

## ***Proposed Retirement of Existing Measure for HEDIS<sup>®1</sup>: Osteoporosis Testing in Older Women (OTO)***

NCQA seeks comments on the proposed retirement of the HEDIS health plan measure *Osteoporosis Testing in Older Women (OTO)*, for HEDIS 2021.

This population screening measure, collected through a question on the Medicare Health Outcomes Survey (HOS), assesses the percentage of women 65–85 years of age who report ever having been screened for osteoporosis using central dual-energy x-ray absorptiometry (DXA). Available HEDIS data for the measure show little change in performance from 2014–2016. The average performance rate across plans decreased slightly, from 75.0% in 2014 to 74.3% in 2016.

Stakeholders have raised concerns about the validity of trying to capture screening through a survey question, given that older women and their caregivers may not accurately recall if they were ever screened for osteoporosis and the type of test they received.

The U.S. Preventive Services Task Force updated its recommendation statement for osteoporosis screening in June 2018. Although there were no changes to the population recommended for screening, the language was updated regarding the tests that may be used to screen for osteoporosis. The 2018 recommendation added peripheral DXA and quantitative ultrasound as tests that similarly predict risk of fracture, while continuing to recommend central DXA for diagnostic and treatment criteria.

The survey question for the OTO measure currently refers to the “back or hip” as the location where the screening test would be performed. This infers the use of central DXA specifically and is therefore out of alignment with the latest task force recommendation statement.

Because this is currently listed as a Display measure for the CMS Star Ratings program, NCQA proposes to retire it from HEDIS 2021 (the HOS that is fielded in 2021), to give health plans advance notice of the retirement.

Supporting documents include the current measure specification, performance data and evidence workup.

**NCQA acknowledges the contributions of the Osteoporosis Expert Work Group,  
the Geriatric Measurement Advisory Panel and the Coding Panel**

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## ***Osteoporosis Testing in Older Women (OTO)***

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### **PROPOSED RETIREMENT FOR HEDIS 2021**

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#### **Description**

This measure assesses the number of women 65–85 years of age who report ever having received a bone density test to check for osteoporosis.

#### **Eligible Population**

<b>Product line</b>	Medicare.
<b>Age</b>	65–85 years as of December 31 of the measurement year.
<b>Exclusion</b>	Evidence from CMS administrative records of a hospice start date.

#### **Protocol and Survey Instrument**

<b>Medicare</b>	Collected using the HOS. MAOs reporting the measure must contract with a CMS-approved HOS survey vendor to administer the survey.
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#### **Questions Included in the Measure**

Table E-4 presents the question included in the measure.

**Table E-4: Osteoporosis Testing in Older Women**

	<b>Question</b>	<b>Response Choices</b>
<b>Q52</b>	Have you ever had a <b>bone density test</b> to check for <b>osteoporosis</b> , sometimes thought of as “brittle bones”? This test would have been done to your back or hip.	Yes No

#### **Calculating Osteoporosis Testing in Older Women Results**

Results are calculated by NCQA using data collected in the combined Baseline and Follow-Up Survey samples from the same measurement year.

The MAO must achieve a denominator of at least 100 to obtain a reportable result. If the denominator is less than 100, NCQA assigns a measure result of *NA*.

#### **Osteoporosis Testing in Older Women**

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<b>Denominator</b>	The number of female members age 65-85 as of December 31 of the measurement year who responded “Yes” or “No” to the question “Have you ever had a bone density test to check for osteoporosis, sometimes thought of as ‘brittle bones’? This test would have been done to your back or hip.”
<b>Numerator</b>	The number of members in the denominator who responded “Yes” to the question “Have you ever had a bone density test to check for osteoporosis, sometimes thought of as ‘brittle bones’? This test would have been done to your back or hip.”

## ***Osteoporosis Testing in Older Women (OTO)*** **Measure Workup**

### **Topic Overview**

The *Osteoporosis Testing in Older Women (OTO)* measure assesses the percentage of women 65–85 years of age who self-report ever having received a bone density test to check for osteoporosis.

### **Importance and Prevalence**

Osteoporosis is the most common metabolic bone disease and is characterized by low bone mineral density and structural deterioration of bone tissue, causing bone fragility and increasing the risk of fractures (National Institutes of Health—The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIH-NIAMS) 2017). It is estimated that by 2020, approximately 12.3 million people 50 and older are expected to have osteoporosis (Wright 2014). Osteoporosis affects about 5% of men 65 and older and about 25% of women 65 and older (Looker 2017). Osteoporosis or low bone mass at the femur neck or lumbar spine increases as individuals age. Table 1 illustrates the prevalence of osteoporosis and low bone mass in men and women 50 and older (Looker 2017).

**Table 1: Percentage of Adults with Osteoporosis or Low Bone Mass**

Age	50-59	60-69	70-79	80+
Women	7%	10%	27%	35%
Men	3%	3%	4%	10%

Prevalence also varies by race and ethnicity. According to the Centers for Disease Control and Prevention, the percentage of women 50 and older with osteoporosis by ethnicity were 8% in non-Hispanic blacks, 16% in non-Hispanic Whites, 17% in Hispanics and 39% in non-Hispanic Asians (Looker 2017).

Researchers applying the National Health and Nutrition Examination Survey (NHANES) data to 2020 and 2030 census population projections estimated that the population 50 years of age or older with osteoporosis or low bone mass is forecast to increase from an estimated 53 million in 2010 to 63.9 million in 2020 and to 70.6 million in 2030 (Wright 2014).

One in two women and up to one in five men will experience an osteoporosis-related fracture at some point in their lifetime (US Department of Health and Human Services (USDHHS) 2004). Individuals who experience an osteoporosis-related fracture are at increased risk of experiencing additional fractures. In one study, women who had a history of vertebral fracture were four times more likely to experience a new fracture within 15 years, relative to women without a history of vertebral fracture (Cauley 2007).

Osteoporotic fractures, particularly hip fractures, are associated with limited mobility, chronic pain and disability, loss of independence and decreased quality of life (Brauer 2009). Between 21% and 30% of patients who experience a hip fracture die within 1 year (Brauer 2009). Hip and vertebral fractures are the most common osteoporosis related fractures. Vertebral fractures can cause chronic back pain and have been linked to increased mortality in older people (NIH NIAMS 2017). Patients with a vertebral fracture have mortality rates twice that of matched controls without vertebral fractures (Lau 2008). Compared with patients without a vertebral fracture, osteoporotic patients with vertebral fractures also report worse overall quality of life, including worse physical function, bodily pain, social function and general health perception (Romagnoli 2004; Salaffi 2007).

Hip fractures are also associated with significant disability. Most hip fractures require surgery; 50% of hip fracture patients are unable to walk without assistance after surgery. Nearly 20% of hip fracture patients over 50 die in the year following their fracture as a result of associated medical complications (NIH NIAMS 2017). 40% of those who survive never return to pre-fracture functional status, which often leads to the need for long-term nursing home care (USDHHS 2004).

**Disparities in osteoporosis screening**

In a national cohort study, non-Hispanic Asian and Hispanic women 50–79 were most likely to be screened for osteoporosis (Gillespie 2017). Non-Hispanic Black women were least likely to have osteoporosis screening (18.2%) than other racial/ethnic categories (Gillespie 2017). In a retrospective cohort study, researchers from the University of California found that Black women and women with more socioeconomic barriers were less likely to be screened for osteoporosis (Amarnath 2015). Interventions targeting population screening are needed to improve the rates of osteoporosis screening for all women 65 and older, but particularly for Black women and those with lower socioeconomic status.

**Financial importance and cost effectiveness**

Osteoporosis-related fractures cost patients, their families and the health care system an estimated \$19 billion annually (National Osteoporosis Foundation 2018). Experts predict that by 2025, osteoporosis will be responsible for 3 million fractures, resulting in \$25.3 billion in costs (National Osteoporosis Foundation 2018).

Between 2000 and 2011, there were 4.9 million hospitalizations for osteoporotic fractures in postmenopausal women in the United States. Osteoporotic fractures account for more than 40% of hospitalizations in this population, compared with myocardial infarction (25%) and stroke (26%) (Singer 2015). The annual total population facility-related hospital cost was highest for hospitalizations due to osteoporotic fractures (\$5.1 billion), followed by myocardial infarction (\$4.3 billion) and stroke (\$3.0 billion) (Singer 2015). In 2002, 50% of the nonfracture osteoporotic elderly Medicare patients received drug treatment for osteoporosis, averaging \$500 per treated patient, or \$2 billion nationwide (Blume 2011).

## Supporting Evidence for Screening

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The US Preventive Services Task Force (USPSTF) recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in women 65 years and older (USPSTF 2018). This is a B recommendation, meaning that the USPSTF recommends the service and there is moderate certainty for the net benefit of screening.

The USPSTF also recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in postmenopausal women younger than 65 years who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool (USPSTF 2018). One such tool, the FRAX, uses bone density information and other risk factors (e.g. smoking, low BMI, alcohol use, previous fracture) to estimate 10-year fracture risk. Based on the FRAX tool, a 65-year-old White woman with no other risk factors has a 9.3% 10-year risk for any osteoporotic fracture (USPSTF 2018).

**Screening tests**

Osteoporosis is characterized by low bone mineral density (BMD) and the resulting increased risk of fractures. The USPSTF found good evidence that BMD measurements accurately predict risk for fractures in the short term and that treatments for asymptomatic women with osteoporosis can reduce their risk of fracture. Although there are several advanced screening methods for low BMD, DXA of the hip and lumbar spine (“central DXA”) is the most common. DXA quantitatively calculates the photon absorption of the minerals in bone tissue. Other machine-based tests include quantitative ultrasound (QUS), peripheral DXA, quantitative computerized tomography (QCT) and radiograph absorptiometry. QUS of the calcaneus (heel) is portable and avoids the risk of radiation, but QUS does not actually measure BMD, so it cannot be used in risk prediction instruments that use BMD. Currently, most diagnostic and treatment criteria for osteoporosis rely on DXA measurements (USPSTF 2018).

<b>Frequency of screening</b>	There is no clear evidence to inform the optimal intervals for repeated screening and whether repeated screening is necessary in a woman with normal bone mineral density. Some observational and modeling studies have suggested screening intervals based on age, baseline BMD and calculated projected time to transition to osteoporosis. However, limited evidence from two good-quality studies found no benefit in predicting fractures from repeating bone measurement testing 4–8 years after initial screening (Viswanathan 2018). A minimum 2-year gap between testing is needed to reliably measure change in bone mineral density (USPSTF 2018). A prospective study of women 65 years or older found that a bone density measurement from a test conducted up to 8 years after an initial bone density test did not result in better prediction of subsequent fractures (Hillier 2007).
<b>Treatment</b>	For postmenopausal women, bisphosphonates, parathyroid hormone, raloxifene and estrogen have been shown to reduce vertebral fractures and are effective for primary prevention. Bisphosphonates and raloxifene have the strongest most consistent evidence of effectiveness in women (Nelson 2010). The most recent USPSTF 2018 evidence review confirms these findings (Viswanathan 2018).
<b>Potential harms of screening</b>	The USPSTF did not find evidence that addressed the potential harms of screening for osteoporosis (Viswanathan 2018). The USPSTF evidence review found a single study that described harms of screening for osteoporosis. It reported no increase in anxiety and no decrease in quality of life from screening (Viswanathan 2018). Harms associated with screening may include radiation exposure from DXA and 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 that the risk of serious adverse events, upper gastrointestinal events or cardiovascular events associated with the most common class of osteoporosis medication (bisphosphonates) is small. Overall, the USPSTF found adequate evidence that the harms of osteoporosis medications are small.

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## Specific Guideline Recommendations

Organization, Year	Population	Recommendation	Grade of Recommendation
<b>U.S. Preventive Services Task Force</b> <i>June 2018</i>	Women age 65 years and older	The USPSTF recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in women age 65 years and older.	Grade B
	Postmenopausal women younger than age 65 years at increased risk of osteoporosis	The USPSTF recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in postmenopausal women younger than 65 years who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool.	
	Men	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for osteoporosis to prevent osteoporotic fractures in men.	Grade I
<b>American Association of Clinical Endocrinologists (AACE)</b> <i>September 2016</i>	All postmenopausal women > 50 years (page 7)	The AACE recommends this population undergo clinical assessment for osteoporosis and fracture risk, including a detailed history and physical examination.	Grade B Level 2
	Women aged 65 and older (page 10)	The AACE recommends bone mineral density testing for women aged 65 and older and younger postmenopausal women at increased risk for bone loss and fracture based on fracture risk analysis.	
	Postmenopausal women under the age of 65	The AACE recommends bone mineral density testing for women aged 65 and older and younger postmenopausal women at increased risk for bone loss and fracture based on fracture risk analysis. Risk factors for osteoporosis include: prior low-trauma fracture as an adult, advanced age, low bone mineral density, low body weight or low body mass index, family history of osteoporosis, use of corticosteroids, cigarette smoking, excessive alcohol consumption, and secondary osteoporosis such as rheumatoid arthritis.	Grade C Level 2
	All patients who have a history of a fracture in the hip or spine	The AACE recommends pharmacologic therapy	Grade A Level 1
	Patients without a history of fractures but with a T-score of -2.5 or lower		
	All patients with a T-score between -1.0 and -2.5 if FRAX major osteoporotic fracture probability is greater than or equal to 20% or hip fracture is greater than or equal to 3%	The AACE recommends pharmacologic therapy	Grade A Level 2

Organization, Year	Population	Recommendation	Grade of Recommendation
<b>National Osteoporosis Foundation</b> <i>June 2014</i>	Women age 65 and older Men age 70 and older Younger postmenopausal women Women in the menopausal transition Men age 50-69 with clinical risk factors for fracture Adults who have a fracture after age 50 Adults with a condition (rheumatoid arthritis) Adults taking a medication associated with low bone mass or bone loss	The NOF recommends Bone Mineral Density Testing in these populations.	
	All postmenopausal women Men age 50 and older	The NOF recommends treating these populations who have had the following outcomes: 1) a hip or vertebral fracture, (2) T-score less than or equal to -2.5 at the femoral neck, total hip or lumbar spine, and (3) low bone mass (T-score between -1.0 and -2.5 at the femoral neck or lumbar spine) and a 10-year probability of a hip fracture greater than or equal to 3% or a 10-year probability of a major osteoporosis-related fracture greater than or equal to 20%.	
	Individuals being treated for osteoporosis	The NOF recommends a repeat bone mineral density test every 1-2 years after initiating therapy to reduce fracture risk and every 2 years after that.	
<b>North American Menopause Society</b> <i>2010</i>	Women age 65 and over, regardless of clinical risk factors Postmenopausal women with medical causes of bone loss (e.g. steroid use), regardless of age Postmenopausal women age 50 and older with additional risk factors Postmenopausal women with a fragility fracture	The NAMS recommends a bone mineral density test in all these populations.	
	All women age 50 and older who have one or more of the following risk factors: fracture after menopause, thinness (body weight <127 or body mass index < 21), history of hip fracture in a parent, current smoker, rheumatoid arthritis diagnoses, and has an alcohol intake of more than two units per day.	The NAMS also recommends that <i>testing be considered</i> in this population.	



Organization, Year	Population	Recommendation	Grade of Recommendation
	<p>Postmenopausal women who have had an osteoporotic vertebral or hip fracture.</p> <p>Postmenopausal women who have bone mineral density values consistent with osteoporosis.</p> <p>All postmenopausal women who have T-scores from -1.0 to -2.5 and a 10-year risk based on the FRAX calculator of major osteoporotic fracture (spine, hip, shoulder, wrist) of at least 20% or of hip fracture of at least 3%.</p>	The NAMS recommends osteoporosis drug therapy in these populations.	
	Women receiving treatment for osteoporosis	NAMS recommends a bone mineral density test after 1-2 years.	
	Postmenopausal women <i>untreated</i> for osteoporosis	NAMS recommends a repeat DXA scan every 2-5 years.	

### Grading System Key

#### ***U.S. Preventive Services Task Force: What the Grade Means and Suggestions for Practice***

Grade	Definition	Suggestion for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	Clinicians may provide this service to selected patients depending on individual circumstances. However, for most individuals without signs or symptoms there is likely to be only a small benefit from this service.	Offer or provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

#### **U.S. Preventive Services Task Force: Levels of Certainty Regarding Net Benefit**

**High:** The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.

**Moderate:** The available evidence is insufficient to determine the effects of the preventive services on health outcomes, but confidence in the estimate is constrained by factors such as: (1) the number, size or quality of individual studies, (2) Inconsistency of findings across individual studies, (3) Limited generalizability of findings to routine primary care practice, (4) Lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.

*Low:* The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: (1) the limited number of size of studies, (2) important flaws in study design and methods, (3) inconsistency of findings across individual studies, (4) gaps in the chain of evidence, (5) findings not generalizable to routine primary care practice, (6) and a lack of information on important health outcomes. More information may allow an estimation of effects on health outcomes.

### **American Association of Clinical Endocrinologists: Criteria for Grading Recommendation**

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<b>Grade</b>	<b>Definition</b>
A	Homogenous evidence from multiple well-designed randomized or cohort controlled trials with sufficient statistical power. $\geq 1$ conclusive level 1 publications demonstrating benefit= risk
B	Evidence from at least 1 large well-designed clinical trial, cohort or case-controlled analytic study, or meta-analysis. No conclusive level 1 publication; $\geq 1$ conclusive level 2 publications demonstrating benefit= risk
C	Evidence based on clinical experience, descriptive studies, or expert consensus opinion. No conclusive level 1 or 2 publications; $\geq 1$ conclusive level 3 publications demonstrating benefit= risk. No conclusive risk at all and no conclusive benefit demonstrated by evidence.
D	Not rated. No conclusive level 1, 2, or 3 publication demonstrating benefit= risk. Conclusive level 1, 2, or 3 publication demonstrating risk= benefit.

**2010 American Association of Clinical Endocrinologists Criteria for Rating of Published Evidence\***

<b>Numerical Descriptor (Evidence Level)</b>	<b>Semantic Descriptor (Reference Methods)</b>
1	Meta-analysis of randomized controlled trials
1	Randomized controlled trial
2	Meta-analysis of nonrandomized prospective or case-controlled trials
2	Nonrandomized controlled trial
2	Prospective cohort study
2	Retrospective case-control study
3	Cross-sectional study
3	Surveillance study (registries, surveys, epidemiologic study)
3	Consecutive case series
3	Single case reports
4	No evidence (theory, opinion, consensus, or review)

\*1 = Strong evidence; 2 = Intermediate evidence; 3 = Weak evidence; 4 = No evidence.

**The American College of Physicians Guideline Grading System**

<b>Quality of Evidence</b>	<b>Strength of Recommendation</b>	
	<b>Benefits Clearly Outweigh Risks and Burden or Risks or Burden Clearly Outweigh Risks</b>	<b>Benefits Finely Balanced With Risks and Burden</b>
High	Strong	Weak
Moderate	Strong	Weak
Low	Strong	Weak
Insufficient evidence to determine net benefits or risks		

**HEDIS Health Plan Performance Rates: Osteoporosis Testing in Older Women (OTO)****Table 1. HEDIS OTO Measure Performance—Medicare Plans**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2016	458	419 (91.5)	74.3	10.5	59.3	66.1	76.4	82.3	86.4
2015	452	414 (91.6)	74.4	9.9	60.0	67.7	76.0	81.9	86.5
2014	474	444 (93.7)	75.0	9.5	61.7	69.3	76.6	82.2	86.2

\*2017 performance data are not yet available due to the time delay required to conduct the survey and obtain survey results.