**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0053

**Measure Title**: Osteoporosis Management in Women Who Had a Fracture

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** N/A

**Date of Submission**: 4/9/2018

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Osteoporosis Management in Women Who Had a Fracture measures the percentage of women age 65 to 85 who receive a bone mineral density test or pharmacologic treatment for osteoporosis in the six months after a fracture.

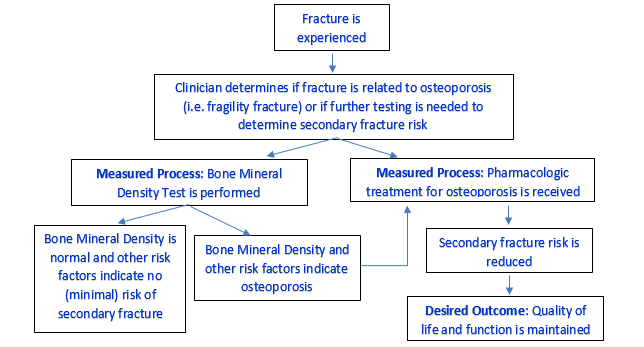
Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

**2014 Submission:**



**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

Clinical Practice Guideline recommendation (with evidence review)

US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

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| **Bone Mineral Density Testing After a Fracture** | |
| **U.S. Preventive Services Task Force (USPSTF)** | |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | **2018 Submission**  NCQA acknowledges that as of April 9, 2018, the U.S. Preventive Services Task Force (USPSTF) has released a DRAFT recommendation statement for osteoporosis screening. A draft Evidence Review was also published in November 2017. When published, NCQA will evaluate the final recommendation statement and supporting evidence review and consider any potential changes that may be needed for this measure. However, based on the draft recommendation statement we do not anticipate that any major revisions will be needed.  U.S. Preventive Services Task Force. 2017. Draft Recommendation Statement: Osteoporosis to Prevent Fractures: Screening. https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/osteoporosis-screening1  U.S. Preventive Services Task Force. 2017. Draft Evidence Review: Osteoporosis to Prevent Fractures: Screening*.* https://www.uspreventiveservicestaskforce.org/Page/Document/draft-evidence-review/osteoporosis-screening1  **2014 Submission**  U.S. Preventive Services Task Force. 2011. Screening for osteoporosis: US preventive services task force recommendation statement. Annals of internal medicine, 154(5), 356.  <http://www.uspreventiveservicestaskforce.org/uspstf10/osteoporosis/osteors.htm>, accessed May 2, 2014. |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | **2018 Submission**  “The USPSTF recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in women age 65 years and older. The USPSTF recommends screening for osteoporosis with bone measurement testing in postmenopausal women younger than age 65 years who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool.” – Experiencing a fracture is a significant factor in increasing fracture risk.  **2014 Submission**  “The USPSTF recommends screening for osteoporosis 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.” – Experiencing a fracture is a significant factor in increasing fracture risk. |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | **2018 Submission**  The USPSTF concludes with moderate certainty that the net benefit of screening for osteoporosis in women age 65 years and older is at least moderate.  **2014 Submission**  Moderate. |
| Provide all other grades and definitions from the evidence grading system | **2014 Submission**  The USPSTF does not grade the evidence in the Evidence Based Practice report; they review the evidence and determine the certainty that there is benefit of an intervention. This certainty is based on the number, size and quality of individual studies but is not a grade of the evidence. |
| Grade assigned to the **recommendation** with definition of the grade | **2018 Submission**  **Grade 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.  **2014 Submission**  **Grade B**: The USPSTF recommends the services. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial  Certainty Moderate: The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as:   * The number, size, or quality of individual studies * Inconsistency of findings across individual studies * Limited generalizability of findings to routine primary care practice * Lack of coherence in the chain of evidence |
| Provide **all other grades and definitions** from the recommendation grading system | **2018 Submission**  Grade A: The USPSTF recommends the service. There is high certainty that the net benefit is substantial.  Grade C: The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.  Grade 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.  Grade I: 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.  **2014 Submission**  **Grade A**: The USPSTF recommends the service. There is high certainty that the net benefit is substantial.  Certainty 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.  **Grade C**: The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.  **Grade 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.  **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.  Certainty Low: The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:   * The limited number or size of studies * Important flaws in study design or methods * Inconsistency of findings across individual studies * Gaps in the chain of evidence * Findings not generalizable to routine primary care practice * Lack of information on important health outcomes |
| Body of evidence:   * **Quantity** – how many studies? * **Quality** – what type of studies? | **2018 Submission**  The DRAFT evidence report (Viswanathan et al 2017) supporting this guideline outlines the quantity and quality of evidence, which are summarized below for the key questions of the review.  Key Question 1. Does Screening (Clinical Risk Assessment, Bone Density Measurement, or Both) for Osteoporotic Fracture Risk Reduce Fractures and Fracture-Related Morbidity and Mortality in Adults?   * As in the previous 2011 review, found no good or fair quality studies eligible for this key question   Key Question 2a. What is the accuracy and reliability of screening approaches to identify adults who are at increased risk for osteoporotic fracture?   * Accuracy of Clinical Risk Assessment Tools for Identifying Osteoporosis: included 37 articles (35 studies, fair or good quality) * Accuracy of Bone Measurement Tests Used to Identify Low Bone Mass and Osteoporosis: included 11 studies, fair or good quality * Accuracy of Bone Measurement Tests Used to Predict Fracture: included 21 studies, fair or good quality * Accuracy of Fracture Risk Prediction Instruments: included 1 systematic review and 13 fair or good quality observational studies   Key Question 2b. What is the evidence to determine screening intervals and how do these vary by baseline fracture risk?   * Included 2 articles (2 studies, good quality)   Key Question 3. What are the harms of screening for osteoporotic fracture risk?   * Found no eligible studies that addressed this question   Key Question 4a. What is the effectiveness of pharmacotherapy for the reduction of fractures and related morbidity and mortality?  Bisphosphonates:   * Alendronate: included 7 studies, fair or good quality * Zoledronic Acid: included 2 studies, fair or good quality * Risedronate: included 4 studies, fair or good quality * Etidronate: included 2 fair quality studies * Ibandronate: identified no studies or trials that assessed the benefits of ibandronate for preventing fractures   Raloxifene:   * Included 1 large good quality RCT   Estrogen:   * No studies included   Denosumab:   * Included 3 fair quality trials   Parathyroid Hormone:   * Included 2 fair quality trials   Key Question 4b. How does the effectiveness of pharmacotherapy for the reduction of fractures and related morbidity and mortality vary by subgroup, specifically in postmenopausal women, premenopausal women, men, younger age groups (age <65 years), older age groups (age ≥65 years), baseline bone mineral density, and baseline fracture risk?  Bisphosphonates:   * Zoledronic Acid, Etidronate, Ibandronate: found no relevant results in included studies for subgroup analysis * Alendronate: included 1 study * Risedronate: included 1 RCT   Raloxifene:   * Included 1 study   Estrogen:   * No studies included   Denosumab:   * Included 1 fair quality trial   Parathyroid Hormone:   * Included 1 fair quality trial   Key Question 5. What are the harms associated with pharmacotherapy?  Bisphosphonates:   * Alendronate: included 16 studies, fair or good quality * Zoledronic Acid: included 4 studies, fair or good quality * Risedronate: included 4 studies, fair or good quality * Etidronate: included 2 fair quality studies * Ibandronate: included 7 fair quality studies   Raloxifene:   * Included 6 studies   Estrogen:   * No studies included   Denosumab:   * Included 3 fair quality studies   Parathyroid Hormone:   * Included 2 fair quality studies   Viswanathan, M., et al. 2017. “Screening to Prevent Osteoporotic Fractures: An Evidence Review for the U.S. Preventive Services Task Force.” Available here: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryDraft/osteoporosis-screening1  **2014 Submission**  N/A – not required in previous submission |
| Estimates of **benefit and consistency** across studies | **2018 Submission**  The following text is quoted directly from the USPSTF recommendation statement.  The USPSTF found no studies that evaluated the effect of screening for osteoporosis on fracture rates or fracture-related morbidity or mortality.  The USPSTF found convincing evidence that bone measurement tests are accurate for detecting osteoporosis and predicting osteoporotic fractures in women and men. The USPSTF found adequate evidence that clinical risk assessment tools are moderately accurate in identifying risk of osteoporosis and osteoporotic fractures.  The USPSTF found convincing evidence that drug therapies reduce subsequent fracture rates in postmenopausal women. The benefit of treating screening-detected osteoporosis is at least moderate in women age 65 years and older and younger postmenopausal women who have similar fracture risk. The harms of treatment 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 these groups of women is at least moderate.  The USPSTF concludes that the evidence is inadequate to assess the effectiveness of drug therapies in reducing subsequent fracture rates in men without previous fractures. Treatments that have been proven effective in women cannot necessarily be presumed to have similar effectiveness in men, and the direct evidence is too limited to draw definitive conclusions. Thus, the USPSTF could not assess the balance of benefits and harms of screening for osteoporosis in men.  **2014 Submission**  N/A |
| What harms were identified? | **2018 Submission**  The following is quoted directly from the USPSTF draft recommendation statement: “The USPSTF found no studies that described harms of screening for osteoporosis in men or women. Based on the nature of screening with bone measurement tests and the low likelihood of serious harms, the USPSTF found adequate evidence to bound these harms as no greater than small. Harms associated with screening may include radiation exposure from DXA and opportunity costs (time and effort required by patients and the health care system).”  **2014 Submission**  Potential harms of bone mineral density testing:  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). 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 (USPSTF 2011). The USPSTF concluded that there is moderate certainty that the net benefit of screening for osteoporosis by using DXA is at least moderate. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | **2018 Submission**  To our knowledge, there have been no published studies since the systematic review that would impact the recommendations above. When the USPSTF final evidence review is published, NCQA will conduct further review to determine if there are any changes to the evidence that would warrant refinements to the measure. |

**Bone Mineral Density Testing after Fracture**

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| **American Association of Clinical Endocrinologists (AACE)** | |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | **2018 Submission**  Screening women who had a fragility fracture. AACE (2016)  **American Association of Clinical Endocrinologists (AACE).** Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis, 2016, Sep. Guideline available from <https://www.aace.com/files/postmenopausal-guidelines.pdf>.  **2014 Submission**  Screening women who had a fragility fracture. AACE (2010)  **American Association of Clinical Endocrinologists (AACE).** Medical Guidelines for Clinical Practice for the Diagnosis and Treatment of Postmenopausal Osteoporosis, 2010 Dec. Guideline available from <https://www.aace.com/files/osteo-guidelines-2010.pdf>, accessed April 25, 2014. |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | **2018 Submission**  “Who needs to be screened for osteoporosis? All postmenopausal women > 50 years should undergo clinical assessment for osteoporosis and fracture risk,  including a detailed history and physical examination.” (page 7)  “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.” (page 10)  **2014 Submission**  Who needs to be screened for osteoporosis?Younger postmenopausal women at increased risk of fracture, based on a list of risk factors - “Indications for bone mineral testing: All postmenopausal women with a history of fracture without major trauma after age 40 to 45.” (page 17) |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | **2018 Submission**  Level 2.  **2014 Submission**  Level 2. |
| Provide all other grades and definitions from the evidence grading system | **2018 Submission**  2016 AACE Guidelines used the 2010 Criteria for Rating of Published Evidence Table submitted in 2014.  **2014 Submission** |
| Grade assigned to the **recommendation** **with definition** of the grade | **2018 Submission**  Grade 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; ≥ 1 conclusive level 2 publications demonstrating benefit > risk. (see Table 2 in section above)   **2014 Submission**  Grade C.   * Evidence based on clinical experience, descriptive studies, or expert consensus opinion. * No conclusive level 1 or 2 publications; ≥ 1conclusive level 3 publications demonstrating benefit > risk. * No conclusive risk at all and no conclusive benefit demonstrated by evidence. (see Table 2) |
| Provide all other grades and definitions from the recommendation grading system | **2018 Submission**  AACE Grade Definition  **Grade A**:   * Homogeneous evidence from multiple well-designed randomized controlled trials with sufficient statistical power. * Homogenous evidence from multiple well-designed randomized or cohort controlled trials with sufficient statistical power. * ≥ 1 conclusive level 1 publications demonstrating benefit > risk. (see Table 2)   **Grade C:**   * Evidence based on clinical experience, descriptive studies, or expert consensus opinion. * No conclusive level 1 or 2 publications; ≥ 1conclusive level 3 publications demonstrating benefit > risk. * No conclusive risk at all and no conclusive benefit demonstrated by evidence. (see Table 2)   **Grade D**:   * Not rated. * No conclusive level 1, 2, or 3 publication demonstrating benefit > risk. * Conclusive level 1, 2, or 3 publication demonstrating risk > benefit. (see table 2)   **2014 Submission**  AACE Grade Definition  **Grade A**:   * Homogeneous evidence from multiple well-designed randomized controlled trials with sufficient statistical power. * Homogenous evidence from multiple well-designed randomized or cohort controlled trials with sufficient statistical power. * ≥ 1 conclusive level 1 publications demonstrating benefit > risk. (see Table 2)   **Grade 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; ≥ 1 conclusive level 2 publications demonstrating benefit > risk. (see Table 2)   **Grade D**:   * Not rated. * No conclusive level 1, 2, or 3 publication demonstrating benefit > risk. * Conclusive level 1, 2, or 3 publication demonstrating risk > benefit. (see table 2) |
| Body of evidence:   * **Quantity** – how many studies? * **Quality** – what type of studies? | **2014 Submission**  Although the AACE guidelines above were based on a systematic evidence reviews, they did not provide a summary of the evidence (quantity, quality and consistently) to answer the questions laid out in the NQF submission for this measure. Therefore, NCQA supplemented the guidelines with the systematic reviews documented below. |
| Estimates of **benefit and consistency** across studies | **2014 Submission**  N/A |
| What **harms** were identified? | **2014 Submission**  N/A |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | **2018 Submission**  To our knowledge, there have been no published studies since the systematic review that would impact the recommendations above. |

**Bone Mineral Density Testing after Fracture**

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| **Other Systematic Review of the Body of Evidence** | |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | **2014 Submission**  Although the AACE guidelines above were based on systematic evidence reviews, they did not provide a summary of the evidence (quantity, quality and consistently) to answer the questions laid out in the NQF submission for this measure. Therefore, we supplemented the guidelines with the following systematic reviews.  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. Rockville (MD): [Agency for Healthcare Research and Quality (US)](http://www.ahrq.gov/).  Crandall, C. J., Newberry, S. J., Diamant, A., Lim, Y. W., Gellad, W. F., Suttorp, M. J., ... & Shekelle, P. G. (2012). Treatment to prevent fractures in men and women with low bone density or osteoporosis: update of a 2007 report. Rockville (MD): [Agency for Healthcare Research and Quality (US)](http://effectivehealthcare.ahrq.gov/index.cfm/)  Levis, S., & Theodore, G. (2012). Summary of AHRQ's comparative effectiveness review of treatment to prevent fractures in men and women with low bone density or osteoporosis: update of the 2007 report. *Journal of managed care pharmacy: JMCP*, *18*(4 Suppl B), S1. |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | **2014 Submission**  This measure assesses whether a patient who had a fracture of any bone other than face, finger, toe, or skull was given the appropriate follow-up care post-fracture to prevent a secondary fracture from occurring. Appropriate follow-up care includes either 1) bone mineral density testing to assess whether a patient has osteoporosis or 2) receiving pharmacologic therapy to treat osteoporosis. This measure is based on guidelines and evidence that patients at high risk of fracture, including patients with a history of fragility fractures, should be screened for osteoporosis (USPSTF 2012, Nelson 2010, AACE 2010) and that patients who have a fragility fracture of the hip or spine should be provided with a treatment for osteoporosis (AACE 2010, Crandall 2012).  AACE defines a fragility fracture as “a fracture that results from trauma less than or equal to that from a fall from a standing height and almost always indicates decreased skeletal strength.” Administrative claims (one of the data sources for this measure) cannot determine if a fracture meets this definition of a fragility fracture. Therefore, we remove fractures from the measure that are rarely fragility related (face, finger, toe or skull) and designed the measure to allow the provider the flexibility to determine if either a bone mineral density test or pharmacologic treatment is the best follow-up intervention for post-menopausal women who experienced a fracture. If a fragility fracture can be assumed the provider can meet the measure numerator criteria by providing the appropriate drug therapy. If a fragility fracture cannot be assumed (i.e. the fracture was associated with trauma such as a car accident) the provider may choose to screen for underlying osteoporosis risk as recommended for all women who experience a fracture. This measure design reduces the possibility of overtreatment of osteoporosis in women who experience fractures. |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | **2014 Submission**  N/A |
| Provide **all other grades and definitions** **from the evidence** grading system | **2014 Submission**  N/A |
| Grade assigned to the **recommendation** with definition of the grade | **2014 Submission**  N/A |
| Provide all **other grades and definitions from the recommendation** grading system | **2014 Submission**  N/A |
| Body of evidence:   * **Quantity** – how many studies? * **Quality** – what type of studies? | **2014 Submission**  **Quantity**  Nelson (2012): This update to the evidence review did not include a key question addressing the efficacy of bone mineral density tests to predict fracture risk. This was established in the 2002 Evidence Review and not re-evaluated in 2012. The evidence review did include a key question of pertinence to this measure. Key Question 3b: How well do peripheral bone measurement tests predict fractures? Six prospective studies and one meta-analysis comparing DXA to Quantitative Ultrasonography were used to address this question.  **Quality**  Nelson (2012): How well do peripheral bone measurement tests predict fractures? The authors described the six prospective studies as large and well-designed and do not note any quality concerns. The meta-analysis used to compare DXA with Qualitative Ultrasonography (QUS) included multiple studies that varied by subject characteristics including location (Europe, United States, Asia), sample size (110-722), prevalence of osteoporosis (7-38 percent), age (46-64 years), and sex. No studies described race or ethnicity of subjects. Potential sources of bias included insufficient information to determine participant selection methods, time between QUS and DXA, and whether QUS and DXA results were interpreted independently of each other. |
| Estimates of benefit and consistency across studies | **2014 Submission**  Nelson (2012): How well do peripheral bone measurement tests predict fractures?  “Several peripheral bone measurement tests have been developed, although clinical practice and recent research focus on QUS of the calcaneous (heel). Large studies of postmenopausal women and men indicate that QUS obtained at the calcaneus using various types of devices can predict fractures as well as DXA of the femoral neck, hip, or spine, although variation exists across studies. However, QUS is not a good predictor of DXA as determined by a recent meta-analysis that indicated AUC estimates of 0.74–0.77 depending on the QUS parameter used. Also, it is unclear how results of QUS can be used to select individuals for drug therapies that were proven efficacious based on DXA criteria.”  “Overall, DXA and QUS have similar area under the curve (AUC) estimates and odds ratios for fracture outcomes ([Table 4](http://www.ncbi.nlm.nih.gov/books/NBK45207/table/ch3.t3/?report=objectonly)). For all fractures combined, AUC estimates range from 0.59–0.66 and ORs from 1.81–2.16 for DXA of the femoral neck. For QUS, AUC estimates are approximately 0.60, and ORs range from 1.26–2.25. In one study that included DXA of the distal radius, the AUC estimate was 0.64 (95% CI, 0.59–0.68) and OR for all fractures 1.47 (95% CI, 1.28–1.68).  “QUS predicts most fractures as well as DXA and offers distinct advantages, such as lower cost, portability, ease of use, and avoidance of ionizing radiation. However, it is not clear how to apply the results of QUS testing to patient management. Currently, standardized diagnostic criteria for osteoporosis uses DXA not QUS cutpoints, and clinical trials of drug therapies used DXA testing in its selection criteria. To be clinically useful, QUS results would need to be similar to DXA.” |
| What harms were identified? | **2014 Submission**  N/A |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | **2014 Submission**  No. |

**Pharmacologic Therapy After a Fracture**

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| **American Association of Clinical Endocrinologists (AACE)** | |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | **2018 Submission**  **American Association of Clinical Endocrinologists (AACE).** Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis, 2016, Sep. Guideline available from <https://www.aace.com/files/postmenopausal-guidelines.pdf>.  **2014 Submission**  **American Association of Clinical Endocrinologists (AACE).** Medical Guidelines for Clinical Practice for the Diagnosis and Treatment of Postmenopausal Osteoporosis, 2010 Dec. Guideline available from <https://www.aace.com/files/osteo-guidelines-2010.pdf>, accessed April 25, 2014. |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | **2018 Submission**  “Strongly recommend pharmacologic therapy for patients with osteopenia or low bone mass and a history of fragility fracture of the hip or spine.” (page 4)  **2014 Submission**  “Patients who have a history of fracture of the hip or spine need pharmacologic therapy.” (Page 4) |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | **2018 Submission**  Level 1.  **2014 Submission**  Level 1. |
| Provide all other grades and definitions from the evidence grading system | **2018 Submission**  2016 AACE Guidelines used the 2010 Criteria for Rating of Published Evidence Table submitted in 2014.  **2014 Submission** |
| Grade assigned to the **recommendation** **with definition** of the grade | **2018 Submission**  Grade A   * Homogeneous evidence from multiple well-designed randomized controlled trials with sufficient statistical power. * Homogenous evidence from multiple well-designed randomized or cohort controlled trials with sufficient statistical power. * ≥ 1 conclusive level 1 publications demonstrating benefit > risk. (see Table 2 in previous section)   **2014 Submission**  Grade A   * Homogeneous evidence from multiple well-designed randomized controlled trials with sufficient statistical power. * Homogenous evidence from multiple well-designed randomized or cohort controlled trials with sufficient statistical power. * ≥ 1 conclusive level 1 publications demonstrating benefit > risk. (see Table 2 in previous section) |
| Provide **all other grades and definitions** from the recommendation grading system | **2018 Submission**  2016 AACE Guidelines used the 2010 AACE Protocol for Production of Clinical Practice Guidelines submitted in 2014.  **2014 Submission**  AACE Grade Definition  **Grade 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; > 1 conclusive level 2 publications demonstrating benefits > risk. (see Table 2)   **Grade C**:   * Evidence based on clinical experience, descriptive studies, or expert consensus opinion. * No conclusive level 1 or 2 publications; ≥ 1conclusive level 3 publications demonstrating benefit > risk. * No conclusive risk at all and no conclusive benefit demonstrated by evidence. (see Table 2)   **Grade D:**   * Not rated. * No conclusive level 1, 2, or 3 publication demonstrating benefit > risk. * Conclusive level 1, 2, or publication demonstrating risk > benefit. (see Table 2) |
| Body of evidence:   * **Quantity** – how many studies? * **Quality** – what type of studies? | **2014 Submission**  Although the AACE guidelines above were based on systematic evidence reviews, they did not provide a summary of the evidence (quantity, quality and consistently) to answer the questions laid out in the NQF submission for this measure. Therefore, NCQA supplemented the guidelines with the systematic reviews below. |
| Estimates of benefit and consistency across studies | **2014 Submission**  N/A |
| What **harms** were identified? | **2014 Submission**  Potential harms of pharmacologic treatment for osteoporosis:  The AACE guideline and evidence above outlines the potential harms and side effects related to each pharmacologic treatment for osteoporosis:   * Bisphosphonates: The most common side effect from bisphosphonates is esophageal irritation. * Calcitonin: Nausea, local inflammatory reactions at the injection site, and vasomotor symptoms including sweating and flushing. * Teriparatide: Nausea, orthostatic hypotension, and leg cramps. Hypercalcemia has been observed but is not common. * Demosumab: Before initiation of therapy, hypocalcemia must be corrected. Serious infections such as skin or cellulitis can occur. Dermatitis, rashes, eczema and osteonecrosis of the jaw has been reported. * Raloxifene: Associated with an approximate three-fold increase in occurrence of venous thromboembolic diseases, menopausal symptoms (hot flashes) and leg cramps. |
| Identify any **new studies conducted since the SR**. Do the new studies change the conclusions from the SR? | **2014 Submission**  No. |

**Pharmacologic Therapy After a Fracture**

|  |  |
| --- | --- |
| **Other Systematic Review of the Body of Evidence** | |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | **2014 Submission**  Although the AACE guidelines above were based on systematic evidence reviews, they did not provide a summary of the evidence (quantity, quality and consistently) to answer the questions laid out in the NQF submission for this measure. Therefore, we supplemented the guidelines with the following systematic reviews.  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. Rockville (MD): [Agency for Healthcare Research and Quality (US)](http://www.ahrq.gov/).  Crandall, C. J., Newberry, S. J., Diamant, A., Lim, Y. W., Gellad, W. F., Suttorp, M. J., ... & Shekelle, P. G. (2012). Treatment to prevent fractures in men and women with low bone density or osteoporosis: update of a 2007 report. Rockville (MD): [Agency for Healthcare Research and Quality (US)](http://effectivehealthcare.ahrq.gov/index.cfm/)  Levis, S., & Theodore, G. (2012). Summary of AHRQ's comparative effectiveness review of treatment to prevent fractures in men and women with low bone density or osteoporosis: update of the 2007 report. *Journal of managed care pharmacy: JMCP*, *18*(4 Suppl B), S1. |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | **2014 Submission**  N/A |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | **2014 Submission**  The only evidence review above with graded evidence was Crandall (2012). The table below provides a summary of the evidence grades presented in Crandall (2012). |
| Provide all **other grades and definitions from the evidence** grading system | **2014 Submission**  Shown in Table above. |
| Grade assigned to the **recommendation** with definition of the grade | **2014 Submission**  N/A |
| Provide **all other grades and definitions from the recommendation** grading system | **2014 Submission**  N/A |
| Body of evidence:   * **Quantity** – how many studies? * **Quality** – what type of studies? | **2014 Submission**  **Quantity**  Crandall 2012: Key Question 1 What Are the Comparative Benefits in Fracture Risk Reduction Among the Following Therapeutic Modalities for low Bone Density: Bisphosphonates, Denosumab, Menopausal Hormone Therapy, Selective Estrogen Receptor Modulators (Raloxifene), Parathyroid Hormone, Calcium, Vitamin D, and Physical Activity?  “For this question, we identified 55 RCTs and 10 observational studies in addition to 58 systematic reviews (from both the original and current report) that assessed the effects of interventions compared to placebo: nine systematic reviews and 10 RCTs for alendronate, 10 systematic reviews and 13 RCTs for risedronate, three systematic reviews and three RCTs for ibandronate, four RCTs for zoledronic acid, one systematic review and two RCTs for denosumab, three systematic review and three RCTs for raloxifene, two systematic reviews and three RCTs for teriparatide, six RCTs for menopausal estrogen therapy, four systematic reviews and six RCTs for calcium alone, 15 systematic reviews and seven RCTs for vitamin D alone, four RCTs for vitamin D plus calcium, and one systematic review and one RCT for physical activity.”  **Quality**  Crandall (2012): Comparative Effectiveness of Treatments: The authors rated the quality of evidence for each study but did not discuss any specific concerns about the quality of evidence or sources of bias. Overall, they found the majority of evidence came from well-designed large RCTs. |
| Estimates of **benefit and consistency** across studies | **2014 Submission**  Overall there is moderate certainty that bone mineral density tests predict future fracture risk and pharmacologic treatment for individuals at risk of future fracture reduces the fracture risk.  Crandall (2012): Comparative Effectiveness of Treatments  There were many different pharmacologic treatments that were determined effective at reducing future fractures in patients who are at high risk. The review concluded that Alendronate, etidronate, ibandronate, risedronate, teriparatide, denosumab, and raloxifene reduce the risk of fractures among high risk groups including postmenopausal women with osteoporosis. For the purposes of this review “High Risk” was defined as the following:   1. transplant population, or 2. study entry criteria require T score ≤ -2.5, or 3. study entry criteria require≥1 fracture, or 4. ≥50% of population has 1 or more fractures at baseline, or 5. Significant neuromuscular impairment   The table below shows selected studies from the review by Crandall et al. and previous review *by McLean et al. covering 1996-2006.* These studies indicate decreased odds of fracture with medicaiton compared to placebo or control group among high/intermediate risk populations.  **Table 3**: Risk of fracture for medication relative to placebo – Selected studies from Crandall et al. 2012 **SEE APPENDIX A for Table Information** |
| What **harms** were identified? | Potential harms of pharmacologic treatment for osteoporosis:  The AACE guideline **and evidence above outlines** the potential harms and side effects related to each pharmacologic treatment for osteoporosis:   * Bisphosphonates: The most common side effect from bisphosphonates is esophageal irritation. * Calcitonin: Nausea, local inflammatory reactions at the injection site, and vasomotor symptoms including sweating and flushing. * Teriparatide: Nausea, orthostatic hypotension, and leg cramps. Hypercalcemia has been observed but is not common. * Demosumab: Before initiation of therapy, hypocalcemia must be corrected. Serious infections such as skin or cellulitis can occur. Dermatitis, rashes, eczema and osteonecrosis of the jaw has been reported. * Raloxifene: Associated with an approximate three-fold increase in occurrence of venous thromboembolic diseases, menopausal symptoms (hot flashes) and leg cramps. |
| Identify any **new studies conducted since the SR**. Do the new studies **change the conclusions** from the SR? | **2014 Submission**  Eriksen et al. (2014) conducted a systematic review on the use of long-term treatment with bisphosphonates for postmenopausal osteoporosis. This review found that long-term use of bisphosphonates resulted in fewer fractures and smaller loss of bone mineral density in women who remained on treatment for three or more years. Residual benefits were found for women who received alendronate or zoledronic acid as long as they received initial treatment of 3-5 years. Residual benefits were seen even after they discontinued treatment for 3-5 years. Overall, this review found “BMD monitoring and fracture risk assessments should be conducted regularly to determine whether treatment could be stopped or if it should be reinitiated.”  Eriksen EF, Díez-Pérez A, Boonen S. Update on long-term treatment with bisphosphonates for postmenopausal osteoporosis: a systematic review. Bone. 2014 Jan;58:126-35. doi: 10.1016/j.bone.2013.09.023. Available at <http://www.thebonejournal.com/article/S8756-3282(13)00378-5/abstract> |

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

**1a.4.2 What process was used to identify the evidence?**

**1a.4.3.** **Provide the citation(s) for the evidence.**

**APPENDIX A**

**Table 3**: Risk of fracture for medication relative to placebo – Selected studies from Crandall et al. 2012

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year** | **Study duration** | **Type of fracture** | **Risk level\*** | **# of fractures, medication** | **# of fractures, placebo or control**† | **Odds ratio (95% CI)** |
| **Alendronate** | | | | | | |
| Quandt, 2005 | 54 months | Vertebral fractures | Intermediate | 12/1878 | 29/1859 | 0.43(0.23, 0.79) |
| **Ibandronate** | | | | | | |
| Chesnut, 2004 | 36 months | clinical vertebral | High | 44/1954 | 41/975 | 0.50 (0.32, 0.79) |
| **Risendronate** | | | | | | |
| Sato, 2005 | 18 months | nonvertebral fracture | High | 8/231 | 29/230 | 0.29 (0.15, 0.57) |
| Sato, 2005 | 18 months | hip fracture | High | 5/231 | 19/230 | 0.29 (0.13, 0.66) |
| **Zoledronic acid (**5 milligrams once) | | | | | | |
| Black, 2007 | 36 months | Any clinical; fracture | High | 308/3667 | 456/3563 | 0.63 (0.54, 0.72) |
| **Calcitonin** | | | | | | |
| Ishida, 2004  20 IU weekly | 24 months | vertebral | High | 8/66 | 17/66 | 0.41 (0.17, 0.99) |
| Toth, 2005  200 IU daily, alternate months | 18 months | vertebral fracture | High | 0/40 | 3/31 | 0.09 (0.01, 0.96) |
| **Teriparatide** | | | | | | |
| Gallagher, 2005 | 21 months | vertebral fracture | High | 22/403 | 62/398 | 0.34 (0.22, 0.54) |
| **Raloxifene** | | | | | | |
| Barrett-Connor, 2006 | 5.6 years | Clinical vertebral | Unknown risk | 64/5,044 | 97/5,057 | 0.66 (0.48. 0.90) |
| **Denosumab** | | | | | | |
| Cummings, 2009 | 36 months | Hip fracture | Unknown risk | 26/3,714 | 43/3,583 | 0.59 (0.36, 0.94) |
| Cummings, 2009 | 36 months | Nonvertebral | Unknown risk | 238/3,662 | 293/3,663 | 0.8 (0.67, 0.95) |