Washington State Health Care Authority

Health Technology Assessment

Screening & Monitoring Tests for Osteopenia/Osteoporosis

Draft Key Questions: Public Comments & Response

June 13, 2014

Health Technology Assessment Program (HTA)
Washington State Health Care Authority
PO Box 42712
Olympia, WA 98504-2712
(360) 725-5126
www.hca.wa.gov/hta
shtap@hca.wa.gov

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Prepared by:

Hayes, Inc.
157 S. Broad Street Suite 200
Lansdale, PA 19446
P: 215.855.0615 F: 215.855.5218

Response to Public Comments, Topic Selection and Draft Key Questions

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.

Draft key questions for each WA HTA report are posted online in order to gather public input and any additional evidence to be considered in the evidence review. Since key questions guide the evidence report, WA HTA seeks input on whether the questions are appropriate to address its mandate to gather evidence on safety, efficacy, and cost-effectiveness relevant to coverage determinations. Input about the following is especially helpful:

- Are appropriate populations or indications identified?
- Are appropriate comparators identified?
- Are appropriate patient-oriented outcome measures included?
- Are there special policy or clinical considerations that could affect the review?

Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only. When comments cited evidence, the vendor was encouraged to consider inclusion of this evidence in the report.

This document responds to comments from the following parties:

- R. Mark Harrell, MD, FACP, FACE, ECNU; President, American Association of Clinical Endocrinologists
- David Lee, MPA; Executive Director, National Bone Health Alliance
- Jason Spangler, MD, MPH; Executive Director, U.S. Health Policy & Reimbursement, Amgen
- Dr. Sunil Wimalawansa; Prof. Medicine/Endocrinology

Table 1 provides a summary of comments with responses.

Table 1. Public Comments on Topic and Key Questions , Screening and Monitoring Tests for Osteopenia/Osteoporosis

Comment and Source	Response
Comments on Topic	
None received	
Comments on Draft Key Questions	
June 2, 2014 letter from Dr. Mack Harrell (American Association of Clinical Endocrinologists)	
"Osteoporosis causes bones to become brittle and porous, which causes bones to break. It is estimated that 43.6 million Americans have either osteoporosis or low bone mass. Over 2 million osteoporotic fractures occur annually, with a direct cost of $19 billion each year. A bone density test is an important clinical tool to test for osteoporosis and to monitor the effectiveness of medical therapy to prevent and treat osteoporosis."	Thank you for these facts. Information on epidemiology and disease burden will be included in the Background section of the report. No changes needed in Key Questions.
"We have reviewed the draft key questions and recognize they have been asked and answered many times by our colleagues in the field. For additional information on the importance and utility of bone mass measurements, we refer you to the following documents: • AACE Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis (An update to these guidelines is in progress; we will be happy to share this with you when finalized.) • NOF Clinician's Guide to the Prevention and Treatment of Osteoporosis • United States Preventive Services Task Force Recommendations on Osteoporosis Screening"	Thank you for these references. They will be discussed in the report. No changes needed in Key Questions.
"AACE is happy to work with you as you finalize the questions and continue to address this important issue. There are over 70 AACE members who are practicing clinical endocrinologists in the State of Washington that we can also refer you to as a local resource."	Thank you for your interest. No changes needed in Key Questions.

Comment and Source	Response
Comments on Topic	
June 2, 2014 letter from Mr. David Lee (National Bone Health Alliance)	
"We read with great interest your draft key questions and would be happy to recommend, as you finalize these questions and work to craft a document that addresses these points, Washington state and other national osteoporosis clinical and academic experts to engage around this effort as well as provide fully referenced documents for your background, given our familiarity with this subject matter."	Thank you for your interest in this project. The WA HTA Program will forward to Hayes any references you might wish to suggest, either at this time or after the First Draft Report has been posted to the website. No changes needed in the Key Questions.
June 2, 2014 email and comments from Dr. Jason Spangler (Amgen)	
"Overall, we support the draft key questions of the assessment but offer the following targeted comments for your consideration."	
PICO "As this HTA is focused on screening and monitoring for osteopenia/osteoporosis, the subject of harms associated with osteoporosis medications seems to be beyond the scope of this assessment. Additionally, the HTA website explicitly states that '(h)ealth technology does not include prescription drugs' and information on prescription drug purchasing falls under the Health Care Authority's Prescription Drug Program. Also, there are no draft questions that directly address the subject. For these reasons, we would recommend clarification of the scope of the HTA and/or the draft key questions."	Thank you for your comment. The likelihood of treatment and the potential harms associated with treatment are among the consequences of screening in an asymptomatic population and as such are conventionally addressed in HTAs of screening tests. The assessment will *not* be designed to evaluate the balance of harms and benefits associated with appropriate use of osteoporosis medications but rather, will use what is known about drug-related complications to assess the implications of screening. We will make sure the rationale for raising these issues is clear in the report. No change required in the PICO statement.

Comment and Source	Response
Comments on Topic	
Key Question #3 " . . . we note that a bone mineral density (BMD) test is just one component of the assessment of risk for fracture (*e.g.,* consider the FRAX screo tool, which incorporates BMD in addition other other clinical factors to determine fracture risk). Question #3 runs the risk of oversimplifying the role of the screening tool. It will be challenging to attempt to quantify the success of treatment of patients identified as being at risk for fracture by BMD testing, given the many factors involved in fracture risk. For these reasons, we urge the committee to consider specifying the 'other risk factors' it has in mind for defining subgroups of fracture risk. Question #3 also raises the issue of which treatment the patient receives, as the various treatments have been shown to have varying benefit regarding skeletal site of fracture protection (*e.g.,* hip vs spine), and have used very different patient populations and historic time frames. We recommend that this question be clarified to address these issues."	Thank you for calling our attention to these important issues. Hayes has recommended to the HTA Program that Key Question #3 be amended to read: 3. What is the number needed to test to prevent one fracture in subgroups defined by age, sex, and other risk factors? We will consult practice guidelines, systematic reviews, and the assigned clinical expert for appropriate assumptions about treatment practices, and representative drug trials.
Key Question #5 "Finally, when evaluating health technologies, many factors must be considered, including not only costs, but also cost-effectiveness, as you note in Question #5. However, in order to adequately evaluate cost-effectiveness, analyses must be designed appropriately. . .cost-effectiveness analyses . . . should not be solely used in decision making . . ." The commenter refers to relevant analytic methods recommended by the Centers for Disease Control and Prevention.	Hayes very much agrees with these comments and will critically appraise any economic evaluations used in the report. Our quality assessment methods follow principles recommended by health economics authorities. Thank you for the CDC information; we will review this. No change needed in Key Question #5.
May 22, 2014 email from Dr. Sunil Wimalawansa	
Key Question #1 "There are several; reports providing evidence (including the *Loven* Report commissioned by the ISCD) that early diagnosis of osteoporosis by DXA leading to appropriate management/treatment, prevent fractures; thus, saving costs and improving quality of lives. Evidence suggests that the treatment, prevention effectiveness depends on the age and	Thank for your input. We have not been able to identify the *Loven* Report but will be on the lookout for this resource. The commenter is invited to send information on how to access this report. No change to the Key Question is needed.

Comment and Source	Response
Comments on Topic	
the sex, as the risks increases with age in both males and females. Giving references indicated here. However, I am not aware of any evidence that general population screening is cost-effective. This is a controversial issue; In individual patients this is certainly meaningful and effective."	
Key Question #2 "Most endocrinologists and bone specialists repeat BMD in their patients at two-year intervals (taken the LSE into account)."	Thank you for this practice information. No change to the Key Question is needed.
Key Question #3 This is highly theoretical and not achievable. However, many groups have calculated data on the number needed to treat to prevent a fracture. You may need to give these references that are also available from the ISCD office.	Thank you for your comment. We will check the ISCD website for relevant publications. No change to the Key Question is needed.
Key Question #4 "Radiation exposure of DXA testing is less than 20% of that of a chest x-ray, and less than the radiation receiving from a transatlantic flight to London from New York. Therefore, it is clearly safe (especially considering that this is done every other year). What messed up are the 'technological issues' related to careless scanning (mostly positioning errors) by technicians and 'poor interpretation' by physicians. Many physicians are now totally relying on the DXA 'computer printouts' as reports; which is pathetic and erroneous. In fact, by definition this considered as a Medicare fraud (i.e., the lack of physicians intellectual input on reporting (any) imaging studies, including DXA)."	Thank you. We will look for discussions of these issues in the literature. No change to the Key Question is needed.