher risk for future fracture might have been part of the study. However, it seems reasonable to assume that this inclusion would have had the effect of shortening, not lengthening, the observed time to one of the study's endpoints. (3) A statement has been added to the discussion in the **TECHNICAL REPORT** to clarify that the authors provided no basis for the cutoff values to distinguish mild, moderate, and advanced osteopenia. (4) The FRAX tool, which was the basis for risk-adjusted analysis in the study, uses BMD of the femoral neck for prediction of hip or major osteoporotic fracture and does not take into account BMD at other anatomic sites. (5) The report has been edited to make this clear. (6) The model was adjusted for most components of the FRAX tool, and the report clarifies that findings may not apply to individuals who have risk factors other than age, sex, or baseline low bone mass.

Comment and Source	Response
	Regarding the Frost study: The model constructed as part of the Frost study included age, sex, and the competing risk of death, as well as initial BMD. All study participants had an initial BMD *greater than* –2.5, and the prediction model was based on actual observations. Thus, there was no assumption that fractures occur only if T-scores are < –2.5. No changes were made in the report.
"The cost effectiveness calculations in Key Question #3 and #5 are heavily dependent on outdated DXA reimbursement values. Using the present actual values would result in significantly better cost-effectiveness, since the present value is two-thirds less than the inflation-adjusted 2010 value cited in the evidence."	Thank you for this information. An acknowledgement of this comment has been added to the report. Actual costs to the different Washington State plans, as reported in the Washington State Agency Utilization Data section of the report, are perhaps more germane, and these have been added to the discussions of Key Question #5 findings. The 2 key cost-effectiveness studies conducted sensitivity analyses in which cost assumptions were varied, and found that conclusions were robust.