NATIONAL QUALITY FORUM

Memo

TO: Consensus Standards Approval Committee (CSAC)

FR: Karen Johnson, Katie Streeter, and Kaitlynn Robinson-Ector

RE: Endocrine Cycle 2 Member Voting Results

DA: November 12, 2014

The CSAC will review recommendations from the *Endocrine* (Cycle 2) project during its November 12, 2014 conference call.

This memo includes a summary of the project, recommended measures, and themes identified from and responses to the public and member comments.

Member voting on these recommended measures ended on October 15, 2014.

Accompanying this memo are the following documents:

1. **Endocrine Cycle 2 Draft Report.** The draft report has been updated to reflect the changes made following Standing Committee discussion of public and member comments. The complete draft report and supplemental materials are available on the project page.
2. **Comment table.** Staff has identified themes within the comments received during the 30-day post-evaluation comment period. This table lists the 13 post-evaluation comments received and the corresponding NQF, Standing Committee, and/or developer responses.

CSAC ACTION REQUIRED
Pursuant to the CDP, the CSAC may consider approval of 6 candidate consensus standards.

Endocrine Measures Recommended for Endorsement:

- 0037: Osteoporosis Testing in Older Women
- 0045: Communication with the physician or other clinician managing on-going care post fracture for men and women aged 50 years and older
- 0046: Screening for Osteoporosis for Women 65-85 Years of Age
- 0053: Osteoporosis Management in Women Who Had a Fracture
- 0416: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear
- 0417: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation

BACKGROUND
This project seeks to identify and endorse performance measures for accountability and quality improvement that address endocrine-specific conditions. The endocrine topic area includes measures for diabetes, thyroid disease, osteoporosis, and metabolic syndrome.

NQF currently has more than thirty endorsed measures in the areas of diabetes and osteoporosis. The diabetes measures in NQF's portfolio are some of the longest-standing NQF endorsed measures.

Because diabetes and osteoporosis are high-volume, high-morbidity, high-cost conditions, endorsement of strong measures for these conditions is critical for continued improvements in care quality.

NQF selected the Endocrine measure evaluation project to pilot more frequent submission and evaluation of measures than what is possible in our current 3-year measure maintenance cycle. This 22-month project will include three full endorsement "cycles," allowing for the submission and review of both new and previously-endorsed measures every six months. In addition, this project is one of the first to transition to the use of Standing Committees. The 20 Standing Committee members recommended 6 out of 6 measures submitted for endorsement in Cycle 2 of the project.

DRAFT REPORT

The Endocrine Cycle 2 Draft Report presents the results of the evaluation of 6 measures considered under the CDP. Six of these measures have been recommended by the Standing Committee for endorsement as voluntary consensus standards suitable for accountability and quality improvement. The measures were evaluated against the 2013 version of the measure evaluation criteria.

	MAINTENANCE	NEW	TOTAL
Measures considered	6	0	6
Withdrawn from Consideration	0	0	0
Recommended	6	0	6
Not recommended	0	0	0

COMMENTS AND THEIR DISPOSITION

The pre-evaluation comment period was open from June 16-30, 2014. No pre-evaluation comments were received for the measures under review in this cycle of the project.

NQF received 13 post-evaluation comments from 2 member organizations and individuals pertaining to the general draft report and to the measures under consideration.

A complete table of comments that were submitted, along with the responses to each comment and the actions taken by the Standing Committee, is posted to the Endocrine project page.

Comment Themes and Committee Responses

Five major themes were identified in the post-evaluation comments, as follows:

1. Osteoporosis: Upper age limit
2. Osteoporosis: Harmonization
3. Osteoporosis: Other
4. Competing foot care measures
5. Foot care measures: Other

At its review of the post-evaluation comments, the Standing Committee had the benefit of developer responses. Committee members focused their discussion on measures with the most significant issues.

Theme 1 - Osteoporosis: Upper age limit

NQF received two comments on measures #0037 (Osteoporosis Testing in Older Women) and #0046 (Screening for Osteoporosis for Women 65-85 Years of Age). These comments noted support for the measures but expressed concern that the upper age limit for the measures would result in under-

diagnosis for those older than 85 years of age, given the frequency of occurrence of osteoporosis in this age group. In the Committee's earlier deliberations, there was some discussion of the lower age thresholds for the measures but not on the upper threshold.

Developer Response: Thank you for your comment. We continue to recommend limiting this measure to assess osteoporosis screening in women under age 85. Continued screening beyond the age of 85 may be appropriate for some individuals and including the upper age cap does not penalize health plans who do this; however, women over the age of 85 may have limited life expectancy and may not live long enough to realize the benefits of osteoporosis treatment if they are screened positive. The USPSTF recommends providers take into account the patient's remaining life expectancy compared to the benefits of treatment when deciding whether to screen. There is a concern that without an upper age cap this measure may incentivize plans and providers to pursue too aggressive management in women with limited life expectancy and competing comorbidity. We encourage providers and patients to engage in shared-decision making to determine the best course of action for the patient.

Committee Response: Committee members found the developer's response regarding the upper age limit to be reasonable and did not recommend a change to the specifications of the measure.

Theme 2 - Osteoporosis: Harmonization

NQF received two comments regarding harmonization of measures #0037 (Osteoporosis Testing in Older Women) and #0046 (Screening for Osteoporosis for Women 65-85 Years of Age). Specifically, the commenters questioned the need for the use of the Health Outcomes Survey in measure #0037.
Committee Response: The two measures assess performance for different entities: measure #0037 is specified for measurement at the health plan level; in contrast, measure #0046 is specified for measurement at the individual clinician or group level. The issue of different data sources for measures #0037 and #0046 was addressed during the Committee's discussion about harmonizing these two measures. In that discussion, the developer explained their reasoning behind using the Health Outcomes Survey for measure #0037 (i.e., for new health plan members, plans may not have access to claims or medical records needed to compute the measure), and acknowledged that the results from the two sources may be different. The Committee accepted this rationale and did not make any harmonization recommendations.

Theme 3 - Osteoporosis: Other

NQF received two comments on measures #0045 (Communication with the physician or other clinician managing on-going care post fracture for men and women aged 50 years and older) and #0053 (Osteoporosis Management in Women Who Had a Fracture). Regarding measure #0045, the commenter noted the importance of communication, expressed concern that the measure is a "low-bar" measure, and suggested that a measure to assess testing and treatment would be more valuable. Regarding measure #0053, the commenter expressed support for the measure but also encouraged development of a drug- or treatment-adherence measure for people with osteoporosis who have had a fracture.

Committee Response: The Committee agreed that measure #0045 meets NQF's current criteria for endorsement. Committee members agreed with the suggestions for future development of treatment measures. Committee members also recommended that if a separate testing/treatment post-fracture measure for men is developed, that it be harmonized with measure #0053.

Theme 4 – Competing foot care measures

NQF received three comments regarding the competing foot care measures (#0417: Diabetic Foot & Ankle Care, Peripheral Neuropathy - Neurological Evaluation, stewarded by the APMA; #0056: Diabetes: Foot exam, stewarded by NCQA). One commenter indicated support for selecting #0417 as the superior measure because it requires a test of motor function. This commenter suggested that a pulse check and visual inspection (elements of measure #0056) be added to #0417 so that all important elements are included in one measure. The second commenter indicated support for continued endorsement of both measures. The third commenter was the developer of measure #0417 (the American Podiatric Medical Association (APMA), stating disagreement with the committee's preliminary recommendation that measure 0056 was superior to measure 0417. A link is provided to a side-by-side comparison of the competing foot measures.

Committee Response: After review of the submitted comments and additional discussion, Committee members agreed to recommend both measures for endorsement. Members recognized the different uses of the two measures, noting the more detailed nature of #0417 as well as the potential to encourage screening with measure #0056. Members also noted that measure #0417 is an eMeasure. Members suggested that endorsement of both measures might result in more people with diabetes having their feet examined than what might be possible if only one measure is endorsed. While most members were comfortable with continued endorsement of both measures at the current time, they expressed a desire for one measure in the future that combines the elements from the two.

Theme 5 - Foot care measures: Other

NQF received four additional comments regarding the two APMA foot care measures (#0416 and #0417). One commenter suggested combining the two measures and also encouraged the developer to specify the measure so that other clinicians (such as physical therapists) are included in the measure.

Another commenter questioned the difference between the two APMA measures and recommended that measures for diabetic foot care be evidence-based. For measure #0417, the commenter requested clarification and expressed concern regarding the specifications of the measure.

Committee Response (for measure #0416): During their deliberations, Committee members acknowledged that the evidence supporting measure #0416 is indirect, but agreed that promoting proper shoe fit likely would decrease rates of foot ulceration and amputation and that an exception to the evidence subcriterion is appropriate. Some members did express concern that the specific "standard measuring device" for measuring the foot was not identified, but overall, the Committee agreed that the measure specifications were precise enough to meet NQF's reliability subcriterion.

Committee Response (for measure #0417): During their deliberations, the Committee agreed that the evidence presented for measure #0417 is supportive of the measure and therefore meets NQF's evidence subcriterion.

NQF MEMBER VOTING RESULTS

A total of 3 votes were cast by NQF Health Plan council members on the six measures recommended for endorsement by the Endocrine Standing Committee (no votes were received from any other council). Three of the measures received 100% percent approval. Three measures (#0045 Communication with the physician or other clinician managing on-going care post fracture for men and women aged 50 years and older, #0416 Diabetic Foot & Ankle Care, Ulcer Prevention - Evaluation of Footwear, and #0417 Diabetic Foot & Ankle Care, Peripheral Neuropathy - Neurological Evaluation) received 0% approval. Links are provided to the full measure summary evaluation tables.

Voting Comments:

Measure #0045 Communication With the Physician or Other Clinician Managing On-Going Care Post Fracture for Men and Women Aged 50 Years and Older

- America's Health Insurance Plans: While communication between the physician treating a fracture and the physician or other clinician managing the patients on-going care is important, we believe this is a low-bar process measure. Additionally, this type of communication and care coordination is occurring in ACO and PCMH programs. We recommend developing an osteoporosis measure that assesses testing and treatment and that would drive improvement of outcomes.

Measure #0416 Diabetic Foot & Ankle Care, Ulcer Prevention - Evaluation of Footwear

- America's Health Insurance Plans: We are concerned this measure is not supported by the available evidence and not well-specified. Additionally, this is a process measure and we recommend moving toward measures that assess outcomes.

Measure #0417 Diabetic Foot & Ankle Care, Peripheral Neuropathy - Neurological Evaluation

- America's Health Insurance Plans: This is a process measure and we recommend moving toward an outcome measure that assesses rate of ulcer formation and/or amputation.

APPENDIX A

Measure Evaluation Summary Tables

Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable; Y=Yes; N=No

0037 Osteoporosis Testing in Older Women

Submission | Specifications

Description: The number of women 65-85 years of age who report ever having received a bone density test to check for osteoporosis.

Numerator Statement: The number of women who report having ever received a bone mineral density test of the hip or spine.

Denominator Statement: Women age 65-85.

Exclusions: N/A

Adjustment/Stratification:

Level of Analysis: Health Plan, Integrated Delivery System

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Patient Reported Data/Survey

Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING [07/06/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **H-11**; **M-5**; **L-2**; **I-0; IE-0**; 1b. Performance Gap: **H-10**; **M-8**; **L-0**; **I-0;** 1c. Impact: **H-12**; **M-4**; **L-2**; **I-0**

Rationale:

- Evidence presented by the developer included a 2011 United States Preventive Services Task Force (USPSTF) recommendation (Grade B, signifying moderate certainty the net benefit of screening for osteoporosis by using DXA is at least moderate). Committee members agreed that the evidence clearly supports the linkage between bone density testing and subsequent treatment, which leads to prevention of fractures.
- HEDIS data provided by the developer indicate that the average performance rate for the 495 participating plans in 2012 is 73.1%. Committee members noted the variation in performance across plans, as well as the information provided by the developer from the literature indicating disparities in offering osteoporosis screening or treatment to racial and ethnic minority women.
- Developers noted the high prevalence of osteoporosis in the US, the high risk for osteoporotic fracture, as well as the dangers of fracture due to osteoporosis. Members agreed osteoporosis is a high priority condition.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-3**; **M-12**; **L-3**; **I-0** 2b. Validity: **H-4**; **M-13**; **L-1**; **I-0**

Rationale:

- Data for this measure are obtained through the Health Outcome Survey. Changes to the measure since initial endorsement include adding an upper age limit of 85 years and specifying location of testing as hip or spine in the survey item.

0037 Osteoporosis Testing in Older Women

- Reliability testing was done using a signal-to-noise analysis of 495 plans participating in HEDIS in 2012. The reliability across all health plans ranged from .920 to .99, with an average of .995. Committee members expressed no concerns about the results of the reliability testing.
- Validity testing was done at the measure score level by correlating the results of this measure with the Osteoporosis Management in Women Who Had a Fracture (#0053) to explore the hypothesis that plans that perform well with screening also perform well with testing/treatment; results indicate a positive and statistically significant correlation between the two measures. Developers also described the HEDIS development and review process as an indicator of face validity and noted additional face validity assessment by various workgroups that helped to develop the measure. Committee members voiced no concerns about the validity testing results.
- Committee members noted the possibility of recall bias and a concern that patients may not understand what is being asked in the survey. Another member noted the cognitive testing done for the survey item to ensure that the question could be understood. The developer clarified that the term "DXA" is not used in the survey; instead, the question is "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".
- Committee members also expressed concern that patients with cognitive impairment might answer the survey. Developers noted that proxy response is allowed and that likely the question would be answered by the proxy. One member noted that proxy response isn't always accurate.
- Developers also provided an analysis of missing data that assessed the differences between responders, late responders, and non-responders. These analyses indicated a <5% missing response to the osteoporosis item in the survey. There were some differences between the responder groups, but these were not considered large or strong by the developer, based on additional analysis. Committee members did not express concern about non-response.

3. Feasibility: H-5; M-12; L-1; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- Committee members noted that the survey used to obtain the data has been in use for a while and that it can be conducted via phone or mail.

4. Use and Usability: H-5; M-12; L-1; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

- Committee members noted that the measure is used in public reporting applications, including Consumer Reports and on the NCQA website.
- HEDIS data submitted by the developer indicate an increase in health performance from 71.0% in 2010 to 73.1% in 2012.
- Committee members did not voice any concerns about potential unintended consequences.

5. Related and Competing Measures

- According to NQF definitions, the following six measures are considered competing and/or related:
  - 0037: Osteoporosis Testing in Older Women (NCQA)
  - 0046: Screening for Osteoporosis for Women 65-85 Years of Age (NCQA)

0037 Osteoporosis Testing in Older Women

- 0053: Osteoporosis Management in Women Who Had a Fracture (NCQA)
- 2417: Risk Assessment/Treatment After Fracture (TJC)
- 0045: Communication with the physician or other clinician managing on-going care post fracture for men and women aged 50 years and older (NCQA)
- 2416: Laboratory Investigation for Secondary Causes of Fracture (TJC)

- Measures #0037 (accountability=health plan) and #0046 (accountability=clinician) each measure assess osteoporosis screening in older women and are thus considered competing. However, the level of analysis is different for the two measures (health plan vs clinician, respectively); therefore, having two competing measures is considered justified per NQF's harmonization protocol. Furthermore, measure #0037 relies on data obtained from the Health Outcomes Survey, while #0046 used data from medical records and claims. The developer noted that health plans may not have access to claims or medical records and thus obtaining data via survey is a reasonable alternative; conversely, clinicians do have access to claims and medical charts, but may not have the resources to conduct a survey. The developer acknowledged that the results from the two sources may be different if, for example, the provider's records are incomplete or there is recall bias in the survey. Committee members discussed potential recommendations for changing the specifications of either measure so as to make them more similar to each other or to the other osteoporosis measures.

  Committee response: Committee members noted that screening is for primary prevention of osteoporosis and testing/treatment is for secondary prevention of future fractures and that the differences in age groups specified for these measures are justified. Committee members agreed that screening is appropriate for women but the evidence for screening men is not strong.

Standing Committee Recommendation for Endorsement: **Y-15**; **N-3**

6. Public and Member Comment

Comments received:

- One commenter supported the measure but expressed concern that the upper age limit for the measures would result in under-diagnosis for those older than 85 years of age, given the frequency of occurrence of osteoporosis in this age group.
- Two commenters raised the issue of competing measures and harmonization for measures #0037 (Osteoporosis Testing in Older Women) and #0046 (Screening for Osteoporosis for Women 65-85 Years of Age), and specifically questioned the use of the Health Outcomes Survey in measure #0037.

Developer response:

- NQCA continues to recommend limiting this measure to assess osteoporosis screening in women under age 85. Continued screening beyond the age of 85 may be appropriate for some individuals and including the upper age cap does not penalize health plans who do this; however, women over the age of 85 may have limited life expectancy and may not live long enough to realize the benefits of osteoporosis treatment if they are screened positive. The USPSTF recommends providers take into account the patient's remaining life expectancy compared to the benefits of treatment when deciding whether to screen. There is a concern that without an upper age cap this measure may incentivize plans and providers to pursue too aggressive management in women with limited life expectancy and competing comorbidity. NCQA encourages providers and patients to engage in shared-decision making to determine the best course of action for the patient.

Committee response:

- Committee members found the developer's response regarding the upper age limit to be reasonable and did not recommend a change to the specifications of the measure.
- Measures #0037 and #0046 assess performance for different entities: measure #0037 is specified for

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measurement at the health plan level; in contrast, measure #0046 is specified for measurement at the individual clinician or group level. The issue of different data sources for measures #0037 and #0046 was addressed during the Committee's discussion about harmonizing these two measures. In that discussion, the developer explained their reasoning behind using the Health Outcomes Survey for measure #0046 (i.e., for new health plan members, health plans may not have access to claims or medical records needed to compute the measure), and acknowledged that the results from the two sources may be different. The Committee accepted this rationale and did not make any harmonization recommendations nor recommend re-specifying this measure.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0045 Communication with the physician or other clinician managing on-going care post fracture for men and women aged 50 years and older
Submission | Specifications
Description: Percentage of adults 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication. **Numerator Statement**: Patients with documentation of communication with the physician or other clinician managing the patient's on-going care that a fracture occurred and that the patient was or should be considered for osteoporosis testing or treatment. Communication may include documentation in the medical record indicating that the clinician treating the fracture communicated (e.g., verbally, by letter, through shared electronic health record, a bone mineral density test report was sent) with the clinician managing the patient's on-going care OR a copy of a letter in the medical record outlining whether the patient was or should be treated for osteoporosis. **Denominator Statement**: Adults aged 50 years and older who experienced a fracture, except fractures of the finger, toe, face or skull. **Exclusions**: None **Adjustment/Stratification**: **Level of Analysis:** Clinician : Group/Practice, Clinician : Individual, Clinician : Team **Setting of Care:** Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Hospital/Acute Care Facility, Ambulatory Care : Urgent Care **Type of Measure**: Process **Data Source**: Electronic Clinical Data, Paper Medical Records **Measure Steward**: National Committee for Quality Assurance
STANDING COMMITTEE MEETING [07/08/2014] **1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>** (1a. Evidence, 1b. Performance Gap, 1c. High Impact) 1a. Evidence: **H-8**; **M-6**; **L-3**; **I-1; IE-0**; 1b. Performance Gap: **H-7**; **M-10**; **L-0**; **I-1;** 1c. Impact: **H-13**; **M-3**; **L-2**; **I-0** <u>Rationale</u>: • Evidence presented by the developer included a systematic review and meta-analysis of four models of care for secondary prevention of osteoporotic fracture. The focus of this measure most closely corresponds to the "Type C" intervention included in the review, which includes both educational and

0045 Communication with the physician or other clinician managing on-going care post fracture for men and women aged 50 years and older

communication components. The review included nine studies from 1996-2011 that are pertinent to this measure. Results of the review indicate that communication leads to increased rates of testing and treatment. Committee members reviewed this evidence and agreed that it linked patient education and communication with additional testing and/or treatment of osteoporosis, given the clinically relevant and statistically significant differences between the intervention and control groups for the studies included in the review.

- Committee members also noted that evidence for communication is weaker than evidence for a fracture liaison service. The developer explained that this measure, along with measure #0053—which focuses on management following a fracture, including treatment or screening—includes the elements of a fracture liaison service (communication and management). Members questioned why the developer did not combine these two measures, given that users are not required to report both together, and that doing either without the other would be less effective than doing both. The developer explained that the level of accountability for communication (measure #0045) is the clinician in the inpatient setting, while the level of accountability for the management (measure #0053) is the outpatient provider. The developer noted that the outpatient provider should be held accountable for management after fracture, but not held accountable for the inpatient provider communicating to them, hence their decision to develop two measures.
- PQRS data provided by the developer indicate that the average performance rate for the 0.4% of eligible professionals reporting the measure was 62.7%. Committee members noted the large variation in performance between the 25th and 75th percentile, and also noted that information provided by the developer from the literature suggest disparities in offering osteoporosis screening or treatment to racial and ethnic minority women.
- Developers noted the high prevalence of osteoporosis in the US and the high rate of under-diagnosis, as well as the dangers of fracture due to osteoporosis. Committee members agreed osteoporosis is a high priority condition.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-6**; **M-10**; **L-2**; **I-0** 2b. Validity: **H-2**; **M-13**; **L-3**; **I-0**
<u>Rationale</u>:

- The reliability testing data presented by the developer was based on comparing the findings of two abstractors who reviewed the full medical record (paper or EHR) for 39 patients from each of the two practice sites examined (note that power calculations indicated a need for 38 patients per site). Percentage agreement statistics for the numerator and denominator were computed, as were kappa statistics when possible (to account for chance agreement). The testing results demonstrated 100% agreement between the abstractors for the denominator, and a 94.4% agreement for the numerator (kappa=.77), generally considered substantial agreement beyond what would be expected by chance alone). Developers also presented an overall agreement rate of 87% (kappa=.68, 95% CI=.43, .94), which also indicates moderate to substantial agreement above what would be expected by chance alone. Committee members expressed no concerns about the results of the reliability testing.
- Developers described the AMA-PCPI development and review process as an indicator of face validity; they also noted that various workgroups involved in the development of the measure agreed that the measure

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demonstrates quality of care. Committee members noted that adequate demonstration of face validity should result in a moderate rating for validity according to the NQF algorithm for rating validity.

- Committee members questioned how the numerator would be captured using ICD-9 codes for coordination of care and communication. The developer clarified that the measure numerator is captured through medical record review and the denominator is identified through claims that are used to identify patients who had a fracture.

3. Feasibility: H-5; M-11; L-1; I-1

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- There was initial confusion among Committee members as to whether this measure is an eMeasure. The developer clarified that this is not an eMeasure and noted under the validity assumption that medical record review is required for the numerator.

4. Use and Usability: H-5; M-11; L-2; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

- Committee members noted that the measure is used in the PQRS system, although they acknowledged the very small percentage of providers who report on the measure.
- PQRS data submitted by the developer indicate an increase in performance from 49% in 2009 to 62.7% in 2012.
- Committee members did not voice any concerns about potential unintended consequences.

5. Related and Competing Measures

- According to NQF definitions, the following six measures are considered competing and/or related:
  - 0037: Osteoporosis Testing in Older Women (NCQA)
  - 0046: Screening for Osteoporosis for Women 65-85 Years of Age (NCQA)
  - 0053: Osteoporosis Management in Women Who Had a Fracture (NCQA)
  - 2417: Risk Assessment/Treatment After Fracture (TJC)
  - 0045: Communication with the physician or other clinician managing on-going care post fracture for men and women aged 50 years and older (NCQA)
  - 2416: Laboratory Investigation for Secondary Causes of Fracture (TJC)
- Regarding measures #0045, #0037, and #0046 (difference in age groups specified)

  Committee response: Committee members noted that screening is for primary prevention of osteoporosis and testing/treatment is for secondary prevention of future fractures and that the differences in age groups specified for these measures are justified.
- Regarding measures #0045 and #0053(differences in age/gender/and timing specifications):

  Committee response: Committee members noted the need for testing/treatment post-fracture for both men and women and questioned why both men and women are included in the communication measure but not in the testing/treatment measure.

  Developer response: The developer for measure #0053 (NCQA) explained that they previously

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maintained a post-fracture measure for both men and women, but that because the guidelines for testing and treatment are different for men compared to women (e.g., different medications; emphasis on treatment for any fragility fracture for women but only on spine/hip fracture for men), they decided to develop separate measures. The developer also explained that they did not have concerns about unintended consequences to men due to communication about a fracture, but were concerned about potential overuse of testing or treatment for men because fractures in men, particularly those aged 50-65, may not be indicative of osteoporosis. They also explained that the timeframe for the two measures (3 months for #0045 and 6 months for #0053) was to encourage earlier communication and to allow sufficient time for testing/treatment.

Committee response: While some Committee members thought that separate management measures for men and women are appropriate, some noted that the TJC measure is specified to distinguish guideline/ treatment differences between men and women without having to split into two measures. Committee members noted that several medications can be used by both men and women and that there are ongoing trials in men for the two that currently are approved for women only.

Developer response: NCQA agreed to take back to their clinical expert panel a recommendation to include men in measure #0053, potentially specifying different denominator criteria for selecting men with spine/hip fracture and women with any fracture. They cautioned, however, that #0053 is in use in PQRS, which may not allow this type of change in specification; they noted that if the change would result in not being able to use the measure in PQRS, they would not make the change.

Standing Committee Recommendation for Endorsement: **Y-16**; **N-2**

6. Public and Member Comment

Comments received:

- One commenter noted the importance of communication, but expressed concern that the measure is a "low-bar" measure and suggested that a measure to assess testing and treatment would be more valuable.

Committee response:

- Committee members agreed that this measure meets NQF's current criteria for endorsement. Committee members agreed with the suggestions for future development of treatment measures. They also recommended that if a separate testing/treatment post-fracture measure for men is developed, that it be harmonized with measure #0053.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0046 Screening for Osteoporosis for Women 65-85 Years of Age

Submission | Specifications

Description: Percentage of women 65-85 years of age who ever had a central dual-energy x-ray absorptiometry (DXA) test to check for osteoporosis.

Numerator Statement: The number of women who have documentation in their medical record of having received a DXA test of the hip or spine.

Denominator Statement: Women age 65-85.

0046 Screening for Osteoporosis for Women 65-85 Years of Age

Exclusions: Diagnosis of osteoporosis at the time of the encounter.
Adjustment/Stratification:
Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting of Care: Ambulatory Care : Clinician Office/Clinic
Type of Measure: Process
Data Source: Electronic Clinical Data, Paper Medical Records
Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING [07/08/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria
(1a. Evidence, 1b. Performance Gap, 1c. High Impact)
1a. Evidence: **H-10**; **M-7**; **L-1**; **I-0; IE-0**; 1b. Performance Gap: **H-13**; **M-5**; **L-0**; **I-0;** 1c. Impact: **H-14**; **M-4**; **L-0**; **I-0**
Rationale:

- Evidence presented by the developer to support the measure is a 2011 Grade B recommendation from the US Preventive Services Task Force (signifying moderate certainty of the net benefit of screening for osteoporosis by using DXA is at least moderate). Overall, the committee agreed that there is strong evidence that screening bone density leads to treatment and treatment leads to prevention of fractures.
- The Committee expressed concerns that there was no time limitation on the measure, meaning that any bone mineral density test done over the course of a women's lifetime would meet the requirements of the measure. The developer noted that there is no clear evidence nor guidelines on how frequently screening should occur and that, in an effort to reduce the potential unintended consequence of overuse of testing (e.g., another screening at age 65 when one had been done previously), any test done over the course of a woman's lifetime is allowed, with no particular length of time between screenings required. One Committee member also noted that there is little evidence regarding the effectiveness of repeated screening.
- One member raised the concern that additional appropriate testing may not be covered by insurance; however, the developer noted that CMS covers the test on a bi-annual basis.
- PQRS data provided by the developer indicate that the average performance rate for the 6.1% of eligible professionals reporting the measure in 2012 was 58.7%. Committee members noted the large variation in performance between the 25th and 75th percentile, but also noted the decline in performance since 2011. Also data provided by the developer from the literature suggest disparities in offering osteoporosis screening or treatment to racial and ethnic minority women.
- Developers noted the high prevalence of osteoporosis in the US, the high risk for osteoporotic fracture, as well as the dangers of fracture due to osteoporosis. Members agreed osteoporosis is a high priority condition.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-3**; **M-12**; **L-3**; **I-0** 2b. Validity: **H-6**; **M-11**; **L-1**; **I-0**
Rationale:

- The developer clarified that the term "fracture" is used as opposed to "fragility fracture" because the data collected in claims using ICD-9 coding does not differentiate between the two; thus, the fractures identified are those likely to be fragility fractures.

0046 Screening for Osteoporosis for Women 65-85 Years of Age

- Committee members voiced concern over the difficulty in obtaining medical records for patients who had the study performed in the more distant past, particularly when under the care of another provider. The developers noted that the measure specifications had changed from what was previously endorsed and now requires the date when the test was conducted and the results of the test. The developer also indicated that their clinical experts reasoned that if a patient has been treated for a year (the time frame of this measure), and the results of the previous test are still unknown, the physician cannot appropriately determine whether or not the patient should be treated for osteoporosis and should probably reorder the test.
- The developer noted that testing using the new specifications has not been conducted and that further testing of the measure is not planned; instead, they are developing an eMeasure that will eventually replace this measure. Committee members noted that reliability and validity testing results likely would be lower with this change in specifications, as data may be hard or impossible to find (a potential threat to the validity of the measure). The developer noted that they are making the assumption that if reviewers can accurately identify whether or not a DXA was ordered, they would be able to accurately identify whether or not a DXA was performed.
- The reliability testing data presented by the developer for the original specifications (DXA ordered, not performed) was based on comparing the findings of two abstractors who reviewed the full medical record (paper or EHR) for 30 patients from each of the two practice sites examined (note that power calculations indicated a need for 28 patients per site). Percentage agreement statistics for the numerator, denominator, and exceptions were computed, as were kappa statistics, when possible, to account for chance agreement. The testing results demonstrated 100% agreement between the abstractors for the denominator and exceptions, and a 90% agreement for the numerator (kappa=.77, generally considered substantial agreement beyond what would be expected by chance alone). Developers also presented an overall agreement rate of 90% (kappa=.77, 95% CI=.53, 1.00), which also indicates moderate to substantial agreement above what would be expected by chance alone. Committee members questioned the small sample size but accepted the developer's explanation regarding the power calculation.
- The developer also acknowledged other changes to the specifications, including addition of an upper age limit of 85 years, removal of a lower age limit, exclusion of patients with a diagnosis of osteoporosis, and removal of medication therapy as a way to meet the measure.
- Developers described the AMA-PCPI development and review process as an indicator of face validity; they also noted that various workgroups involved in the development of the measure agreed that the measure demonstrates quality of care.

3. Feasibility: H-3; M-12; L-3; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- Some Committee members questioned the feasibility of obtaining test results in a non-electronic environment (i.e., if the patient was under the care of another physician when the test was done). Members noted that those who report on the measure in PQRS likely have systems that will allow this data capture and that physicians without electronic capabilities may choose to not report on the measure in PQRS.

0046 Screening for Osteoporosis for Women 65-85 Years of Age

3. Use and Usability: H-4; M-11; L-3; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

- The measure is currently used in the PQRS program.
- Committee members were concerned that only 6% of providers were reporting on this measure. However, the developer pointed out that, of the NCQA measures in PQRS that are focused on the geriatric population, this measure is one of the more widely reported measures; thus, while a 6% reporting rate may seem low, it is relatively high for PQRS.
- PQRS data submitted by the developer indicate an increase in performance from 56.1% in 2009 to 58.7% in 2012.
- Committee members expressed concern that overuse of the bone mineral density testing may be an unintended consequence of the measure.

5. Related and Competing Measures

- According to NQF definitions, the following six measures are considered competing and/or related:
  - 0037: Osteoporosis Testing in Older Women (NCQA)
  - 0046: Screening for Osteoporosis for Women 65-85 Years of Age (NCQA)
  - 0053: Osteoporosis Management in Women Who Had a Fracture (NCQA)
  - 2417: Risk Assessment/Treatment After Fracture (TJC)
  - 0045: Communication with the physician or other clinician managing on-going care post fracture for men and women aged 50 years and older (NCQA)
  - 2416: Laboratory Investigation for Secondary Causes of Fracture (TJC)
- Measures #0037 (accountability=health plan) and #0046 accountability=clinician) each measure osteoporosis screening in older women and are thus considered competing. However, the level of analysis is different for the two measures (health plan vs clinician, respectively), and thus having two competing measures is considered justified. Furthermore, measure #0037 relies on data obtained from the Health Outcomes Survey, while #0047 used data from medical records and claims. The developer noted that health plans may not have access to claims or medical records and thus obtaining data via survey is a reasonable alternative; conversely, clinicians do have access to claims and medical charts, but may not have the resources to conduct a survey. The developer acknowledged that the results from the two sources may be different if, for example, the provider's records are incomplete or there is recall bias in the survey. Committee members discussed potential recommendations for changing the specifications of either measure so as to make them more similar to each other or to the other osteoporosis measures.

  Committee response: Committee members noted that screening is for primary prevention of osteoporosis and testing/treatment is for secondary prevention of future fractures and that the differences in age groups specified for these measures are justified. Committee members agreed that screening is appropriate for women but the evidence for screening men is not strong.

Standing Committee Recommendation for Endorsement: **Y-15**; **N-3**

6. Public and Member Comment

Comments received:

- One commenter supported the measure but expressed concern that the upper age limit for the measures would result in under-diagnosis for those older than 85 years of age, given the frequency of

0046 Screening for Osteoporosis for Women 65-85 Years of Age
occurrence of osteoporosis in this age group. • Two commenters raised the issue of competing measures and harmonization for measures #0037 (Osteoporosis Testing in Older Women) and #0046 (Screening for Osteoporosis for Women 65-85 Years of Age), and specifically questioned the use of the Health Outcomes Survey in measure #0037. Developer response: • NQCA continues to recommend limiting this measure to assess osteoporosis screening in women under age 85. Continued screening beyond the age of 85 may be appropriate for some individuals and including the upper age cap does not penalize health plans who do this; however, women over the age of 85 may have limited life expectancy and may not live long enough to realize the benefits of osteoporosis treatment if they are screened positive. The USPSTF recommends providers take into account the patient's remaining life expectancy compared to the benefits of treatment when deciding whether to screen. There is a concern that without an upper age cap this measure may incentivize plans and providers to pursue too aggressive management in women with limited life expectancy and competing comorbidity. NCQA encourages providers and patients to engage in shared-decision making to determine the best course of action for the patient. Committee response: • Committee members found the developer's response regarding the upper age limit to be reasonable and did not recommend a change to the specifications of the measure. • Measures #0037 and #0046 assess performance for different entities: measure #0037 is specified for measurement at the health plan level; in contrast, measure #0046 is specified for measurement at the individual clinician or group level. The issue of different data sources for measures #0037 and #0046 was addressed during the Committee's discussion about harmonizing these two measures. In that discussion, the developer explained their reasoning behind using the Health Outcomes Survey for measure #0046 (i.e., for new health plan members, health plans may not have access to claims or medical records needed to compute the measure), and acknowledged that the results from the two sources may be different. The Committee accepted this rationale and did not make any harmonization recommendations.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0053 Osteoporosis Management in Women Who Had a Fracture
Submission | Specifications
Description: The percentage of women age 50-85 who suffered a fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis. **Numerator Statement**: Patients who received either a bone mineral density test or a prescription for a drug to treat osteoporosis after a fracture occurs **Denominator Statement**: Women who experienced a fracture, except fractures of the finger, toe, face or skull. Three denominator age strata are reported for this measure: Women age 50-64 Women age 65-85 Women age 50-85 **Exclusions**: 1) Exclude women who had a fracture in the 60 days prior to the index fracture 2) Exclude women who had a bone mineral density test in the 2 years prior to the index fracture 3) Exclude women who had received osteoporosis therapy or medication in the 12 months prior to the index

0053 Osteoporosis Management in Women Who Had a Fracture

fracture

Adjustment/Stratification:

Level of Analysis: Clinician : Group/Practice, Health Plan, Clinician : Individual, Integrated Delivery System, Clinician : Team

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility, Pharmacy, Ambulatory Care : Urgent Care

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Imaging/Diagnostic Study, Paper Medical Records, Electronic Clinical Data : Pharmacy

Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING [07/08/2014]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **H-10**; **M-7**; **L-1**; **I-0; IE-0**; 1b. Performance Gap: **H-9**; **M-8**; **L-0**; **I-0;** 1c. Impact: **H-14**; **M-3**; **L-1**; **I-0**

<u>Rationale</u>:

- Evidence presented by the developer for screening included an American Association of Clinical Endocrinologists (AACE) recommendation (Grade C, evidence based on clinical experience, descriptive studies, or clinical expert opinion) and a USPSTF recommendation (Grade B); and evidence for pharmacologic therapy included an AACE recommendation (Grade A, evidence based on well-designed RCTs or controlled cohort trails). The developer also summarized the quality, quantity, and consistency of evidence from three recent systematic reviews. Committee members agreed the evidence supports the utility of bone density testing to predict fracture risk and pharmacologic treatment to reduce fracture risk.
- HEDIS data provided by the developer for the health plan level of analysis indicate that the average performance rate for the 347 participating plans in 2013 was 23.1%. PQRS data provided by the developer for the clinician level of analysis indicate that the average performance rate in 2012 for the 0.8% of eligible professionals reporting the measure was 70.0%. Information provided by the developer from the literature suggests disparities in offering osteoporosis screening or treatment to racial and ethnic minority women. Committee members noted the large difference in performance rates in health plans vs. clinicians, possibly due to the voluntary nature of the PQRS program.
- Developers noted the high prevalence of osteoporosis in the US and the high rate of under-diagnosis, as well as the dangers of fracture due to osteoporosis. Members agreed osteoporosis is a high priority condition.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-11**; **M-7**; **L-0**; **I-0** 2b. Validity: **H-9**; **M-9**; **L-0**; **I-0**

<u>Rationale</u>:

- Reliability testing was done for the health plan level of analysis using a signal-to-noise analysis of 347 plans participating in HEDIS. The reliability across all health plans ranged from .81 (the 10th percentile) to .99 (the 90th percentile), with an average of .92. Developers state that the majority of plans met or exceeded the generally recognized minimal threshold of .7, signifying very good reliability.
- Validity testing was done for the health plan level of analysis by correlating the results of this measure with the Osteoporosis Testing in Older Women measure (#0037) to explore the hypothesis that plans that perform well with screening also perform well with testing/treatment; results indicate a positive and

0053 Osteoporosis Management in Women Who Had a Fracture

statistically significant correlation between the two measures. Data element validity testing also was conducted using data from 100 randomly selected patients from five health plans; data from claims were compared (using percentage agreement) to those from the medical record for the numerator and denominator, and results indicate good agreement. (NOTE: these testing results can serve as testing for the clinician level of analysis and be used as data element reliability testing results). Developers also described the HEDIS development and review process as an indicator of face validity for the health plan level of analysis and noted additional face validity assessment by various workgroups that helped to develop the measure. Committee members voiced no concerns about the reliability and validity of the measure.

- Committee members asked why women with a fracture within 60 days prior are excluded from the measure. The developer agreed that such patients likely were included in the measure anyway, but that the exclusion is intended to help identify new fractures rather than follow-up visits for earlier fractures.
- Committee members also asked how new pharmaceutical agents are handled in the measure. The developer noted that they update the medical list on an annual basis.

4. Feasibility: H-9; **M-9**; **L-0**; **I-0**

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- Committee members agreed that the measure is feasible, as it is used in several accountability programs.

3. Use and Usability: H-9; **M-9**; **L-0**; **I-0**

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

- Committee members noted that the health plan measure is used in several accountability applications, including health plan accreditation, Quality Compass, and the Medicare Advantage Star Rating program. The clinician-level measure is used in PQRS.
- HEDIS data submitted by the developer indicate an increase in health performance from 20.1% in 2011 to 23.1% in 2013. PQRS data submitted by the developer indicate an increase in clinician performance from 56.5% in 2009 to 70.0% in 2012.
- Committee members did not voice any concerns about potential unintended consequences.

5. Related and Competing Measures

- According to NQF definitions, the following six measures are considered competing and/or related:
  - 0037: Osteoporosis Testing in Older Women (NCQA)
  - 0046: Screening for Osteoporosis for Women 65-85 Years of Age (NCQA)
  - 0053: Osteoporosis Management in Women Who Had a Fracture (NCQA)
  - 2417: Risk Assessment/Treatment After Fracture (TJC)
  - 0045: Communication with the physician or other clinician managing on-going care post fracture for men and women aged 50 years and older (NCQA)
  - 2416: Laboratory Investigation for Secondary Causes of Fracture (TJC)
- Regarding measures #0045 and #0053 (differences in age/gender/and timing specifications):

  Committee response: Committee members noted the need for testing/treatment post-fracture for both men and women and asked why both men and women are included in the communication measure but

0053 Osteoporosis Management in Women Who Had a Fracture

not in the testing/treatment measure.

Developer response: The developer for measure #0053 (NCQA) explained that they previously maintained a post-fracture measure for both men and women, but that because the guidelines for testing and treatment are different for men compared to women (e.g., different medications; emphasis on treatment for any fragility fracture for women but only on spine/hip fracture for men), they decided to develop separate measures for men and women. The developer also explained that they did not have concerns about unintended consequences to men due to communication about a fracture, but were concerned about potential overuse of testing or treatment for men because fractures in men, particularly those aged 50-65, may not be indicative of osteoporosis. They also explained that the timeframe for the two measures (3 months for #0045 and 6 months for #0053) was to encourage earlier communication but allow sufficient time for testing/treatment.

Committee response: While some Committee members thought that separate management measures for men and women are appropriate, some noted that the TJC measure is specified so as to distinguish guideline/ treatment differences between men and women without having to split into two measures. Committee members noted that several medications can be used by both men and women and that there are ongoing trials in men for the two that currently are approved for women only.

Developer response: NCQA agreed to take back to their clinical expert panel a recommendation to include men in measure #0053, potentially specifying different denominator criteria so as to select men with spine/hip fracture and women with any fracture. They cautioned, however, that #0053 is in use in PQRS, which may not allow this type of change in specification; they noted that if the change would result in not being able to use the measure in PQRS, they would not make the change.

- Regarding measures #0053 and #2417: Both measure testing and treatment in adults with a (presumed) fragility fracture and are thus are considered competing measures. However, the level of analysis is different for the two measures (clinician vs. facility, respectively), and thus having two competing measures is considered justified. However, measure #2417 has a more expansive set of options for the numerator.

  Committee response: Committee members emphasized the strong evidence supporting fracture liaison service and asked NCQA if they had considered adding a link to a fracture liaison service to #0053.

  Developer response: NQCA explained that the communication/coordination component of a fracture liaison service is covered by measure #0045. They also noted that their testing/treatment measure (#0053) measures delivery rather than referral. They will take back the suggestion to include this in their measure if their analyses indicate that referral to a fracture liaison service consistently translates to actual delivery of services.

Standing Committee Recommendation for Endorsement: **Y-17**; **N-1**

6. Public and Member Comment

Comments received:

- One commenter expressed support of the measure but also encouraged development of a drug- or treatment-adherence measure for people with osteoporosis who have had a fracture.

Committee response:

- Committee members agreed with the suggestion for future measure development.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

0053 Osteoporosis Management in Women Who Had a Fracture
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0416 Diabetic Foot & Ankle Care, Ulcer Prevention – Evaluation of Footwear
Submission | Specifications
Description: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing **Numerator Statement**: Patients who were evaluated for proper footwear and sizing at least once within 12 months Definition: Evaluation for Proper Footwear – Includes a foot examination documenting the vascular, neurological, dermatological, and structural/biomechanical findings. The foot should be measured using a standard measuring device, and counseling on appropriate footwear should be based on risk categorization. Numerator Quality-Data Coding Options for Reporting Satisfactorily: Footwear Evaluation Performed G8410: Footwear evaluation performed and documented OR Footwear Evaluation not Performed for Documented Reasons G8416: Clinician documented that patient was not an eligible candidate for footwear evaluation measure OR Footwear Evaluation not Performed G8415: Footwear evaluation was not performed **Denominator Statement**: All patients aged 18 years and older with a diagnosis of diabetes mellitus **Exclusions**: Footwear evaluation not performed for documented reasons. For example bilateral amputee. **Adjustment/Stratification**: **Level of Analysis:** Clinician : Individual **Setting of Care:** Ambulatory Care : Clinician Office/Clinic **Type of Measure**: Process **Data Source**: Administrative claims, Electronic Clinical Data : Electronic Health Record, Paper Medical Records **Measure Steward**: American Podiatric Medical Association
STANDING COMMITTEE MEETING [07/11/2014] **1. Importance to Measure and Report: he measure meets the Importance criteria** (1a. Evidence, 1b. Performance Gap, 1c. High Impact) 1a. Evidence: **H-0**; **M-2**; **L-1**; **I-3; IE-10**; 1b. Performance Gap: **H-10**; **M-5**; **L-1**; **I-0;** 1c. Impact: **H-10**; **M-4**; **L-1**; **I-1** Rationale: • Evidence provided by the developer included the 2008 American Diabetes Association expert-opinion recommendation that an assessment of footwear be included as part of a comprehensive foot exam for adult patients with diabetes and two articles that examined the prevalence of poorly-fitting shoes. Committee members acknowledged that the evidence supporting this measure is indirect, indicating only that many people with diabetes wear poorly fitting shoes, that diabetics with foot ulcers are more likely to have poorly fitting shoes, and that poorly-fitting (tight) shoes contribute to foot ulcers. However, members agreed that promoting proper shoe fit likely would decrease rates of foot

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ulceration and amputation. Several members agreed that, per the evidence algorithm, an exception to the evidence subcriterion would be appropriate.

- PQRS data provided by the developer indicate that the average performance rate (for the 1% of eligible professionals reporting the measure) was 69.2%. Committee members also noted that given the relatively low rate of diabetic foot exams overall, assessment of footwear would also be relatively infrequent.
- Developers noted that diabetes affects 26 million people in the US, that 60-70% of diabetics will develop peripheral neuropathy, that as many as 25% of diabetics will develop a foot ulcer, that more than half of these will become infected, and that 20% of infected ulcers will result in amputation. Accordingly, members agreed that the area of measure focus is high priority.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-0**; **M-9**; **L-6**; **I-0** 2b. Validity: **H-1**; **M-10**; **L-4**; **I-1**
<u>Rationale</u>:

- Committee members in general agreed that the measure was well-specified and included appropriate codes for documenting performance of the measure. Members did raise the concern that the specific "standard measuring device" for measuring the foot was not identified, which may lead to inconsistencies in performance of the measure, particularly between podiatrists and non-podiatrists. Some Committee members noted that it may be possible for a medical assistant or nurse to perform this evaluation using a standard footwear assessment device.
- The testing data presented by the developer was based on comparing claims data submitted to the PQRS to the medical record. Data for 286 patients, from 3 practice sites, were examined. Percentage agreement statistics for the numerator, denominator, and exclusions were computed, as were kappa statistics when possible (to account for chance agreement). The testing results demonstrated 100% agreement between the clinical record and the codes captured in PQRS for the denominator and the exceptions, and a 93% agreement for the numerator (kappa=.256, generally considered fair agreement). Because this testing included a comparison against the gold standard (the medical chart), the results can be used to assess both data element reliability and data element validity. Committee members agreed that the testing results demonstrated adequate reliability and validity. However, some members expressed concern about the validity of the measure, given the small sample size used in testing (particularly given that only podiatric practices were included in the testing).

3. Feasibility: H-5; M-6; L-4; I-1
(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)
<u>Rationale</u>:

- Committee members noted that the required data elements are routinely generated during care delivery in podiatric practices, although some expressed concern about feasibility in non-podiatric practices.
- Members noted that once EHRs have a specified field designated for measuring shoe, this measure will become much more feasible to implement.

4. Use and Usability: H-3; M-9; L-3; I-1
(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

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Rationale:

- The measure has been in use in PQRS since 2008; however, few practices are reporting the measure. It is also included in the US Wound Registry and in the American Board of Podiatric Surgeon's maintenance of certification program.
- The developer provided PQRS data from 2008-2011, which show an increase in both the reporting of the measure and in average performance rate.
- Committee members were not concerned about potential unintended consequences, noting that information about better shoe fit could only benefit patients.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-10**; **N-6**

6. Public and Member Comment

Comments received:

- One commenter suggested combining measures #0416 and #0417, and also encouraged the developer to specify the measure so that other clinicians (such as physical therapists) could report on the measure.
- Another commenter questioned the difference between this measure and measure #0417 (Diabetic Foot & Ankle Care, Peripheral Neuropathy – Neurological Evaluation).
- Another commenter questioned whether this measure is evidence-based and also noted a need for more detailed specifications, including how to reliably measure shoe fit; this commenter also questioned the ease of use of G-codes by podiatrists.

Developer response:

- The developer clarified that the measure is designed to be reported by any eligible provider and is not designed to be specific to any specialty. With regards to combining the measures, the developer agreed that ideally there should be a single measure that is a comprehensive diabetic foot examination and encompasses all aspect of evaluating the diabetic foot. The developer noted the suggestion for potential future measure development.
- The developer clarified the differences between measures #0416 and #0417. Measure #0416 is focused on evaluation of the footwear for people with diabetes, and measure #0417 involves the components of performing a neurological exam of the person's feet.
- The developer noted that there is expert opinion acceptance that wearing the wrong size shoes contributes to diabetic foot complications and that there is evidence that a percentage of people with diabetes wear the wrong size shoe. The developer also stated the clarity in the specifications as to how to measure the foot and noted that podiatrists often use G codes on claims.

Committee response:

- Committee members acknowledged that although the evidence presented to support measure #0416 is indirect, but agreed that promoting proper shoe fit likely would decrease rates of foot ulceration and amputation and that an exception to the evidence subcriterion is appropriate. Some members expressed concern that the specific “standard measuring device” for measuring the foot was not identified. The developer clarified that either the “Brannock device” or the “Ritz Stick” are the “standard measuring devices “used for measuring the foot. Overall, the Committee agreed that the measure meets NQF's reliability subcriterion and made no changes to their recommendation for endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0417 Diabetic Foot & Ankle Care, Peripheral Neuropathy – Neurological Evaluation

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months

Numerator Statement: Patients who had a lower extremity neurological exam performed at least once within 12 months

Definition:

Lower Extremity Neurological Exam – Consists of a documented evaluation of motor and sensory abilities and should include: 10-g monofilament plus testing any one of the following: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold), however the clinician should perform all necessary tests to make the proper evaluation.

Numerator Quality-Data Coding Options for Reporting Satisfactorily:

Lower Extremity Neurological Exam Performed

G8404: Lower extremity neurological exam performed and documented

OR

Lower Extremity Neurological Exam not Performed for Documented Reasons

G8406: Clinician documented that patient was not an eligible candidate for lower extremity neurological exam measure

OR

Lower Extremity Neurological Exam not Performed

G8405: Lower extremity neurological exam not performed

Denominator Statement: All patients aged 18 years and older with a diagnosis of diabetes mellitus

Exclusions: Clinician documented that patient was not an eligible candidate for lower extremity neurological exam measure, for example patient bilateral amputee, patient has condition that would not allow them to accurately respond to a neurological exam (dementia, Alzheimer's, etc.), patient has previously documented diabetic peripheral neuropathy with loss of protective sensation.

Adjustment/Stratification:

Level of Analysis: Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data : Electronic Health Record, Paper Medical Records

Measure Steward: American Podiatric Medical Association

STANDING COMMITTEE MEETING [07/11/2014]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **H-1**; **M-9**; **L-0**; **I-1; IE-5**; 1b. Performance Gap: **H-11**; **M-5**; **L-0**; **I-0;** 1c. Impact: **H-10**; **M-5**; **L-1**; **I-1**

<u>Rationale</u>:

- Evidence provided by the developer included the 2013 American Diabetes Associatiation grade B recommendation for conduct of an anuual comprehensive foot exam for diabetic patients. Committee members noted that the evidence presented is supportive of the measure.
- PQRS data provided by the developer indicate that the average performance rate (for the 1.4% of eligible professionals reporting the measure) was 86.6% in 2011 and 43.6% in 2012. The developer also cited an AMA/NCQA report indicating that only 55% of patients with diabetes obtain an annual foot exam and referenced CDC data indicating disparities in performance of foot exams by race,

0417 Diabetic Foot & Ankle Care, Peripheral Neuropathy – Neurological Evaluation

ethnicity, age, and educational status.

- Developers noted that diabetes affects 26 million people in the US, that 60-70% of diabetics will develop peripheral neuropathy, that as many as 25% of diabetics will develop a foot ulcer, that more than half of these will become infected, and that 20% of infected ulcers will result in amputation. Accordingly, Committee members agreed that the area of measure focus is high priority.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-1**; **M-13**; **L-2**; **I-0** 2b. Validity: **H-3**; **M-11**; **L-0**; **I-2**
<u>Rationale</u>:

- Committee members in general agreed that the measure was well-specified. Members noted that the measure specifications are consistent with the evidence presented, requiring performance of the 10g monofilament examination plus at least one of any of the following: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold). The specifications caveat that the clinician should perform all necessary tests to make the proper evaluation.
- The testing data presented by the developer was based on comparing claims data submitted to the PQRS to the medical record. Data for 286 patients, from 3 practice sites, were examined. Percentage agreement statistics for the numerator, denominator, and exclusions were computed. The testing results demonstrated 100% agreement between the clinical record and the codes captured in PQRS for the denominator and the exceptions, and a 99.3% agreement for the numerator (kappa value not calculable) when percentage agreement is 100. Because this testing included a comparison against the gold standard (the medical chart), the results can be used to assess both data element reliability and data element validity. Committee members agreed that the testing results demonstrated adequate reliability and validity. However, some members expressed concern about the validity of the measure, given the small sample size used in testing (particularly given that only podiatric practices were included in the testing). Members also noted that the testing focused only on the Medicare population, although the measure is not limited to the 65+ age group; however, they were not concerned that the reliability and validity of the measure at the data element level would be different for younger patients.

4. Feasibility: H-6; M-8; L-1; I-1
(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)
<u>Rationale</u>:

- The Committee agreed that the required data elements are routinely generated during care delivery and are captured electronically.

3. Use and Usability: H-4; M-11; L-0; I-1
(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
<u>Rationale</u>:

- The measure has been in use in PQRS since 2008; however, few practices are reporting the measure. It is also included in the US Wound Registry and in the American Board of Podiatric Surgeon's maintenance of certification program.
- The developer provided PQRS data from 2008-2011, which show a slight increase in the reporting of the measure and a substantial increase in the average performance rate. However, the PQRS data reported

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by the developer for 2012 indicates a large drop in the performance rate; it is unclear why this may have occurred.

- Committee members expressed no concerns about potential unintended consequences of the measure

5. Related and Competing Measures

- This measure directly competes with measure #0056 (Diabetes: Foot exam). Both measures apply to the clinician office setting and have the same level of analysis (clinician: individual, group/practice). The data sources for the two measures are comparable, though measure #0056 also includes pharmacy data that are used in identification of diabetic patients for the denominator. The requirements for meeting the numerator for the two measures differ slightly:
- Measure #0056 requires a visual inspection, a sensory exam using monofilament, and a pulse exam.
- Measure #0417 requires performance of the 10g monofilament examination plus at least one of any of the following: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold.

Committee response: Committee members discussed which of these approaches (in the numerator) is more evidence-based and would be more likely to drive improvements in healthcare. Some members stated that the evidence supporting the numerator specifications for measure #0056 (performing a monofilament exam in conjunction with a sensory exam) is greater than the evidence for performing a monofilament exam in conjunction with any of the other options listed in the numerator for measure #0417. One member mentioned the pulse check required by measure #0056, noting its usefulness in assessing for vascular disease and increasing the value of the foot examination (because vascular disease is present in many diabetic patients and increases the risk for non-healing foot lesions). Another member suggested that #0417 is better at documenting diabetic peripheral neuropathy than #0056 but the latter is a relatively more inclusive exam assessing vascularity as well as dermatologic risk factors such as athlete's foot, calluses, and obvious structural changes. The Committee questioned why measure #0056 excludes patients with gestational and steroid-induced diabetes and the developer clarified that because the algorithm for specifying the measure denominator includes use of diabetes medications, patients with these conditions would be captured in the denominator, and thus need to be explicitly excluded. The Committee suggested that both measures would benefit from including an assessment of foot pain for the diabetic patient in future iterations of the measures; they also noted the importance of foot exams in patients under age 18, even though neither measure includes this population in their specifications.

In a preliminary round of voting, a majority of members agreed that the measure #0417 is superior and recommended that measure #0417 **not** be put forward for endorsement; however, a sizeable minority thought that neither measure is superior and recommended that both endorsed. The Committee will discuss these issues further on a call after the public- and member comment period closes.

Standing Committee Recommendation for Endorsement: **Y-13**; **N-3**

6. Public and Member Comment

Comments received:

- One commenter suggested combining measures #0416 and #0417, and also encouraged the developer to specify the measure so that other clinicians (such as physical therapists) are included in the measure.
- Another commenter questioned the difference between measures #0416 and #0417 (Diabetic Foot & Ankle Care, Peripheral Neuropathy – Neurological Evaluation) and recommended that measures for diabetic foot care be evidence-based.

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- Two commenters also commented on the competing measures issue between measure #0056 and #0417: one favored #0417 as the superior measure and one supported endorsement of both measures.

Developer response:

- The developer clarified that the measure is designed to be reported by any eligible provider and is not designed to be specific to any specialty. The developer also noted that the measure is open to all clinicians who have the knowledge to perform the processes.
- With regards to combining the measures, the developer agreed that ideally there should be a single measure that is a comprehensive diabetic foot examination and encompasses all aspect of evaluating the diabetic foot. The developer noted the suggestion for potential future measure development.
- The developer clarified that measure #0416 is focused on evaluation of the footwear for people with diabetes, and measure #0417 involves the components of performing a neurological exam of the person's feet.

Committee response:

- Committee members agreed that the evidence presented for measure #0417 is supportive of the measure and therefore meets NQF's evidence subcriterion.
- After review of the comments submitted and additional discussion, Committee members agreed to recommend this measure as well as #0056 for endorsement. Members recognized the different uses of the two measures, noting the more detailed nature of #0417 as well as the potential to encourage screening with measure #0056. Members also noted that measure #0417 is an eMeasure. Members suggested that endorsement of both measures might result in more people with diabetes having their feet examined than what might be possible if only one measure is endorsed. While most members were comfortable with continued endorsement of both measures at the current time, they expressed a desire for one measure in the future that combines the elements from the two measure numerators and is useable by the broadest range of providers.

Standing Committee Vote on Competing Measures #0056 and #0417 [09/16/2014]:

Measure #0056 is the superior measure. It should be recommended for endorsement and measure #0417 should not be recommended for endorsement – 1; Measure #0417 is the superior measure. It should be recommended for endorsement and measure #0056 should not be recommended for endorsement – 1; Neither measure is superior to the other. Both should be recommended for endorsement - 13

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

APPENDIX B

	0417: Diabetic Foot & Ankle Care, Peripheral Neuropathy – Neurological Evaluation	0056: Diabetes: Foot Exam
Steward	American Podiatric Medical Association	National Committee for Quality Assurance
Description	Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months	The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year.
Type	Process	Process
Data Source	Administrative claims, Electronic Clinical Data : Electronic Health Record, Paper Medical Records DATA COLLECTION TOOL To assist with the data collection at each physician practice site, an On-Site Adjudication Tool (OSAT) was developed by Telligen. The tool was customized to capture the data elements for Evaluation of Footwear and Neurological Evaluation performance measures. In addition to assisting the auditor with verification of age, diabetes mellitus, and history of bilateral foot/leg amputation, the tool provided the ability to capture location of documentation for each individual data element. Upon completion of abstraction at each on-site visit, the auditors performed back-up onto an encrypted flash drive. At the completion of the audit, the case results were exported from the tool and analyzed. No patient or physician identifiable information was captured. The tool provided the ability to enter data for a maximum of 100 cases per practice site. OSAT was developed using the Product Designer Module. The module is used to compose abstraction resource files which define abstraction components. The module allows for unique project creation, while tailoring features to each customer's needs. Questions, answers, and measures are added as defined by the project. In addition, the tool is sophisticated enough to allow for the creation of skip, edit, and measure logic, based on the needs of the project. Skip logic defines rules for enabling questions based on defined patterns. Edit logic defines validations to be performed on	Administrative claims, Paper Medical Records, Electronic Clinical Data : Pharmacy No data collection instrument provided Attachment 0056_CDC_Foot_Exam_Value_Sets-635219463363519462.xlsx

	0417: Diabetic Foot & Ankle Care, Peripheral Neuropathy – Neurological Evaluation	0056: Diabetes: Foot Exam
	answers provided by users of the tool. During the design phase, functionality tests were conducted with ongoing abstractor recommendations being incorporated into the application. Once the design functionality was complete, an OSAT build was created and tested to ensure readiness for field use. Available in attached appendix at A.1 Attachment NQF_0417_codes-635284935772565257.xlsx	
Level	Clinician : Individual	Clinician : Group/Practice, Clinician : Individual
Setting	Ambulatory Care : Clinician Office/Clinic	Ambulatory Care : Clinician Office/Clinic
Numerator Statement	Patients who had a lower extremity neurological exam performed at least once within 12 months Definition: Lower Extremity Neurological Exam – Consists of a documented evaluation of motor and sensory abilities and should include: 10-g monofilament plus testing any one of the following: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold), however the clinician should perform all necessary tests to make the proper evaluation. Numerator Quality-Data Coding Options for Reporting Satisfactorily: Lower Extremity Neurological Exam Performed G8404: Lower extremity neurological exam performed and documented OR Lower Extremity Neurological Exam not Performed for Documented Reasons G8406: Clinician documented that patient was not an eligible candidate for lower extremity neurological exam measure OR Lower Extremity Neurological Exam not Performed G8405: Lower extremity neurological exam not performed	Patients who received a foot exam (visual inspection and sensory exam with monofilament and pulse exam) during the measurement period.
Numerator Details	GXXXX- Lower extremity neurological exam performed, GXXXX Lower Extremity Neurologcial Exam not Performed for Documented Reasons, OR GXXXX Lower Extremity Neurological Exam not	ADMINISTRATIVE CLAIMS: Due to the extensive volume of codes associated with identifying numerator events for this measure, we are attaching a separate file with code value sets. See code value

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	performed	sets located in question S.2b. MEDICAL RECORD: At a minimum, documentation in the medical record must include a note indicating the date when the exam was performed and the result. The patient is numerator compliant if a foot exam during the measurement year and result are documented. The patient is not numerator compliant if the result for the foot exam and result during the measurement year are missing. Ranges and thresholds do not meet criteria for this measure. A distinct numeric result is required for numerator compliance.
Denominator Statement	All patients aged 18 years and older with a diagnosis of diabetes mellitus	Patients 18-75 years of age by the end of the measurement year who had a diagnosis of diabetes (type 1 or type 2) during the measurement year or the year prior to the measurement year.
Denominator Details	Denominator Criteria (Eligible Cases): Patients aged = 18 years on date of encounter AND Diagnosis for diabetes (ICD-9-CM) [for use 1/1/2014-9/30/2014]: 250.00, 250.01, 250.02, 250.03, 250.10, 250.11, 250.12, 250.13, 250.20, 250.21, 250.22, 250.23, 250.30, 250.31, 250.32, 250.33, 250.40, 250.41, 250.42, 250.43, 250.50, 250.51, 250.52, 250.53, 250.60, 250.61, 250.62, 250.63, 250.70, 250.71, 250.72, 250.73, 250.80, 250.81, 250.82, 250.83, 250.90, 250.91, 250.92, 250.93 Diagnosis for diabetes (ICD-10-CM) [for use 10/01/2014-12/31/2014]: E10.10, E10.11, E10.21, E10.22, E10.29, E10.311, E10.319, E10.321, E10.329, E10.331, E10.339, E10.341, E10.349, E10.351, E10.359, E10.36, E10.39, E10.40, E10.41, E10.42, E10.43, E10.44, E10.49, E10.51, E10.52, E10.59, E10.610, E10.618, E10.620, E10.621, E10.622, E10.628, E10.630, E10.638, E10.641, E10.649, E10.65, E10.69, E10.8, E10.9, E11.00, E11.01, E11.21, E11.22, E11.29, E11.311, E11.319, E11.321, E11.329, E11.331,E11.339, E11.341, E11.349, E11.351, E11.359, E11.36, E11.39, E11.40, E11.41, E11.42, E11.43, E11.44, E11.49, E11.51, E11.52, E11.59, E11.610, E11.618, E11.620, E11.621, E11.622, E11.628, E11.630, E11.638, E11.641, E11.649, E11.65, E11.69, E11.8, E11.9, E13.00, E13.01, E13.10, E13.11, E13.21, E13.22, E13.29, E13.311, E13.319, E13.321, E13.329, E13.331, E13.339, E13.341, E13.349, E13.351, E13.359, E13.36,	PRESCRIPTIONS TO IDENTIFY PATIENTS WITH DIABETES Alpha-glucosidase inhibitors: Acarbose, Miglitol Amylin analogs: Pramlinitide Antidiabetic combinations: Glimepiride-pioglitazone, Glimepiride-rosiglitazone, Glipizide-metformin, Glyburide-metformin, Metformin-pioglitazone, Metformin-rosilitazone, Metformin-sitagliptin, Saxagliptin, Sitagliptin-simvastatin Insulin: Insulin aspart, Insulin aspart-insulin aspart protamine, Insulin detemir, Insulin glargine, Insulin glulisine, Insulin inhalation, Insulin isophane beef-pork, Insulin isophane human, Insulin isophane-insulin regular, Insulin lispro, Insulin lispro-insulin lispro protamine, Insulin regular human, Insulin zinc human Meglitinides: Nateglinide, Repaglinide Miscellaneous antidiabetic agents: Exenatide, Liraglutide, Metformin-repaglinide, Sitagliptin Sulfonylureas:

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	E13.39, E13.40, E13.41, E13.42, E13.43, E13.44, E13.49, E13.51, E13.52, E13.59, E13.610, E13.618, E13.620, E13.621, E13.622, E13.628, E13.630, E13.638, E13.641, E13.649, E13.65, E13.69, E13.8, E13.9 AND Patient encounter during the reporting period (CPT): 11042, 11043, 11044, 11055, 11056, 11057, 11719, 11720, 11721, 11730, 11740, 97001, 97002, 97597, 97598, 97802, 97803, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350	Acetohexamide, Chlorpropamide, Glimepiride, Glipizide, Glyburide, Tolazamide, Tolbutamide Thiazolidinediones: Pioglitazone, Rosiglitazone --- CODES TO IDENTIFY DIABETES ICD-9-CM Diagnosis: 250, 357.2, 362.0, 366.41, 648.0
Exclusions	Clinician documented that patient was not an eligible candidate for lower extremity neurological exam measure, for example patient bilateral amputee, patient has condition that would not allow them to accurately respond to a neurological exam (dementia, Alzheimer's, etc.), patient has previously documented diabetic peripheral neuropathy with loss of protective sensation.	-A diagnosis of gestational or steroid-induced diabetes
Exclusion Details	896.2 Amputation, foot, bilateral, partial or complete, traumatic, not complicated 896.3 Amputation, foot, bilateral, partial or complete, traumatic, complicated 897.0 Amputation, below knee, unilateral, traumatic, not complicated 897.1 Amputation, below knee, unilateral, traumatic, complicated 897.2	ADMINISTRATIVE CLAIMS CODES TO IDENTIFY EXCLUSIONS Steroid induced: 249, 251.8, 962.0 Gestational diabetes: 648.8 --- MEDICAL RECORD Exclusionary evidence in the medical record must include a note indicating a diagnosis of gestational or steroid-induced diabetes

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	Amputation, at or above knee, unilateral, traumatic, not complicated 897.3 Amputation, at or above knee, unilateral, traumatic, complicated 897.6 Amputation, bilateral, any level, traumatic, not complicated 897.7 Amputation, bilateral, any level, traumatic, complicated	
Risk Adjustment	No risk adjustment or risk stratification	No risk adjustment or risk stratification N/A
Stratification		N/A
Type Score	Ratio better quality = higher score	Rate/proportion better quality = higher score
Algorithm	A (# of patients meeting numerator criteria)/ PD (# of patients in denominator) – C (# of patients with valid denominator exclusions) Available in attached appendix at A.1	STEP 1. Determine the eligible population. To do so, identify patients who meet all the specified criteria. -AGES: 18-75 years as of December 31 of the reporting period. -EVENT/DIAGNOSIS: Identify patients who had a diagnosis of diabetes with a visit during the measurement period. Claim/Encounter Data: Codes to identify diabetes: -ICD-9-CM Diagnosis: 250.00, 250.01, 250.02, 250.03, 250.10, 250.11, 250.12, 250.13, 250.20, 250.21, 250.22, 250.23, 250.30, 250.31, 250.32, 250.33, 250.40, 250.41, 250.42, 250.43, 250.50, 250.51, 250.52, 250.53, 250.60, 250.61, 250.62, 250.63, 250.70, 250.71, 250.72, 250.73, 250.80, 250.81, 250.82, 250.83, 250.90, 250.91, 250.92, 250.93, 357.2, 362.01, 362.02, 362.03, 362.04, 362.05, 362.06, 362.07, 366.41, 648.00, 648.01, 648.02, 648.03, 648.04 -ICD-10-CM Diagnosis: E10.8, E10.9, E10.10, E10.11, E10.21, E10.22, E10.29, E10.311, E10.319, E10.321, E10.329, E10.331, E10.339,

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		E10.341, E10.349, E10.351, E10.359, E10.36, E10.39, E10.40, E10.41, E10.42, E10.43, E10.44, E10.49, E10.51, E10.52, E10.59, E10.610, E10.618, E10.620, E10.621, E10.622, E10.628, E10.630, E10.638, E10.641, E10.649, E10.65, E10.69, E11.00, E11.01, E11.21, E11.22, E11.29, E11.311, E11.319, E11.321, E11.329, E11.331, E11.339, E11.341, E11.349, E11.351, E11.359, E11.36, E11.39, E11.40, E11.41, E11.42, E11.43, E11.44, E11.49, E11.51, E11.52, E11.59, E11.65, E11.69, E11.610, E11.618, E11.620, E11.621, E11.622, E11.628 AND Patient encounter (CPT or HCPCS): 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99217, 99218, 99219, 99220, 99221, 99222, 99223, 99231, 99232, 99233, 99238, 99239, 99281, 99282, 99283, 99284, 99285, 99291, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99315, 99316, 99318, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, 99455, 99456, G0402, G0438, G0439 - STEP 2. Determine the number of patients in the eligible population who had a recent foot exam (visual inspection with a sensory exam and a pulse exam) exam during the measurement year through the search of administrative data systems. STEP 3. Identify patients with a most recent foot exam performed and the result. STEP 4. Identify the most recent foot exam with a result during the reporting period (numerator compliant). Identify the most recent result foot exam without a result or a missing foot exam (not numerator compliant). STEP 5. Exclude from the eligible population patients from step 2 for whom administrative system data identified an exclusion to the service/procedure being measured. *SEE DENOMINATOR EXCLUSION CRITERIA IN QUESTION S.10 STEP 6. Calculate the rate (number of patients that received a foot exam during the measurement year). No diagram provided

	0417: Diabetic Foot & Ankle Care, Peripheral Neuropathy – Neurological Evaluation	0056: Diabetes: Foot Exam
Submission items	5.1 Identified measures: 0056 : Diabetes: Foot Exam 5a.1 Are specs completely harmonized? No 5a.2 If not completely harmonized, identify difference, rationale, impact: Age range of 18-75 years in measure 0056 limits data collection and leaves an vulnerable population unaddressed. 5b.1 If competing, why superior or rationale for additive value: The most significant factor related to the development of a diabetic foot ulceration is the loss of protective sensation related to peripheral neuropathy. Visual inspection and vascular evaluation have shown little predictive value related to development of diabetic foot ulcerations. Measure 0056 only requires a sensory exam by monofilament, yet the ADA 2014 Standards of Care under Foot Exam specify the following: "For all patients with diabetes, perform an annual comprehensive foot examination to identify risk factors predictive of ulcers and amputations. The foot examination should include inspection, assessment of foot pulses, and testing for loss of protective sensation (LOPS) (10-g monofilament plus testing any one of the following: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold)." The above description for a neurological examination is exactly reflected in measure 0417. With the discrepancy in age and the difference in the exams required, measure 0417 should be maintained. Ideally, a composite measure that incorporates all components of an annual diabetic foot exam should be implemented. APMA is working on the development of such a measure and it is included as part of the USWR QCDR for 2014. This should help with testing of this composite measure as well as developing measure specifications. Until such a measure is	5.1 Identified measures: 0417 : Diabetic Foot & Ankle Care, Peripheral Neuropathy – Neurological Evaluation 5a.1 Are specs completely harmonized? No 5a.2 If not completely harmonized, identify difference, rationale, impact: Measure 0056 identifies adults with diabetes (age 18-75) that had a foot exam (visual inspection with sensory and pulse exam) during the reporting year. Measure 0417 identifies adults with diabetes (age 18 and older) who had a lower extremity neurological exam at least once during the measurement year. HARMONIZED ELEMENTS: Both measures are harmonized on the target population of diabetic adults and the measure focus of lower extremity exam. The denominator for each measure are harmonized to include all adult patients with a diagnosis of diabetes mellitus. The care setting is harmonized for measure 0056 and 0417 in at least one care setting (Ambulatory Care: Clinician Office/ Clinic). In addition, the data source (administrative claims) and level of analysis (clinicians: individual) are harmonized for both measures. UNHARMONIZED MEASURE ELEMENTS: Data Source: Measure 0056 is specified for paper medical records, administrative claims and electronic clinical data while measure 0417 is specified for administrative claims only. Measure 0056 is included in the CMS PQRS program and in NCQA's Diabetes Recognition Program (DRP) for physician reporting. IMPACT ON INTERPRETABILITY AND DATA COLLECTION BURDEN: Measure 0056 provide more options for reporting based on available data sources. Measure 0417 is specified for only administrative claims. 5b.1 If competing, why superior or rationale for additive value: 0056 has a long history of use and is implemented in two national programs (PRQS and DRP).

	0417: Diabetic Foot & Ankle Care, Peripheral Neuropathy – Neurological Evaluation	0056: Diabetes: Foot Exam
	approved, it would make sense to maintain both measure 0056 and 0417. Also, measure 0056 previously in PQRS was described as doing one of the three components to report (either visual inspection, sensory exam or pulse evaluation) so any data reported prior to 2014 would not necessarily include a neurological examination. The measure has changed for PQRS 2014 to now require all three elements, but prior to 2014 could be achieved with just visual inspection--a very low level requirement with questionable value.	