

## ***Proposed Changes to Existing Measure for HEDIS 2020<sup>®1</sup>: Osteoporosis Management in Women Who Had a Fracture (OMW)***

NCQA seeks comments on four proposed modifications to the HEDIS health plan measure *Osteoporosis Management in Women Who Had a Fracture (OMW)*.

This long-standing HEDIS measure, collected through administrative claims and reported by Medicare plans, assesses the percentage of women 65–85 years of age who suffered a fracture and had either a bone measurement test or treatment for osteoporosis in the six months after the fracture. The intent of the measure is to prevent future fractures.

HEDIS data reported for the OMW measure indicate an overall increase in the average performance rate between 2014 (35.9%) and 2017 (44.9%).

### **Proposed Measure Changes**

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***Remove single-energy X-ray absorptiometry (SEXA) as a bone measurement test after fracture.***

The technology is considered outdated and inferior to central dual-energy x-ray absorptiometry (DXA) and the other bone measurement tests included in the measure.

***Remove calcitonin from the list of medications used to treat osteoporosis after a fracture.***

Calcitonin is not considered a first-line treatment for osteoporosis because it is ineffective in reducing risk of future fractures.

***Update timing of the frailty and long-term care exclusions to include the intake period.*** In the current specifications, the long-term care and frailty exclusions are not considered during the intake period. NCQA proposes to revise the timing of these exclusions to include the intake period.

***Update the measure specifications to include subsequent fractures during the intake period.*** NCQA proposes to assess all episodes of fragility fracture for eligibility, not just the first episode of fracture. This proposed change helps us ensure that individuals not captured at the first episode of fracture may be included in the measure if a subsequent fracture occurs and is found to meet the eligibility criteria.

Our expert panels supported these proposed changes.

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

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

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## Osteoporosis Management in Women Who Had a Fracture (OMW)

### SUMMARY OF CHANGES TO HEDIS 2020

- Remove single energy X-ray absorptiometry (SEXA) test from the Bone Mineral Density Tests Value Set.
- Remove calcitonin from the Osteoporosis Medications List, and Osteoporosis Medications Value Set.
- Revise timing for the long-term care and frailty exclusions.
- Revise inclusion of subsequent fractures late in the intake period.

### Description

The percentage of women 67–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.

### Definitions

<b>Intake Period</b>	A 12-month (1 year) window that begins on July 1 of the year prior to the measurement year and ends on June 30 of the measurement year. The Intake Period is used to capture the first fracture.
<b>IESD</b>	Index Episode Start Date. The earliest <b>Episode Date during the Intake Period that meets all eligible population criteria</b> <del>eligibility criteria</del> .
<b><del>Index Date</del> <del>Episode Date</del></b>	<b><del>Index Episode Start Date</del></b> . The <b><del>earliest</del></b> date of service for any encounter during the Intake Period with a diagnosis of fracture.  <i>For an outpatient, observation or ED visit, the <del>IESD Episode Date</del> is date of service.</i> <i>For an inpatient stay, the <del>IESD Episode Date</del> is the date of discharge.</i> <i>For direct transfers, the <del>IESD Episode Date</del> is the discharge date from the last admission.</i>
<b><del>Negative</del> <del>Diagnosis History</del></b>	<b><del>A period of 60 days (2 months) prior to the IESD when the member had no diagnosis of fracture.</del></b>  <i><del>For fractures requiring an inpatient stay, use the date of admission to determine Negative Diagnosis History.</del></i> <i><del>For direct transfers, use the first admission date to determine the Negative Diagnosis History.</del></i> <i><del>For inpatient stays that were a result of an ED or observation visit, use the date of the ED or observation visit to determine Negative Diagnosis History.</del></i>

**Direct transfer** A **direct transfer** is when the discharge date from the first inpatient setting precedes the admission date to a second inpatient setting by one calendar day or less. For example:

- An inpatient discharge on June 1, followed by an admission to another inpatient setting on June 1, is a direct transfer.
- An inpatient discharge on June 1, followed by an admission to an inpatient setting on June 2, is a direct transfer.
- An inpatient discharge on June 1, followed by an admission to another inpatient setting on June 3, is not a direct transfer; these are two distinct inpatient stays.

Use the following method to identify admissions to and discharges from inpatient settings.

1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
2. Identify the admission and discharge dates for the stay.

**Active prescription** A prescription is considered active if the “days supply” indicated on the date the member filled the prescription is the number of days or more between that date and the relevant service date.

## Eligible Population

**Note:** Members in hospice are excluded from the eligible population. Refer to General Guideline 17: Members in Hospice.

<b>Product line</b>	Medicare.
<b>Age</b>	Women 67–85 years as of December 31 of the measurement year.
<b>Continuous enrollment</b>	12 months (1 year) before the <del>IESD Episode Date</del> through 180 days (6 months) after the <del>IESD Episode Date</del> .
<b>Allowable gap</b>	No more than one gap in enrollment of up to 45 days during the continuous enrollment period.
<b>Anchor date</b>	<del>IESD Episode Date</del> .
<b>Benefits</b>	Medical and pharmacy.
<b>Event/ diagnosis</b>	<del>The earliest fracture during the Intake Period</del>

Follow the steps below to identify the eligible population.

- Step 1** Identify all members who had either of the following during the Intake Period.
- An outpatient visit (Outpatient Value Set), an observation visit (Observation Value Set) or an ED visit (ED Value Set), for a fracture (Fractures Value Set) **without** (Telehealth Modifier Value Set; Telehealth POS Value Set).
    - Do not include ED visits or observation visits that result in an inpatient stay (Inpatient Stay Value Set).
  - An acute or nonacute inpatient discharge for a fracture (Fractures Value Set). To identify acute and nonacute inpatient discharges:
    1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
    2. Identify the discharge date for the stay.

If the member had more than one fracture, ~~identify all fractures-include-only-the-first fracture.~~

**Step 2** Test for ~~N~~egative ~~D~~diagnosis ~~H~~istory. Exclude fractures where either of the following occurred during the 60-day (2 months) period prior to the ~~IESD~~ Episode Date.

- An outpatient visit (Outpatient Value Set), with or without a telehealth modifier (Telehealth Modifier Value Set), a telephone visit (Telephone Visits Value Set), an online assessment (Online Assessments Value Set), an observation visit (Observation Value Set) or an ED visit (ED Value Set) for a fracture (Fractures Value Set).
  - Do not include ED visits or observation visits that result in an inpatient stay (Inpatient Stay Value Set).
- An acute or nonacute inpatient discharge for a fracture (Fractures Value Set). To identify acute and nonacute inpatient discharges:
  1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
  2. Identify the discharge date for the stay.
    - For an acute or nonacute inpatient ~~IESD Episode Date~~ event, use the ~~IESD Episode Date~~ date of admission to determine the 60-day period.
    - For direct transfers, use the first admission to determine the Negative Diagnosis History.

**Step 3** Calculate continuous enrollment. Members must be continuously enrolled during the 12 months prior to the ~~fracture~~ Episode Date through 180 days (6 months) post-~~fracture~~ Episode Date.

**Step 4: Required exclusions** Exclude ~~members who meet any of the following criteria~~ Episode Dates where any of the following are met:

- Members who had a BMD test (Bone Mineral Density Tests Value Set) during the 730 days (24 months) prior to the ~~IESD~~ Episode Date.
- Members who had a claim/encounter for osteoporosis therapy (Osteoporosis Medications Value Set) during the 365 days (12 months) prior to the ~~IESD~~ Episode Date.
- Members who received a dispensed prescription or had an active prescription to treat osteoporosis (Osteoporosis Medications List) during the 365 days (12 months) prior to the ~~IESD~~ Episode Date.

~~For an acute or nonacute inpatient IESD Episode Date event use the IESD Episode Date date of admission to determine the number of identify the days prior to the IESD Episode Date.~~

~~For direct transfers, use the first admission date to determine the number of identify the days prior to the IESD Episode Date.~~

**Step 5:** Select the IESD. The measure examines the earliest eligible episode per member.

**Step 5: Step 6: Exclusions** Exclude members who meet any of the following criteria:

**Note:** Supplemental and medical record data may not be used for these exclusions.

- Members 67 years of age and older as of December 31 of the measurement year who meet either of the following:
  - Enrolled in an Institutional SNP (I-SNP) any time during the intake period through the end of ~~or~~ the measurement year.
  - Living long-term in an institution any time during the intake period through the end of the measurement year as identified by the LTI flag in the Monthly Membership Detail Data File. Use the run date of the file to determine if a member had an LTI flag during the intake period through the end of the measurement year.

- Members 67–80 years of age as of December 31 of the measurement year with frailty **and** advanced illness. Members must meet **BOTH** of the following frailty and advanced illness criteria to be excluded:
  1. At least one claim/encounter for frailty (Frailty Value Set) during the **intake period through the end of the** measurement year.
  2. Any of the following during the measurement year or the year prior to the measurement year (count services that occur over both years):
    - At least two outpatient visits (Outpatient Value Set), observation visits (Observation Value Set), ED visits (ED Value Set) or nonacute inpatient encounters (Nonacute Inpatient Value Set) on different dates of service, with an advanced illness diagnosis (Advanced Illness Value Set). Visit type need not be the same for the two visits.
    - At least one acute inpatient encounter (Acute Inpatient Value Set) with an advanced illness diagnosis (Advanced Illness Value Set).
    - A dispensed dementia medication (Dementia Medications List).
- Members 81 years of age and older as of December 31 of the measurement year with frailty (Frailty Value Set) during the **intake period through the end of the** measurement year.

### Dementia Medications

Description	Prescription
Cholinesterase inhibitors	<ul style="list-style-type: none"> <li style="margin-right: 10px;">• Donepezil</li> <li style="margin-right: 10px;">• Galantamine</li> <li>• Rivastigmine</li> </ul>
Miscellaneous central nervous system agents	<ul style="list-style-type: none"> <li>• Memantine</li> </ul>

### Administrative Specification

<b>Denominator</b>	The eligible population.
<b>Numerator</b>	<p>Appropriate testing or treatment for osteoporosis after the fracture defined by any of the following criteria:</p> <ul style="list-style-type: none"> <li>• A BMD test (<u>Bone Mineral Density Tests Value Set</u>), in any setting, on the IESD or in the 180-day (6-month) period after the IESD.</li> <li>• If the IESD was an inpatient stay, a BMD test (<u>Bone Mineral Density Tests Value Set</u>) during the inpatient stay.</li> <li>• Osteoporosis therapy (<u>Osteoporosis Medications Value Set</u>) on the IESD or in the 180-day (6-month) period after the IESD.</li> <li>• If the IESD was an inpatient stay, long-acting osteoporosis therapy (<u>Long-Acting Osteoporosis Medications Value Set</u>) during the inpatient stay.</li> <li>• A dispensed prescription to treat osteoporosis (<u>Osteoporosis Medications List</u>) on the IESD or in the 180-day (6-month) period after the IESD.</li> </ul>

### Osteoporosis Medications

Description	Prescription
Biphosphonates	<ul style="list-style-type: none"> <li style="margin-right: 10px;">• Alendronate</li> <li style="margin-right: 10px;">• Alendronate-cholecalciferol</li> <li style="margin-right: 10px;">• Ibandronate</li> <li style="margin-right: 10px;">• Risedronate</li> <li>• Zoledronic acid</li> </ul>
Other agents	<ul style="list-style-type: none"> <li style="margin-right: 10px;">• Abaloparatide</li> <li style="margin-right: 10px;">• <del>Calcitonin</del></li> <li style="margin-right: 10px;">• Denosumab</li> <li style="margin-right: 10px;">• Raloxifene</li> <li>• Teriparatide</li> </ul>

**Note**

- *Fractures of finger, toe, face and skull are not included in this measure.*

**Data Elements for Reporting**

Organizations that submit HEDIS data to NCQA must provide the following data elements.

**Table OMW-3: Data Elements for Osteoporosis Management in Women Who Had a Fracture**

	Administrative
Measurement year	✓
Data collection methodology (Administrative)	✓
Eligible population	✓
Number of required exclusions	✓
Numerator events by administrative data	✓
Numerator events by supplemental data	✓
Reported rate	✓

## ***Osteoporosis Management in Women Who Had a Fracture (OMW)***

### **Measure Workup**

#### **Topic Overview**

*Osteoporosis Management in Women Who Had a Fracture (OMW)* assesses the percentage of women 65–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 6 months after the fracture.

#### **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 (Centers for Disease Control (Looker 2017).

Osteoporosis can often go undiagnosed. According to data compiled from the National Health and Nutrition Examination Survey (NHANES), 11% of women 65 and older reported having osteoporosis; however, testing revealed the true prevalence to be 26% (USDHHS 2004). Due to underdiagnosis, many adults are unaware they have osteoporosis until they break a bone; most commonly, the hip, spine or wrist. Postmenopausal women who experience a fracture are at significant increased risk of experiencing additional fractures. In a longitudinal cohort study, women who had a history of vertebral fracture were four times more likely to experience a new fracture within the 15-year study period, compared with women without a history of vertebral fracture within the same time period (Cauley et al 2007).

Approximately 2 million osteoporotic fractures occurred in the United States in 2005 (Burge 2007). Nearly 40% of persons who experience a hip fracture are unable to walk independently at one year, and 60% require assistance with at least one essential activity of daily living (U.S. Congress, Office of Technology Assessment 1994). Hip fractures account for a large portion of the morbidity and mortality associated with osteoporotic fractures; 21%–30% of patients die within a year of a hip fracture (Brauer 2009). Older adults have a five- to eight-fold increased risk for all-cause mortality during the first 3 months after hip fracture. Excess annual mortality persists over time for both women and men, but at any given age, excess annual mortality after hip fracture is higher in men than in women (Haentjens 2010).

#### **Financial importance and cost effectiveness**

Osteoporosis-related fractures cost patients, their families and the health care system \$19 billion annually (National Osteoporosis Foundation 2018). By 2025, experts predict that osteoporosis will be responsible for 3 million fractures, resulting in \$25.3 billion in costs (National Osteoporosis Foundation 2018). From 2000–2011, there were 4.9 million hospitalizations for osteoporotic fractures in postmenopausal women in the US. 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).

#### **Disparities in osteoporosis and fractures**

In a national cohort study, non-Hispanic Asian and Hispanic women 50–79 years were most likely to be screened for osteoporosis (Gillespie 2017). Non-Hispanic Black women were least likely to have osteoporosis screening (18.2%), compared with other racial/ethnic categories (Gillespie 2017). Hip fracture rates are highest for White women (140.7 per 100,000) and Asian women (85.4 per 100,000) but are still prevalent in African American women (57.3 per 100,000) and Hispanic women (49.7 per 100,000) (Silverman 1988).

## Supporting Evidence for Testing and Treatment after a Fracture

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Fragility fractures (fractures from falls from a standing position) are considered one of the most serious warning signs of osteoporosis or low bone density. Individuals who experience a fragility fracture have a 1.5- to 9.5-fold increased risk of further fracture. Pharmacologic treatment can reduce the risk of subsequent fractures by 30%–50%. Unfortunately, testing and treatment for low bone mass after fracture has been shown to be as low as 20% (Posen 2013).

Multiple organizations have recognized the need for these types of follow-up and recommend that postmenopausal women who experience a fragility fracture be tested for osteoporosis with a BMD test or treated for osteoporosis (The International Society for Clinical Densitometry 2015; National Osteoporosis Foundation 2014; North American Menopause Society 2010; US Department of Health and Human Services 2004).

### Testing for osteoporosis after a fragility fracture

Testing for osteoporosis after a fragility fracture provides needed information for diagnosis and treatment. Several bone-measurement testing methods are currently used to assess osteoporosis after a fracture.

*Central dual-energy X-ray absorptiometry (DXA):* Central DXA measures BMD at the hip and spine. It is the most commonly used bone measurement test to screen for osteoporosis. Most treatment guidelines recommend using BMD, as measured by central DXA, to define osteoporosis and the treatment threshold to prevent osteoporotic fractures.

*Peripheral DXA:* Peripheral DXA measures BMD at the lower forearm and heel. Peripheral DXA is completed using a portable, less costly and potentially more accessible device. Most treatment guidelines recommend follow-up with central DXA before initiating treatment for osteoporosis, if peripheral DXA is used. Peripheral DXA may help increase access to screening in locations where machines that perform central DXA may not be available, such as rural areas (USPSTF 2018).

*Quantitative ultrasound (QUS):* QUS also is used at peripheral bone sites such as the heel. It does not measure BMD, however, so it cannot be used in risk-prediction instruments that require BMD. QUS is a portable device, making it less costly and more accessible than central DXA. QUS also avoids the risk of radiation (Viswanathan 2018).

*Quantitative computed tomography (QCT):* QCT provides a volumetric measure of bone density, which may improve detection of osteoporosis, compared with areal BMD by DXA (Link 2012). There is little data on how T-scores generated by QCT predict fracture risk when compared to the those based on DXA (Viswanathan 2018).

*Single-energy X-ray absorptiometry (SEXA):* This method of assessing bone mineral density uses a single energy X-ray beam. It is now widely considered inferior to DXA, which uses a second energy beam to correct for absorption of X-ray energy by noncalcium-containing tissues (Adams 1997).

### Treating osteoporosis after a fragility fracture

The National Osteoporosis Foundation (NOF) recommends treating these populations who have had the following outcomes for osteoporosis: 1.) a hip or vertebral fracture; 2.) T-score  $\leq -2.5$  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  $\geq 3\%$  or a 10-year probability of a major osteoporosis-related fracture  $\geq 20\%$  (NOF 2014). The American Association of Clinical Endocrinologists (AACE) recommends pharmacologic therapy for all patients who have a history of a fracture in the hip and spine (Camacho 2016).

In addition to adequate calcium and vitamin D intake and weight-bearing exercise, the USPSTF evidence review found that bisphosphonates, parathyroid hormone (teriparatide), raloxifene and estrogen reduce vertebral fractures in postmenopausal women. Bisphosphonates and raloxifene have the strongest and most consistent evidence (Viswanathan 2018). The USPSTF evidence review also found convincing evidence that drug therapies reduce subsequent fracture rates in postmenopausal women (Viswanathan 2018).

*Bisphosphonates:* The bisphosphonates alendronate, risedronate and ibandronate are approved for prevention and treatment of osteoporosis in the US. Zoledronic acid is approved for treatment of osteoporosis only. In the most recent evidence review conducted for the USPSTF, bisphosphonates were studied most frequently: 7 studies on alendronate, 2 trials on zoledronic acid, 4 trials on risedronate, 2 trials on etidronate were reviewed (Viswanathan 2018). All but 1 study was conducted in postmenopausal women. For women, bisphosphonates were found to significantly reduce vertebral fractures and nonvertebral fractures (Viswanathan 2018).

The USPSTF evidence review highlighted studies on bisphosphonates that showed no increased risk of discontinuation, serious adverse events or upper gastrointestinal events (Viswanathan 2018). There is limited evidence on bisphosphonates and cardiovascular events, and the evidence generally shows no significant difference or nonsignificant increases in atrial fibrillation when using bisphosphonate therapy (Viswanathan 2018).

In 2012, the U.S. Food and Drug Administration released an article discussing the appropriate time frame for a patient to be on bisphosphonates, recommending that some patients may be able to stop after 3–5 years and still continue to benefit from their use, while at the same time decreasing their potential risk of side effects from the medication (USDHHS FDA 2014). However, recent evidence suggests that drug holidays be stopped when an individual experiences a fracture or shows signs of significant bone loss (Diab 2014).

The 2017 American College of Physician (ACP) Guidelines recommend (weak recommendation and low-quality evidence) that clinicians treat osteoporotic women with pharmacologic therapy for 5 years. The guidelines further state that continuing treatment after the initial 5 years may be beneficial for patients and may be appropriate after reassessing the risks and benefits of continuing therapy (Qaseem 2017).

The 2016 AACE Guidelines recommend the following for oral bisphosphonates: 1.) consider a holiday after 5 years of stability in moderate-risk patients (Grade B); 2.) consider a holiday after 6–10 years of stability in higher-risk patients. AACE also recommends that this bisphosphonate holiday be based on individual patient circumstances, such as fracture risk and current BMD (Camacho 2016).

*Raloxifene:* Raloxifene is approved for prevention and treatment of osteoporosis. In a pooled analysis of two randomized controlled trials, raloxifene reduced vertebral fractures, but not nonvertebral fractures. Fracture risk was reduced for women with and without previous fractures. Studies of raloxifene suggest a trend toward higher risk of deep vein thrombosis (Viswanathan 2018). The 2018 USPSTF Guidelines state that the harms of treatment range from small to moderate for raloxifene and estrogen (USPSTF 2018). Raloxifene increases the risk for thromboembolic events, but not coronary heart disease or stroke (Nelson 2010).

The ACP recommends against raloxifene as a first-line pharmacologic treatment. The ACP 2017 Guidelines state that although raloxifene has some benefit in reducing vertebral fractures, it does not reduce hip fracture or nonvertebral fractures and is associated with serious harms, including thromboembolism (Qaseem 2017). The 2016 AACE Guidelines state that raloxifene may be appropriate initial therapy in some cases where patients require drugs with spine-specific efficacy and may also be considered for use by higher-risk patients during a bisphosphonate holiday (Camacho 2016).

*Denosumab:* Denosumab is approved for the treatment of osteoporosis of women at high risk of fracture. It has been shown to significantly reduce the incidence of vertebral, hip and nonvertebral fractures in women up to 89 years (Chua 2011).

*Parathyroid Hormone:* Teriparatide is approved for treatment of osteoporosis in postmenopausal women who are at high risk for fracture. The USPSTF reviewed evidence from 2 trials on parathyroid hormone, 1 with women, 1 with men. Women were found to have a significant reduction in vertebral fractures, but not in nonvertebral fractures. The study in men found a nonsignificant reduction in nonvertebral fractures (Orwoll 2003). Evidence of harms associated with parathyroid hormone is limited (Nelson 2010).

*Calcitonin:* Salmon calcitonin is a peptide hormone approved by the FDA to treat postmenopausal osteoporosis. Current forms of calcitonin include injection and nasal spray (USDHHS FDA 2015). In the 2017 ACP Guidelines, calcitonin was no longer recommended as a drug treatment therapy for osteoporosis because it is no longer widely used for osteoporosis treatment (Qaseem 2017). The USPSTF 2018 Guidelines did not summarize the evidence on calcitonin because it is no longer considered a first-line therapy for osteoporosis (USPSTF 2018). More effective drugs, such as bisphosphonates, are available for prevention of bone loss and reduction of fracture and often are used as first-line therapy, rather than calcitonin (Downs 2000). Calcitonin has been shown to be useful as a pain reliever for some patients with fractures (Knopp-Sihota 2011).

*Estrogen:* The Women's Health Initiative study reported reduced clinical vertebral, hip and all fractures combined among women using estrogen, compared with women using a placebo (Manson 2013). However, estrogen with progestin and estrogen alone have been shown to increase thromboembolic events, strokes, risk for coronary heart disease and breast cancer (Viswanathan 2018, Nelson 2010). In 2015, the American Geriatrics Society (AGS) included estrogen in the updated Beers criteria as high-risk medication for women over 65 (AGS 2015). The ACP recommends against using menopausal estrogen therapy or menopausal estrogen plus progestogen therapy for the treatment of osteoporosis in women (Qaseem 2017). Bazedoxifene, a selective estrogen receptor modulator (SERM), was approved by the FDA in 2013 when used with conjugated estrogen for prevention of osteoporosis (USDHHS FDA 2013).

### **Gaps in care**

Despite the availability of effective treatments, osteoporosis testing and treatment among patients who are at risk and those who have already sustained a fracture remains low. For this measure's first 4 years in the HEDIS<sup>®</sup> measure set (2007–2010), rates showed almost no improvement. However, since 2014, rates have increased about 9 percentage points for Medicare plans nationally. In 2017, the national average for all Medicare plans was 44.9% (SD=19.2), with a spread of 21.7%–70.7% (10th–90th percentiles). 2017 results were based on reporting by 283 Medicare plans.

Interventions aimed at coordination of care between hospitals (which often treat the fracture) and outpatient care (which often manages osteoporosis treatment) have the potential to greatly increase the rate of appropriate follow-up after a fracture. In one intervention the rate of appropriate osteoporosis management (receipt of a bone mineral density test or osteoporosis medication within 6 months after the fracture) increased from 13.4%–44% after implementation of an outreach program at the health plan (Feldstein 2007).

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## Specific Guideline Recommendations

Organization, Year	Population	Recommendation	Grade of Recommendation
U.S. Preventive Services Task Force <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.	Grade B
	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
American College of Physicians <i>2017</i>	Women who have known osteoporosis	ACP recommends clinicians offer pharmacologic treatment with alendronate, risedronate, zoledronic acid, or denosumab to reduce the risk for hip and vertebral fractures	Strong recommendation High-quality evidence
		ACP recommends that clinicians treat osteoporotic women with pharmacologic therapy for 5 years.	Weak recommendation Low-quality evidence
	Men who have clinically recognized osteoporosis	ACP recommends that clinicians offer pharmacologic treatment with bisphosphonates to reduce the risk for vertebral fracture	Weak recommendation Low-quality evidence
	Women with osteoporosis	ACP recommends against bone density monitoring during the 5-year pharmacologic treatment period for osteoporosis in women.	Weak recommendation Low quality evidence
		ACP recommends <i>against</i> using menopausal estrogen therapy or menopausal estrogen plus progestogen therapy or raloxifene for the treatment of osteoporosis in women.	Strong recommendation Moderate-quality evidence
	Women 65 years of age or older with osteopenia and at a high risk for fracture	ACP recommends that clinicians should make the decision whether to treat osteopenic women 65 years of age or older who are at a high risk for fracture based on a discussion of patient preferences, fracture risk profile, and benefits, harms, and costs of medications	Weak recommendation Low-quality evidence
American Association of Clinical Endocrinologists (AACE)	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

Organization, Year	Population	Recommendation	Grade of Recommendation
<p><i>September 2016</i></p>	<p>Women aged 65 and older (page 10)</p>	<p>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.</p>	<p>Grade B Level 2</p>
	<p>Postmenopausal women under the age of 65</p>	<p>The AACE recommends BMD 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.</p>	<p>Grade C Level 2</p>
	<p>All patients who have a history of a fracture in the hip or spine</p>	<p>The AACE recommends pharmacologic therapy</p>	<p>Grade A Level 1</p>
	<p>Patients without a history of fractures but with a T-score of -2.5 or lower</p>	<p>The AACE recommends pharmacologic therapy</p>	<p>Grade A Level 1</p>
	<p>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%</p>	<p>The AACE recommends pharmacologic therapy</p>	<p>Grade A Level 2</p>
<p><b>National Osteoporosis Foundation</b> <i>June 2014</i></p>	<p>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</p>	<p>The NOF recommends Bone Mineral Density Testing in these populations.</p>	

Organization, Year	Population	Recommendation	Grade of Recommendation
	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> 2010	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.	
	Postmenopausal women who have had an osteoporotic vertebral or hip fracture. Postmenopausal women who have bone mineral density values consistent with osteoporosis. 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%.	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**

Grade	Definition
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

\*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 Management in Women Who Had a Fracture (OMW)****Table 1. HEDIS OMW 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
2017*	505	283 (56.0)	44.9	19.2	21.7	30.9	44.6	58.0	70.7
2016	506	277 (54.7)	40.0	19.0	17.4	24.6	38.6	51.7	76.4
2015	505	279 (55.3)	38.7	17.9	17.6	24.1	36.4	49.0	75.5
2014	507	303 (59.8)	35.9	17.3	15.8	22.6	33.7	45.9	58.0

\*For 2017 the average denominator across plans was 381 individuals, with a standard deviation of 678. The median denominator across plans was 158 individuals.