



**STEERING COMMITTEE MEETING FOR THE RENAL
ENDORSEMENT MAINTENANCE (EM) PROJECT**

August 16-17, 2011

Committee Members Present: Peter Crooks, MD (o-chair); Constance Anderson, BSN, MBA; Jeffrey Berns, MD; Andrew Fenves, MD; Michael Fischer, MD, MSPH; Jerry Jackson, MD; Frederick Kaskel, MD, PhD; Myra Kleinpeter, MD, MPH; Alan Kliger, MD; Lisa Latts, MD, MSPH, MBA; Kathe LeBeau; Stephen D. McMurray, MD; Joseph V. Nally, Jr., MD; Andrew Narva, MD (ex officio); Jessie Pavlinac, MS, RD, CSR, LD; Michael Somers, MD; Ruben Velez, MD; Roberta Wager, RN, MSN; Janet Welch, PhD, RN; Harvey Wells

Committee Members Present By Phone: Kristine Schonder, PharmD (co-chair) (day 1); Lorien Dalrymple, MD, MPH (day 1 and day 2)

NQF Staff Present: Helen Burstin, MD, MPH, Senior Vice President of Performance Measures; Heidi Bossley, Vice President of Performance Measures; Karen Pace, PhD, RN, Senior Program Director; Lauren Richie, MA, Project Manager; Tenee Davenport, Research Analyst; Sheila Crawford, Administrative Coordinator

Others Present:

(Day 1)

Ashfaq Akhtar, Amgen; Mureen Allen, ActiveHealth Management*; Katherine Ast, American Medical Association; Keri Christensen, American Medical Association; Barbara Fivush, American Society of Pediatric Nephrology; Edward Jones, Renal Physicians Association; Diedra Joseph, American Medical Association; Lisa McGonigal, Kidney Care Partners; Joseph Messana, Arbor Research; Robyn Nishimi, KCP/KCQA; Kathryn Schubert, American Society of Pediatric Nephrology; Robert Wolfe, Arbor Research

(Day 2)

Keri Christensen, American Medical Association; Edward Jones, Renal Physicians Association; Diedra Joseph, American Medical Association; Lisa McGonigal, Kidney Care Partners; Joseph Messana, Arbor Research; William Goodman, Amgen; Xia He, Duke Clinical Research Institute*; Tim Kresowik, Society for Vascular Surgery*; Robyn Nishimi, KCP/KCQA; Tom Nusbickel, Amgen; Jeffrey Pearson, CMS; Robert Wolfe, Arbor Research, Eleftherios Xenos, Society for Vascular Surgery*; Irina Yermilov, IMS Health

*Participated via teleconference

The full transcripts and audio recordings from the meeting can be found [here](#).

MEETING PROCESS



Dr. Crooks welcomed the Steering Committee members and thanked them for their continued participation. The Steering Committee members introduced themselves and stated any disclosures of interest. Dr. Crooks reviewed the purpose and agenda.

The purpose of the meeting was to:

- achieve the purpose and scope of the project;
- review and evaluate the 34 submitted measures according to NQF criteria to determine if they are suitable to recommend for endorsement as voluntary consensus standards;
- review related and competing measures to facilitate harmonization and select the best measure from among competing measures; and
- identify gaps in performance measures for renal care.

Dr. Pace and Ms. Richie provided background information on the National Quality Forum (NQF) and its Consensus Development Process (CDP) including an overview of the current Renal EM project, the role of the Steering Committee, NQF's Measure Evaluation Criteria, and the measure evaluation and electronic voting processes.

Every measure was evaluated prior to the meeting by a subgroup of five to six Committee members. Those preliminary evaluations were entered online and the results were compiled and provided to the Committee. All Committee members participated in the final evaluation and recommendations for all measures.

The [measures](#) were grouped into the following broad topic areas:

- anemia
- cardiovascular
- dialysis adequacy
- mineral metabolism
- mortality
- patient education
- quality of life
- vascular access

Each measure was introduced by a Committee member who was asked to briefly describe the measure and summarize the preliminary Committee evaluations with particular attention to areas of concern or differences in the ratings. This introduction was followed by discussion by the entire Committee. After discussion, the Committee voted on the rating for each of the major criteria and subcriteria (*Importance to Measure and Report, Scientific Acceptability of Measure Properties, Usability, and Feasibility*) and a preliminary recommendation for endorsement.

Measure developers provided a brief introduction of their group of measures by topic that were being reviewed that day. They were asked to address their rationale for the set of measures submitted for consideration, approach to measure development and testing, and any unique issues for specific measures. Measure developers also were asked to respond to the Committee's questions regarding specific measures as they were evaluated during the two-day meeting.



Comment periods occurred twice on each day for NQF members and the public to provide input to the Steering Committee. These comment periods also provided another opportunity for measure developers to address the Committee.

EVALUATION OF RENAL MEASURES

The Steering Committee evaluated 18 measures and identified the following six measures as suitable for endorsement (pending identification and review of any related and competing measures):

- **0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose**
- **0323 Hemodialysis Adequacy: Solute**
- **0369 Dialysis Facility Risk-Adjusted Standardized Mortality Ratio (32) Level**
- **1666 Patients on Erythropoiesis Stimulating Agent (ESA)--Hgb Level > or = 12g/dL**
- **1667(Pediatric) ESRD Patients Receiving Dialysis: Hgb Level < 10g/dL**
- **1668 Laboratory Testing (Lipid Profile)**

After review of related measures for harmonization issues, the Steering Committee may make its recommendations conditional on changes needed for measure harmonization. The Committee also will select the best measure from among competing measures.

OVERARCHING ISSUES

During the Steering Committee's discussion of the measures, several overarching issues emerged and were discussed. These issues factored into the Committee's ratings and recommendations for multiple measures and are not repeated in detail with each individual measure. This is one of the first projects implementing the 2010 task force recommendations regarding evaluating evidence and measure testing. The Steering Committee faced major challenges when measure submissions were incomplete or did not address the questions asked. NQF will continue to work with developers to increase understanding of what information is useful to Steering Committees.

Evidence

Measure developers were asked to submit more information on evidence to support process or structure measures. The goal is greater transparency in regards to the evidence that does or does not exist. The intent is not to have developers reviewing and grading evidence but to use existing systematic reviews and grading of evidence. In this early implementation, several issues were identified:

- not summarizing the quality and consistency of a body of evidence and instead making conclusions such as the evidence is strong without any substantive data, or describing individual studies included in the body of evidence;
- relying only a guideline recommendation without summarizing the quality and consistency of the body of evidence on which the guideline is based;
- providing a literature search instead of a systematic evidence review;

- not recognizing the difference between the focus of measurement and the topic of the body of evidence;
- indicating that the method of grading the evidence or recommendation was GRADE, when some modification was used without explaining the differences; and
- identifying a different system of grading the evidence or recommendation (which is acceptable), but not providing a description or definitions.

Measure Focus not Proximal to Desired Outcomes

Some measures have a focus that is fairly far removed from desired outcomes (e.g., assessment). This is essentially an issue about evidence. The evidence provided for such measures is not often directly about the specific focus of measurement and relies on expert opinion (e.g., frequency of assessing a lab value). In evaluating measures, it is important to distinguish between something that is important to do in clinical practice from something that should be measured and reported as a national voluntary consensus standard for assessing performance on quality. At the Consensus Standards Approval Committee (CSAC) July 13-14, 2011 meeting CSAC emphasized the guidance for processes closely linked by evidence to desired outcomes and voiced concern over the pediatric end-stage renal disease (ESRD) measures focused on frequency or method of assessment. For these types of measures, the Steering Committee needs to consider not only the directness of the evidence for the particular measure, but also the state of the science that exists to support a more proximal intermediate clinical outcome (e.g., Hgb <10) or a more proximal process measure for a specific treatment intervention (e.g., prescribe and ESA). For example, although there is good observational evidence that abnormal lab values in ESRD patients (e.g., Hgb, Ca, Ph, PTH) are associated with higher risk of mortality, there also are studies that demonstrate a higher risk of mortality related to some treatments to change lab values (e.g., ESA for anemia); or there are no studies that indicate changing a lab value to normal has any effect on mortality risk. The recent guidance on evidence directs that inconsistent evidence of benefit over harm to patients should result in not passing the evidence criterion, which would stop consideration for a national voluntary consensus standard. Expert opinion might be considered an exception to evidence but should be reserved for exceptional circumstance.

Measure Testing (Reliability and Validity)

The new guidance directs that Scientific Acceptability of Measure Properties is also a threshold criterion and measures must demonstrate adequate reliability and validity to pass the criterion. The validity rating includes validity testing as well as testing related to potential threats to validity such as risk adjustment, exclusions, etc. The items on the measure submission form for testing are essentially unchanged from the prior version. Some issues identified include:

- some measure developers seem to have difficulty identifying and conducting appropriate testing; or wish to rely on descriptive statistics and experience rather than empirical evidence as directed in the guidance;
- no rationale for method of testing provided;
- conducting testing that is not consistent with the measure as specified regarding data source or level of analysis);
- a reliance on face validity, which is the weakest approach (although currently accepted); and
- face validity not systematically assessed (or inadequate description).



NQF will continue work to clarify what is expected for measure testing.

MEASURES EVALUATIONS

Following are brief summaries of the evaluations of the 18 measures reviewed, along with the Steering Committee’s votes and rationale. Questions to and answers from the measure developers are also included, as well as follow-up questions to the Committee.

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Evaluation Summary—Candidate Consensus Standards

LEGEND: Y- ‘Yes’; N-‘No’; H – High; M – Moderate; L – Low; I – Insufficient evidence or information to evaluate

Anemia

<p>0252 Assessment of Iron Stores</p> <p>Description: Percentage of all adult (>=18 years old) hemodialysis or peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb <11.0 g/dL in at least one month of the study period for whom serum ferritin concentration AND either percent transferrin saturation or reticulocyte Hb content (CHR) are measured at least once in a three-month period for in-center hemodialysis patients, peritoneal dialysis patients, and home hemodialysis patients.</p> <p>Numerator Statement: Number of dialysis patients in the denominator for whom serum ferritin concentration AND either percent transferrin saturation or reticulocyte Hb content (CHR) are measured at least once in a three-month period for in-center hemodialysis patients, peritoneal dialysis patients, and home hemodialysis patients.</p> <p>Denominator Statement: All adult (>=18 years old) hemodialysis or peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb <11.0 g/dL in at least one month of the study period. The study period consists of 3 consecutive months for in-center hemodialysis patients, peritoneal dialysis patients and home hemodialysis. The hemoglobin value reported for the end of each study month (end-of-month Hb) is used for this calculation.</p> <p>Exclusions: Acute HD, transient dialysis patients (seen at the specific center for less than 30 days), and kidney transplant patients are excluded from the calculation this CPM.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification No risk adjustment necessary No stratification is required for this measure.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>Importance to Measure and Report (based on decision logic): No</p> <p>1a. Impact: H-5; M-14; L-2; I-0; 1b. Performance Gap: H-; M-5; L-16; I-0</p> <p>Rationale: 1b. Mean percentage of patients with assessment of iron stores is 97%, 1st quartile 97% and median 100%. The data by population group show essentially the same range by race/ethnicity *Black 94.0-94.9%; White 94.1-94.9%; Hispanic 93.6-94.8%). Although there was overall high performance with little variability, it was noted that validity testing showed that the two lowest quintiles of performance on this assessment of iron stores measure (94% and 98%) were associated with an 8% higher standardized mortality ratio. The Committee was asked if this measure should be evaluated further for potential reserve status. Consider Reserve Status: Y-10; N-11</p> <p>1c. Evidence (based on decision logic): Evidence Exception Y-16; N-5 IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-; M-13; L-6; I-2; Quality: H-; M-4; L-8; I-9; Consistency: H-; M-7; L-4; I-10</p> <p>Rationale: The focus of the measure - assessing iron stores in patients receiving ESAs at least every 3 months - is not proximal to the desired outcome and is indirectly supported by the evidence. The evidence presented supports the relationship between Hgb levels and mortality/morbidity and describe the impact of ESAs on Hgb levels and mortality/morbidity. The studies do not describe the impact of iron supplementation on mortality/morbidity or Hgb levels. Because the empirical evidence does not directly address the measure focus, the SC voted on whether to consider an exception to empirical evidence if the benefits greatly outweighed any potential harm to patients.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): 2a. Reliability: H-; M-; L-; I- 2b. Validity: H-; M-; L-; I- Rationale:</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p>
<p>3. Usability: H-; M-; L-; I- (Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</p>

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0252 Assessment of Iron Stores
Rationale:
4. Feasibility: H-; M-; L-; I- <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i> Rationale:
Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-; N-; A- <i>(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</i> Comments: If applicable, Questions for Committee: Given that there is no facility level measure of anemia (Hgb<10 for adult and pediatric were withdrawn) should this measure be reconsidered for recommendation for endorsement? If applicable, Conditions/Questions for Developer: Developer Response: Steering Committee Follow-up:
5. Related and Competing Measures <i>(5a. Harmonization; 5b. Superior to competing measures)</i> Comments:
Steering Committee Recommendation for Endorsement: Rationale:

<p>1660 ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL</p> <p>Description: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD who are receiving hemodialysis or peritoneal dialysis have a Hemoglobin level <10g/dL</p> <p>Numerator Statement: Calendar months during which patients have a Hemoglobin level <10g/dL*</p> <p>*The hemoglobin values used for this measure should be a most recent (last) hemoglobin value recorded for each calendar month</p> <p>Denominator Statement: All calendar months during which patients aged 18 years and older with a diagnosis of ESRD are receiving hemodialysis or peritoneal dialysis</p> <p>Exclusions: Documentation of medical reason(s) for patient having a Hemoglobin level <10g/dL (eg, patients who have non-renal etiologies of anemia [eg, sickle cell anemia or other hemoglobinopathies, multiple myeloma, primary bone marrow disease, anemia related to chemotherapy for diagnosis of malignancy], other medical reasons)</p> <p>Adjustment/Stratification: Other We account for risk adjustment by inclusion of the exceptions for this measure. Exceptions for this measure are listed above, in section 2a1.8. We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association - Physician Consortium for Performance Improvement</p>
<p>Importance to Measure and Report (based on decision logic): <u>No</u></p> <p>1a. Impact: H-12; M-9; L-; I-1; 1b. Performance Gap: H-6; M-8; L-; I-8</p> <p>Rationale: The submitter stated that in the PQRI 2008 data 36.51% of patients did not achieve "optimal care", but was not defined - does it mean that patients did not achieve the lower end of the target range or they exceeded the target range? The developer clarified that it meant did not achieve a Hgb of 10. Physician performance on the measure was variable with a median of 66.23%, 25th percentile of 38.17% and 75 percentile of 84.04%.</p> <p>1c. Evidence (based on decision logic): <u>No</u> IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-1; M-2; L-4; I-15; Quality: H-; M-3; L-3; I-15; Consistency: H-; M-3; L-1; I-17</p> <p>Rationale: The Steering Committee discussed that the current understanding of the accumulation of evidence is that there is insufficient evidence to set a definitive target. Additionally, there are significant and substantial risks of complications and mortality associated with use of ESAs in treating anemia. The recent 6/24/11 FDA announcement (http://www.fda.gov/cder/drug/infopage/RHE/default.htm) is not based on new evidence but the FDA is focused on minimizing harm. Given the current state of the science, a Hgb <10 is not always an indication of poor care. The data support that treatment with ESAs and higher Hgb levels are bad, but do not provide a clear indication about lower levels. The focus of anemia management in dialysis patients is individualization, which is nearly impossible to capture in a standardized performance measure. For example, individual factors such as trends of decline, responsiveness to ESAs, cardiovascular risk, and avoidance of allogeneic transfusions should be considered. Individualization of treatment also should include how the patient feels/functions at different levels of Hgb.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): 2a. Reliability: H-; M-; L-; I- 2b. Validity: H-; M-; L-; I- Rationale:</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p>
<p>3. Usability: H-; M-; L-; I- <i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i> Rationale:</p>
<p>4. Feasibility: H-; M-; L-; I- <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i> Rationale:</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: <u>Y-; N-; A-</u> (All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures) Comments: If applicable, Questions for Committee: See question under 1667. Why was a comparable pediatric measure passed? Not passed because not sufficient scientific data to support harm with Hgb<10 based on the FDA label changes. Need more RCT to provide a scientific basis for measure < 10. If applicable, Conditions/Questions for Developer:</p>

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1660 ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL
Developer Response: Steering Committee Follow-up:
5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures) Comments:
Steering Committee Recommendation for Endorsement: Rationale:

<p>1666 Patients on Erythropoiesis Stimulating Agent (ESA)--Hemoglobin Level > 12.0 g/dL</p> <p>Description: Percentage of calendar months within a 12-month period during which a Hemoglobin is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy and have a Hemoglobin Level > 12.0 g/dL</p> <p>Numerator Statement: Calendar months during which patients have a Hemoglobin level > 12.0 g/dL*</p> <p>*The hemoglobin values used for this measure should be a most recent (last) hemoglobin value recorded for each calendar month</p> <p>Denominator Statement: All calendar months during which a Hemoglobin is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy</p> <p>Definitions: RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification This measure is not risk adjusted. We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association - Physician Consortium for Performance Improvement</p> <p>Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: H-16; M-5; L-1; I-0; 1b. Performance Gap: H-7; M-12; L-0; I-3</p> <p>Rationale: 1b. The data on performance gap was only for ESRD patients, not CKD patients who also are included in the measure and the prior ESRD measure also include plan of care. The developer stated that 63.5 of patients did not receive "optimal care" per USRDS. However, "optimal care" was not defined - does this refer to number of patients meeting guideline target (Hgb 10-12) or number of patients with Hgb > 12 per measure specification? THE PQRI performance data indicated variability on the ESRD measure with a median performance of 66.23%; 25th percentile of 38.17%; and 75th percentile of 84.04%.</p> <p>1c. Evidence (based on decision logic): <u>Yes</u> IF a Health Outcome, rationale supports: NA Quantity: H-4; M-17; L-0; I-0; Quality: H-1; M-18; L-1; I-0; Consistency: H-2; M-16; L-2; I-0</p> <p>Rationale: The evidence is clear about harm with higher Hgb values when on ESAs. This should be considered a safety measure. There is a difference between lack of evidence at low end vs. a safety signal.</p> <p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>Yes</u> 2a. Reliability: H-4; M-9; L-5; I-3 2b. Validity: H-0; M-15; L-4; I-2</p> <p>Rationale: 2a1. Specifications - developer states could be implemented in one of 3 ways - medical record, CPTII codes on physician claims, or electronic health record. The Committee noted several problems with eSpecs and they were removed from consideration with the measure. 2a2. Although measure has been implemented in CMS PQRS program using CPTII codes, reliability of data elements was tested on a small sample of 4 group practices. 2b2. Submitted systematic assessment of face validity using the expert group who developed the measure. A committee member suggested that a measure of persistent high levels vs. single measurement would be a more valid indicator of poor care; however, the Committee did not recommend that change. The developer indicated that constructing the measure based on months rather than patients takes into account if a patient's Hgb is elevated for 1 out of 12 months vs. elevated for multiple months. That raised the question of whether the measure will obscure the signal for patients with chronic high levels.</p> <p>2c. Disparities: H-; M-; L-; I- Rationale: No disparities by race were identified.</p> <p>3. Usability: <u>H-2; M-13; L-3; I-2</u> (Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</p> <p>Rationale: Used in CMS physician reporting initiatives, however performance data for physicians are not publicly available. Developer indicates will be used in 2011 but only information about participation in reporting not performance results are planned.</p> <p>4. Feasibility: <u>H-1; M-10; L-8; I-2</u> (4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</p> <p>Rationale: CPTII codes seem to be currently feasible.</p> <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: <u>Y-15; N-6; A-0</u></p>

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1666 Patients on Erythropoiesis Stimulating Agent (ESA)--Hemoglobin Level > 12.0 g/dL
(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures) <u>Comments:</u> eSpecs not considered because incorrect - would need crosswalk to specifications before further consideration. Does the construction using months instead of patients obscure the signal for patients with chronic high levels? If applicable, Questions for Committee: If applicable, Conditions/Questions for Developer: eSpecs not considered because incorrect - would need crosswalk to specifications before further consideration. Does the construction using months instead of patients obscure the signal for patients with chronic high levels? Developer Response: Steering Committee Follow-up:
5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures) <u>Comments:</u>
Steering Committee Recommendation for Endorsement: Rationale:

<p>1667 (Pediatric) ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL</p> <p>Description: Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of ESRD receiving hemodialysis or peritoneal dialysis have a Hemoglobin level <10 g/dL</p> <p>Numerator Statement: Calendar months during which patients have a Hemoglobin level <10 g/dL*</p> <p>*The hemoglobin values used for this measure should be the most recent (last) hemoglobin value recorded for each calendar month</p> <p>Denominator Statement: All calendar months during which patients aged 17 years and younger with a diagnosis of ESRD are receiving hemodialysis or peritoneal dialysis</p> <p>Exclusions: Documentation of medical reason(s) for patient having a Hemoglobin level <10g/dL (eg, patients who have non-renal etiologies of anemia [eg, sickle cell anemia or other hemoglobinopathies, hypersplenism, primary bone marrow disease, anemia related to chemo])</p> <p>Adjustment/Stratification: Other We account for risk adjustment by inclusion of the exceptions for this measure. Exceptions for this measure are listed above, in section 2a1.8. We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association - Physician Consortium for Performance Improvement</p>
<p>Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: H-8; M-10; L-0; I-0; 1b. Performance Gap: H-0; M-9; L-0; I-11</p> <p>Rationale: 1b.Data presented was for adult measure; no data identified for pediatric patients. A Committee member noted that a prospective longitudinal cohort study identified that 40% of stage 2-4 CKD children are anemic. There should be some data in the literature that indicates performance gap and PCPI should submit.</p> <p>1c. Evidence (based on decision logic): <u>Yes</u> IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-1; M-17; L-1; I-1; Quality: H-0; M-11; L-7; I-0; Consistency: H-2; M-16; L-0; I-2</p> <p>Rationale: The developer submitted the same evidence for the pediatric measure as the adult measure and highlighted the pediatric studies. The developer noted that the adult targets are considered only opinion-based for children. The pediatric studies included a single RCT with 11 children; 2 observational studies with size not reported; and a nonrandomized interventional study of 18 children. The pediatric members of the Committee advocated for the greater importance of adequate Hgb on growing children and discussed two studies. A newer observational study of 700 children (Ameral, 2006) showed a 70% difference in mortality with HB <10 and >10 and differences in rates of hospitalizations. A prospective cohort study of 105 adolescents (Gerson, 2004) showed that anemia negatively impacts health-related QoL, physical development, cognitive development, and school. Smaller studies showed improvement in measures of cardiac health as Hgb increases. A Committee member noted the problems with the conclusions made about Hgb in adults from the retrospective observational studies and asked if that could be an issue with the pediatric studies. Don't think there is the same issue with high Hgb levels in children as in adult studies. The evidence demonstrated a substantial benefit of Hgb = >10 and there was no evidence of harm with ESAs in children as in the studies of adults that prompted the newest FDA safety announcement. The pediatric experts advocated that the benefits of treating anemia in children to Hgb =>10 greatly outweigh the potential harms of ESAs that may be used to treat anemia and the Steering Committee agreed.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>Yes</u> 2a. Reliability: H-1; M-13; L-4; I-2 2b. Validity: H-0; M-16; L-1; I-2</p> <p>Rationale: 2a1. Specifications - developer states could be implemented in one of 3 ways - medical record, CPT-II codes on physician claims, or electronic health record. The Committee noted several problems with eSpecs and they were removed from consideration with the measure. 2a2. Appears to be testing for the adult measure not the pediatric measure; however there is no reason to expect a difference in reliability. Although the adult measure has been implemented in CMS PQRS program using CPT-II codes, reliability of data elements was tested for chart abstraction on a sample of 4 group practices. 2b2. Submitted systematic assessment of face validity using the expert group who developed the measure. Exclusions give good examples, but have open statement of "other medical reasons", which can be interpreted with wide variety</p> <p>2c. Disparities: H-; M-12; L-1; I-7 Rationale: Race/ethnicity in eSpecs but not in specifications.</p>
<p>3. Usability: H-6; M-14; L-0; I-0</p> <p><i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale:</p>
<p>4. Feasibility: H-12; M-8; L-0; I-0</p>

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<p>1667 (Pediatric) ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL</p> <p><i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale:</p> <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-17; N-2; A-0 (All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</p> <p><u>Comments:</u> Please provide some data in the literature that indicates performance gap. eSpecs not considered because incorrect - would need crosswalk to specifications before further consideration.</p> <p>If applicable, Questions for Committee: <i>**Please note that the following question is about a standardized performance measure, NOT about the value of achieving an optimal Hgb value.</i></p> <p><i>What is the justification for passing this pediatric measure on evidence and not the adult measure for Hgb<10?</i></p> <p>Although there is no scientific data, the argument by the experts is that hgb<10 is significant in the pediatric patients. Measure passed based on expert opinions. Additionally, there is no evidence of harm for ESA use in children and the Committee agreed that the benefits outweigh potential harms to patients.</p> <p>If applicable, Conditions/Questions for Developer: Please provide some data in the literature that indicates performance gap. eSpecs not considered because incorrect - would need crosswalk to specifications before further consideration.</p> <p>Developer Response:</p> <p>Steering Committee Follow-up:</p>
<p>5. Related and Competing Measures <i>(5a. Harmonization; 5b. Superior to competing measures)</i></p> <p><u>Comments:</u></p>
<p>Steering Committee Recommendation for Endorsement:</p> <p>Rationale:</p>

Cardiovascular

<p>0626 Chronic Kidney Disease - Lipid Profile Monitoring</p> <p>Description: The percentage of patients with chronic kidney disease that have been screened for dyslipidemia with a lipid profile.</p> <p>Numerator Statement: Patients who had a lipid profile.</p> <p>Denominator Statement: All patients, males > 10 and females > 13 years of age, diagnosed with chronic kidney disease.</p> <p>Exclusions: DENOMINATOR EXCLUSIONS</p> <p>Specific Exclusions: None</p> <p>General exclusion: Patients with active cancer or metastatic diseases. Patients who were in a skilled nursing facility recently.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification No risk model applied to this measure. The results are not stratified.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Facility, Health Plan, Integrated Delivery System, Population : Community, Population : County or City, Population : National, Population : Regional, Population : State</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy, Electronic Clinical Data : Registry, Patient Reported Data/Survey</p> <p>Measure Steward: ActiveHealth Management</p>
<p>Importance to Measure and Report (based on decision logic): <u>No</u></p> <p>1a. Impact: H-3; M-12; L-4; I-2; 1b. Performance Gap: H-0; M-8; L-5; I-7</p> <p>Rationale: Lipids are a national health priority. No performance data on this previously endorsed measure even though indicated measure is in use. Performance gap data is for all adults but measure also includes children. A lot of heterogeneity in the measure - kids and adults, on/off dialysis, pre-existing CV disease - includes primary and secondary prevention - evidence varies. Performance gap depends on evidence of whether should be doing it.</p> <p>1c. Evidence (based on decision logic): <u>No</u> IF a Health Outcome, rationale supports: NA Quantity: H-1; M-9; L-8; I-3; Quality: H-0; M-7; L-6; I-7; Consistency: H-0; M-4; L-5; I-12</p> <p>Rationale: Assessing lipid levels is not proximal to desired outcome. Does lipid monitoring affect outcomes? Evidence from clinical practice guidelines. Observational study links CKD to hyperlipidemia, some small-volume studies that statins reduce microinflammation and may have beneficial effects in CKD. CKid study 690 children enrolled showing that over half have lipid abnormalities, now studying affect on outcomes. Two bodies of evidence with RCTs not mentioned: 1) 4D trial German diabetic dialysis patients and Aurora counterpart both statin/placebo trials - negative trials with no specific difference in ESRD population; 2) newest SHARP trial of 6000 CKD patients 3000 on dialysis PD and HD patients on lipid lowering therapy showed less CV events but no difference in renal outcomes. Would strengthen the evidence for a measure, not necessarily this one - perhaps a measure for use of lipid-lowering agents.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): 2a. Reliability: H-; M-; L-; I- 2b. Validity: H-; M-; L-; I-</p> <p>Rationale: Concern that CKD will be missed because of reliance on ICD or CPT codes, rather than low GFR. In registry majority are entered because of GFR rather than diagnosis by physician.</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p>
<p>3. Usability: H-; M-; L-; I- (Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</p> <p>Rationale:</p>
<p>4. Feasibility: H-; M-; L-; I- (4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</p> <p>Rationale:</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: <u>Y-; N-; A-</u> (All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</p> <p>Comments: If applicable, Questions for Committee: If applicable, Conditions/Questions for Developer: Developer Response: Steering Committee Follow-up:</p>
<p>5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures) Comments:</p>

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0626 Chronic Kidney Disease - Lipid Profile Monitoring

Steering Committee Recommendation for Endorsement:

Rationale:

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<p>0627 Chronic Kidney Disease with LDL Greater than or equal to 130 – Use of Lipid Lowering Agent</p> <p>Description: The percentage of patients with chronic kidney disease and an LDL greater than or equal to 130 mg/dl that have a current refill for a lipid lowering agent.</p> <p>Numerator Statement: Patients with a current refill for a lipid lowering agent.</p> <p>Denominator Statement: All patients, ages 18 and older, diagnosed with chronic kidney disease, including CKD stage 5, dialysis, or kidney transplant, and an LDL level above 130 mg/dL.</p> <p>Exclusions: Specific Exclusions: None General Exclusions:</p> <ul style="list-style-type: none"> • Evidence of metastatic disease or active treatment of malignancy (chemotherapy or radiation therapy) in the last 6 months • Patients who have been in a skilled nursing facility in the last 3 months • Patient or provider feedback indicating allergy or intolerance to the drug in the past • Patient or provider feedback indicating that there is a contraindication to adding the drug <p>Adjustment/Stratification: No risk adjustment or risk stratification No risk model applied to this measure. The results are not stratified.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Facility, Health Plan, Integrated Delivery System, Population : Community, Population : County or City, Population : National, Population : Regional, Population : State</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy, Patient Reported Data/Survey</p> <p>Measure Steward: ActiveHealth Management</p>
<p>Importance to Measure and Report (based on decision logic): No</p> <p>1a. Impact: H-3; M-14; L-3; I-0; 1b. Performance Gap: H-0; M-3; L-1; I-16</p> <p>Rationale: In response to a question about whether the target population is CKD 5 (dialysis and transplant), the developer clarified that the NOS codes are in conjunction with creatinine clearance so intended to limit to CKD stage 5. 1b. Performance gap data is for CKD stage 3-4 - less than half had LDL levels less than 100. No information on performance on this previously endorsed measure as specified, though developer stated it is in use. Developer stated that the performance gap is based on KDOQI guidelines. Developer stated it could supply data on performance if given the opportunity.</p> <p>1c. Evidence (based on decision logic): No IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-0; M-6; L-9; I-5; Quality: H-0; M-4; L-11; I-5; Consistency: H-0; M-3; L-10; I-7</p> <p>Rationale: Small number of dated studies cited with no RCT information as discussed under 0626. A SC member asked what was the achieved LDL in the SHARP study and another responded cholesterol 5.3 international units (about 230 with LDL about 120). NKF and KDOQI strongly supported measurement.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): 2a. Reliability: H-; M-; L-; I- 2b. Validity: H-; M-; L-; I-</p> <p>Rationale:</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p>
<p>3. Usability: H-; M-; L-; I-</p> <p><i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale:</p>
<p>4. Feasibility: H-; M-; L-; I-</p> <p><i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale:</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-; N-; A-</p> <p><i>(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</i></p> <p>Comments: What is the data on the performance gap for this measure as specified? Is there specific evidence supporting the effectiveness of lipid lowering drugs in CKD5?</p> <p>If applicable, Questions for Committee:</p> <p>If applicable, Conditions/Questions for Developer: What is the data on the performance gap for this measure as specified? Is there specific evidence supporting the effectiveness of lipid lowering drugs in CKD5?</p> <p>Developer Response:</p> <p>Steering Committee Follow-up:</p>
<p>5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)</p>

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0627 Chronic Kidney Disease with LDL Greater than or equal to 130 – Use of Lipid Lowering Agent
Comments:
Steering Committee Recommendation for Endorsement:
Rationale:

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<p>1668 Laboratory Testing (Lipid Profile)</p> <p>Description: Percentage of patients aged 18 years and older with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) who had a fasting lipid profile performed and results documented at least once within a 12-month period</p> <p>Numerator Statement: Patients who had a fasting lipid profile performed and results documented at least once within a 12-month period</p> <p>Denominator Statement: All patients aged 18 years and older with a diagnosis of CKD (stage 3, stage 4 or 5, not receiving RRT)</p> <p>Definition: RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation</p> <p>Exclusions: Documentation of patient reason(s) for not performing a fasting lipid profile (eg, patient declined, other patient reasons)</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification As a process measure, no risk adjustment is necessary. We encourage the results of this measure to be stratified by race, ethnicity, primary language, and gender, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association</p>
<p>Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: H-6; M-14; L-1; I-0; 1b. Performance Gap: H-5; M-13; L-0; I-1</p> <p>Rationale: Performance gap data for PQRI program median performance 46.7% and 56.6% of patients did not receive lipid profile.</p> <p>1c. Evidence (based on decision logic): <u>Yes</u> IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-13; M-6; L-; I-1; Quality: H-1; M-19; L-1; I-0; Consistency: H-0; M-16; L-4; I-1</p> <p>Rationale: Evidence from clinical practice guidelines. No data on final quantity of studies but started with 100s. Assessing lipid levels is not proximal to desired outcome. Does lipid monitoring affect outcomes? Primary reason is to reduce ACVD, which is unproven; affect on progression of CKD was speculative until SHARP trial which demonstrated no affect on renal outcomes. Inferring what's good for general pop may be good for CKD population. The SHARP trial directly addresses the question of benefit - 9000 patient study nondialysis avg GFR at baseline was 27 among 6,000 nondialysis patients - includes CKD3 - treating improves CV outcomes, which strengthens evidence that screening is worthwhile. SHARP only one so far that treatment improves CV mortality in dialysis patients; 4D and Aurora show improvement with CKD patients.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>Yes</u> 2a. Reliability: H-2; M-14; L-4; I-0 2b. Validity: H-1; M-13; L6-; I-1</p> <p>Rationale: Reliability testing in 4 nephrology practices only for chart abstraction. eSpecs include CPT-II or actual lab data for numerator but eSpecs need to be checked and cross walked. Face validity systematically assessed by expert group that developed measure. CD coding may miss large numbers of CKD patients cared for by non-nephrologists. Is that a function of the measure or the process? Developer considering adding 2 GFR results <60. Two papers have demonstrated that ICD-9 not sensitive to identify CKD therefore will under-report CKD. No upper age limit - is it necessary to do lipid testing in 85-90 year olds? NHANES arbitray cut-off of 85. No evidence either way. In the very old this as risk factor fades away because will die of something.</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p>
<p>3. Usability: H-2; M-16; L-2; I-0</p> <p><i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale: The measure using CPT-II codes is reported but physician performance data not publicly available. Stated will be used in 2011 physician reporting; no information on when publicly available.</p>
<p>4. Feasibility: H-; M-12; L-8; I-1</p> <p><i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale: If using medical record what if no note about review of result? The measure is not about review just that result is in the chart. Referring to "documentation" may be confusing.</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-18; N-3; A-</p> <p><i>(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</i></p> <p>Comments: Developer considering adding 2 GFR results <60. eSpecs include CPT-II or actual lab data but eSpecs need to be checked and crosswalked. No upper age limit - is it necessary to do lipid testing in 85-90 year olds? Referring to "documentation" may be confusing.</p> <p>If applicable, Questions for Committee: Performance gap data for patients with CKD based on a study showed that less than half had LDL levels less than 100, but no data on laboratory testing was provided and no data on performance of this endorsed measure. So no</p>

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1668 Laboratory Testing (Lipid Profile)
data on performance gap for the focus of this measure was provided.
If applicable, Conditions/Questions for Developer: Developer considering adding 2 GFR results <60. eSpecs include CPT-II or actual lab data but eSpecs need to be checked and crosswalked. No upper age limit - is it necessary to do lipid testing in 85-90 year olds? Referring to "documentation" may be confusing.
Developer Response:
Steering Committee Follow-up:
5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)
Comments:
Steering Committee Recommendation for Endorsement:
Rationale:

<p>1633 Blood Pressure Management</p> <p>Description: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) and albuminuria with a blood pressure <130/80 mmHg OR >= 130/80 mmHg with a documented plan of care</p> <p>Numerator Statement: Patient visits with blood pressure < 130/80 mmHg OR >= 130/80 mmHg with a documented plan of care*</p> <p>Definitions:</p> <p>Plan of Care: *A documented plan of care should include one or more of the following: recheck blood pressure within 90 days; initiate or alter pharmacologic therapy for blood pressure control; initiate or alter non-pharmacologic therapy (lifestyle changes) for blood pressure control; documented review of patient's home blood pressure log which indicates that patient's blood pressure is or is not well controlled</p> <p>Numerator Instructions: If multiple blood pressure measurements are taken at a single visit, use the most recent measurement taken at that visit.</p> <p>The PCPI recommends that this measure be reported as follows:</p> <p>% of patient visits meeting blood pressure < 130/80 mmHg (component 1)</p> <p>% of patient visits meeting blood pressure >= 130/80 mmHg with plan of care (component 2)</p> <p>% of patient visits meeting blood pressure < 130/80 mmHg AND patient visits meeting blood pressure >= 130/80 mmHg with plan of care (total measure score)</p> <p>Denominator Statement: All patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) and albuminuria</p> <p>Definitions:</p> <p>Albuminuria: >300mg of albumin in the urine per 24 hours</p> <p>RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT (Renal Replacement Therapy) includes hemodialysis, peritoneal dialysis, and kidney transplantation</p> <p>Exclusions: None</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification This measure is not risk adjusted. We encourage the results of this measure to be stratified by race, ethnicity, primary language, and gender, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association</p>
<p>Importance to Measure and Report (based on decision logic): No</p> <p>1a. Impact: H-20; M-1; L-0; I-0; 1b. Performance Gap: H-14; M-6; L-0; I-0</p> <p>Rationale: Hypertension is a high impact topic. Performance on this measure from PQRS data demonstrated median performance at 67.53%; 25th percentil 25.76%; and 75th percentile 92.54%. Data on differences in Bp control among races cited.</p> <p>1c. Evidence (based on decision logic): No IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-8; M-4; L-2; I-6; Quality: H-0; M-7; L-3; I-10; Consistency: H-0; M-7; L-6; I-8</p> <p>Rationale: No studies for this patient population, extrapolating from other populations. Proteinuria is a worse prognostic indicator, but studies with or without proteinuria not done. KDOQI review is 7-8 yrs old; KDIGO indicates not a high grade for evidence. JNC8 recommendations scheduled for release in November 2011. JNC using a different process and will be strictly evidence-based and it is likely will see different numbers.</p> <p>Encourage resubmission based on latest evidence reviews and recommendations after they are published.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): 2a. Reliability: H-; M-; L-; I- 2b. Validity: H-; M-; L-; I-</p> <p>Rationale:</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p>
<p>3. Usability: H-; M-; L-; I-</p> <p><i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale:</p>
<p>4. Feasibility: H-; M-; L-; I-</p> <p><i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale:</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-; N-; A-</p> <p><i>(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</i></p> <p>Comments:</p>

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1633 Blood Pressure Management
If applicable, Questions for Committee:
If applicable, Conditions/Questions for Developer:
Developer Response:
Steering Committee Follow-up:
5. Related and Competing Measures (<i>5a. Harmonization; 5b. Superior to competing measures</i>)
Comments:
Steering Committee Recommendation for Endorsement:
Rationale:

<p>1662 Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy</p> <p>Description: Percentage of patients aged 18 years and older with a diagnosis of CKD (not receiving RRT) and albuminuria (overt) who were prescribed ACE inhibitor or ARB therapy within a 12-month period</p> <p>Numerator Statement: Patients who were prescribed ACE inhibitor or ARB therapy within a 12-month period</p> <p>*The above list of medications/drug names is based on clinical guidelines and other evidence. The specified drugs were selected based on the strength of evidence for their clinical effectiveness. This list of selected drugs may not be all-inclusive or current. Physicians and other health care professionals should refer to the FDA's web site page entitled "Drug Safety Communications" for up-to-date drug recall and alert information when prescribing medications.</p> <p>Definitions: Prescribed – May include prescription given to the patient for ACE Inhibitor or ARB therapy OR patient already taking ACE Inhibitor or ARB therapy as documented in the current medication list</p> <p>Denominator Statement: All patients aged 18 years and older with the diagnosis of CKD (Stages 1-5, not receiving RRT) and albuminuria (overt)</p> <p>Definitions: Albuminuria: >300mg of albumin in the urine per 24 hours RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation</p> <p>Exclusions: Documentation of medical reason(s) for not prescribing ACE inhibitor or ARB therapy (eg, pregnancy, history of angioedema, cough due to ACE Inhibitor or ARB therapy, allergy to medications, other medical reasons) Documentation of patient reason(s) for no</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification As a process measure, no risk adjustment is necessary. We encourage the results of this measure to be stratified by race, ethnicity, primary language, and gender, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association</p>
<p>Importance to Measure and Report (based on decision logic): Yes</p> <p>1a. Impact: H-13; M-7; L-0; I-0; 1b. Performance Gap: H-2; M-14; L-2; I-2</p> <p>Rationale: Hypertension is a high impact topic. 1b State that among patients with CKD, use of ACEi/ARBs is 56-57% - but what about use among those with albuminuria/proteinuria (focus of measure)? Performance data on this measure from PQRS: median performance 62.5%; 25th percentile 33.3% and 75th percentile 100%. Disparity in care demonstrated for prevalence of hypertension, but not for use of ACEi/ARB.</p> <p>1c. Evidence (based on decision logic): Yes IF a Health Outcome, rationale supports: NA Quantity: H-1; M-19; L-0; I-1; Quality: H-1; M-18; L-1; I-1; Consistency: H-1; M-17; L-1; I-1</p> <p>Rationale: Although numerous studies have been completed there are still considerable discrepancies in the final outcomes of treatment in various cohorts with high blood pressure and albuminuria, with and without diabetes. Does not clarify quantity of studies examining ACEi/ARB use for CKD with albuminuria independent of blood pressure (measure does not require patients to be hypertensive). However, hard to find patients with no hypertension. Most studies in diabetes with hypertensive patients demonstrate benefit. One-quarter of diabetic patients did not have hypertension and had same benefit. Evidence strong for normotensive diabetics with >300 proteinuria. Most trials include hypertensive patients. What are data to support 300? Most benefit shown at 500. Overt albuminuria is a critical definition in this measure, but few patients may have a 24-hour urine for albuminuria - developer stated working on better definition for proteinuria (>300 in urine over 24 hr, albumin/creatinine ratio >300, protein/creatinine ratio >0.3).</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): No 2a. Reliability: H-0; M-7; L-11; I-3 2b. Validity: H-0; M-7; L-12; I-1</p> <p>Rationale: eSpecs have problems, so removed from consideration for now. Reliability testing in 4 practices for chart abstraction only. What was reliability and validity of exclusion data? Face validity systematically assessed by expert group who developed the measure. There was an 18% exception rate and it may be an issue when using electronic record. Some reasons identified for exceptions are actually reasons patient should be on ACE/ARB - demonstrates problem with lack of standardized defined exclusions that are then defined by each individual physician.</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p>
<p>3. Usability: H-; M-; L-; I- (Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</p>

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1662 Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy
Rationale:
4. Feasibility: H-; M-; L-; I- <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i> Rationale:
Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-; N-; A- <i>(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</i> Comments: If applicable, Questions for Committee: If applicable, Conditions/Questions for Developer: Developer Response: Steering Committee Follow-up:
5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures) Comments:
Steering Committee Recommendation for Endorsement: Rationale:

Dialysis Adequacy

<p>0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose</p> <p>Description: Percentage of all adult (≥ 18 years old) patients in the sample for analysis who have been on hemodialysis for 6 months or more and dialyzing thrice weekly whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a $\text{spKt/V} \geq 1.2$ during the study period.</p> <p>Numerator Statement: Number of patients in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a $\text{spKt/V} \geq 1.2$.</p> <p>Denominator Statement: All adult (≥ 18 years old) patients in the sample for analysis who have been on hemodialysis for 6 months or more and dialyzing thrice weekly.</p> <p>Exclusions: Patients on HD less than 6 months; HD patients dialyzing < 3 times per week or > 3 times per week.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. No stratification for this measure.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Outcome</p> <p>Data Source: Electronic Clinical Data</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: H-19; M-1; L-0; I-0; 1b. Performance Gap: H-1; M-19; L-1; I-0</p> <p>Rationale: CROWNWeb data 2010 shows better adherence to adequacy "standard" than before, but still shows an important performance gap. No disparities in performance were observed.</p> <p>1c. Evidence (based on decision logic): <u>Yes</u> IF a Health Outcome, rationale supports: <u>NA</u></p> <p>Quantity: H-17; M-4; L-0; I-0; Quality: H-6; M-15; L-0; I-0; Consistency: H-10; M-11; L-0; I-0</p> <p>Rationale: Evidence still supports better mortality in highest Kt/V group. There is a consistent correlation with mortality in observational retrospective studies. No RCTs other than HEMO which studied the target specified in this measure and a 16% higher dose, which did not demonstrate a survival advantage. DOPPS data not from an RCT but is prospective and provides evidence for 1.2 in spKt/V. Some DOPPS data on duration of dialysis indicates an independent affect on outcome. No substantial additional studies to address whether Kt/V is the best measure.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>Yes</u> 2a. Reliability: H-12; M-9; L-0; I-0 2b. Validity: H-2; M-19; L-0; I-0</p> <p>Rationale: The developer submitted additional testing information. Precision of the measure score was analyzed and for this measure the interunit reliability was 0.97.</p> <p>When using spKt/V rather than standard Kt/V can only compare if same frequency but there is an increasing # of patients on different frequencies who will not be included in the measure, so the Committee urges the developer to explore changing to standard Kt/V. A question was raised as to whether this measure should address persistent values vs. every month. The developer stated the numerator and denominator are in months but the specifications do not appear that way. Concern was expressed about the exclusion time of 6 mo and asked if the developer could provide some analysis about reducing to 3 mo. It was noted that there is facility variation on proportion of referred patients on a catheter which could differentially affect performance on this measure for a shorter time. Others suggested that would increase the incentive to not use catheters. Validity testing demonstrated that lower performance scores on dialysis adequacy were associated with higher standardized mortality ratio (especially for the 2 lowest quintiles of performance, not strictly linear). One way to potentially game this measure is to encourage patients to stay maximum time for last dialysis session of the month, which is used to calculate the spKt/V.</p> <p>2c. Disparities: H-; M-; L-; I- <u>Rationale:</u> No disparities in performance were observed.</p>
<p>3. Usability: <u>H-17; M-4; L-0; I-0</u></p> <p><i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale:</p>
<p>4. Feasibility: <u>H-21; M-0; L-0; I-0</u></p> <p><i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale: One way to potentially game this measure is to encourage patients to stay maximum time for last dialysis session of the month, which is used to calculate the spKt/V.</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: <u>Y-21; N-0; A-0</u></p> <p><i>(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</i></p> <p>Comments: The developer stated the numerator and denominator are in months but the specifications do not appear that way. Concern</p>

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0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose
was expressed about the exclusion time of 6 mo and asked if the developer could provide some analysis about reducing to 3 mo. If applicable, Questions for Committee: If applicable, Conditions/Questions for Developer: The developer stated the numerator and denominator are in months but the specifications do not appear that way. Concern was expressed about the exclusion time of 6 mo and asked if the developer could provide some analysis about reducing to 3 mo. Developer Response: Steering Committee Follow-up:
5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures) <u>Comments:</u>
Steering Committee Recommendation for Endorsement: Rationale:

<p>0250 ESRD- HD Adequacy CPM III: Minimum Delivered Hemodialysis Dose for ESRD hemodialysis patients undergoing dialytic treatment for a period of 90 days or greater.</p>
<p>Description: Percentage of all adult (≥ 18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly, and have a residual renal function (if measured in the last three months) less than 2 ml/min/1.73m², whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2 during the reporting period.</p> <p>Numerator Statement: Number of patients in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2.</p> <p>Denominator Statement: All adult (≥ 18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly and whose RRF is unmeasured or whose RRF < 2 ml/min/1.73m² (if measured in the last three months).</p> <p>Exclusions: Patients on HD less than 90 days. Patients with RRF > 2 ml/min/1.73m² (measured in the last three months). Patients not in thrice weekly dialysis.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>Importance to Measure and Report (based on decision logic):</p> <p>1a. Impact: H-; M-; L-; I-; 1b. Performance Gap: H-; M-; L-; I- Rationale:</p> <p>1c. Evidence (based on decision logic): IF a Health Outcome, rationale supports: NA Quantity: H-; M-; L-; I-; Quality: H-; M-; L-; I-; Consistency: H-; M-; L-; I- Rationale:</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): 2a. Reliability: H-; M-; L-; I- 2b. Validity: H-; M-; L-; I- Rationale:</p> <p>2c. Disparities: H-; M-; L-; I- Rationale: The measure is untested.</p>
<p>3. Usability: H-; M-; L-; I- (Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) Rationale:</p>
<p>4. Feasibility: H-; M-; L-; I- (4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented) Rationale:</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: No (All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures) Comments: The measure is untested and because another measure of dialysis adequacy (0249) is available, the Committee suggested that this measure not be considered. It recommended that CMS test the dialysis adequacy measure with the inclusion of residual renal function and submit a modified measure at the next opportunity for endorsement maintenance.</p> <p>If applicable, Questions for Committee:</p> <p>If applicable, Conditions/Questions for Developer:</p> <p>Developer Response:</p> <p>Steering Committee Follow-up:</p>
<p>5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures) Comments:</p>
<p>Steering Committee Recommendation for Endorsement: Rationale:</p>
<p>0323 Hemodialysis Adequacy: Solute</p>
<p>Description: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD receiving hemodialysis three times a week have a spKt/V ≥ 1.2</p> <p>Numerator Statement: Calendar months during which patients have a spKt/V ≥ 1.2</p> <p>Denominator Statement: All calendar months during which patients aged 18 years and older with a diagnosis of ESRD are receiving hemodialysis three times a week</p>

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<p>0250 ESRD- HD Adequacy CPM III: Minimum Delivered Hemodialysis Dose for ESRD hemodialysis patients undergoing dialytic treatment for a period of 90 days or greater.</p>
<p>Exclusions: Documentation of medical reason(s) for patient not having a spKt/V > or = 1.2 (eg, patient has residual kidney function, other medical reasons)</p> <p>Adjustment/Stratification: Other We account for risk adjustment by inclusion of the exceptions for this measure. Exceptions for this measure are listed above, in section 2a1.8. We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association - Physician Consortium for Performance Improvement</p>
<p>Importance to Measure and Report (based on decision logic): Yes</p> <p>1a. Impact: H-20; M-0; L-0; I-0; 1b. Performance Gap: H-4; M-17; L-0; I-0</p> <p>Rationale: 2008 PQRI data indicate 41% of patients did not achieve Kt/V of 1.2; physician performance at 25th percentile 29.77%, median at 60%, and 75th percentile at 79.29%. Disparities old data from the 90's.</p> <p>1c. Evidence (based on decision logic): Yes IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-17; M-4; L-0; I-0; Quality: H-5; M-16; L-0; I-0; Consistency: H-4; M-16; L-1; I-0</p> <p>Rationale: Observational studies show better outcomes with higher dialysis dose. Relatively few RCTs, and one major (HEMO) does not show evidence of improved outcomes with higher Kt/V urea. HEMO dose separation between test and control groups was only about 15% different.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): Yes 2a. Reliability: H-0; M-17; L-2; I-2 2b. Validity: H-0; M-18; L-1; I-2</p> <p>Rationale: Electronic specs removed from consideration due to inaccuracies until developer checks and crosswalks to specifications. Measure has been implemented using CPT-II codes but reliability testing conducted with inter-rate reliability for chart abstraction in 4 physician practices. Chart abstraction demonstrated good reliability. Prior measure included a plan of care component, which has been eliminated; but added a non-specific exclusion of "medical reason" that is determined by each physician being measured. No data was provided on this new exclusion. Face validity systematically assessed by group who developed the measure.</p> <p>2c. Disparities: H-; M-; L-; I- Rationale: Developer stated results can be stratified by race, gender, etc to examine potential disparities.</p>
<p>3. Usability: H-14; M-7; L-0; I-0</p> <p><i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale:</p>
<p>4. Feasibility: H-13; M-8; L-0; I-0</p> <p><i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale:</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-20; N-1; A-0</p> <p>(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</p> <p>Comments: eSpecs need to be checked and crosswalked to specifications. Please provide more up-to-date data on disparities.</p> <p>If applicable, Questions for Committee:</p> <p>If applicable, Conditions/Questions for Developer: eSpecs need to be checked and crosswalked to specifications. Please provide more up-to-date data on disparities.</p> <p>Developer Response:</p> <p>Steering Committee Follow-up:</p>
<p>5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)</p> <p>Comments:</p>
<p>Steering Committee Recommendation for Endorsement:</p> <p>Rationale:</p>

Mortality

<p>0369 Dialysis Facility Risk-adjusted Standardized Mortality Ratio (32) Level</p> <p>Description: Risk-adjusted standardized mortality ratio for dialysis facility patients.</p> <p>Numerator Statement: Number of deaths among eligible patients at the facility during the 4-year time period.</p> <p>Denominator Statement: Number of deaths that would be expected among eligible dialysis patients at the facility during the 4-year time period, given the mortality rate is at the national average and the patient mix at the facility.</p> <p>Exclusions: N/A</p> <p>Adjustment/Stratification: Statistical risk model Cox Model (Proportional Hazards Regression Model): The SMR calculation adjusts for patient age, sex, race, Hispanic ethnicity, diabetes as a cause of ESRD, nursing home status, duration of ESRD, BMI at incidence, and comorbidities at incidence, as well as N/A</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: H-21; M-0; L-0; I-0; 1b. Performance Gap: H-18; M-3; L-0; I-0</p> <p>Rationale:</p> <p>1c. Evidence (based on decision logic): <u>Yes</u> IF a Health Outcome, rationale supports: Y-21; N-0 Quantity: H-; M-; L-; I-; Quality: H-; M-; L-; I-; Consistency: H-; M-; L-; I-</p> <p>Rationale: Although structure-process-outcome relationships not identified in submission form, the Committee recognized that intermediate outcomes (e.g., dialysis adequacy, anemia) are linked to mortality and healthcare interventions affect those intermediate outcomes and ultimately mortality.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>Yes</u> 2a. Reliability: H-7; M-14; L-0; I-0 2b. Validity: H-5; M-16; L-0; I-0</p> <p>Rationale: Developer used correlation of scores across years as demonstrating reliability; however, that is not a test of reliability (reproducibility, repeatability) of data because it's a different population and different time period, or the precision of the measure score. For validity testing, the developer correlated scores on SMR with compliance to KDOQI guidelines related to URR and hematocrit, which demonstrated that facilities in the lowest quintile of performance on the KDOQI recommended targets had greater mortality. The risk-adjustment model includes race and ethnicity, which the NQF criteria suggest not be included in risk models because it tends to obscure disparities in care. Therefore, the developer was asked for justification of including race/ethnicity in the risk model. In the case of dialysis patients, black patients have a lower death rate than whites, which is not consistent with disparities in access and quality and lower survival of black CKD patients. A committee member asked if the difference by race was primarily due to age differences in dialysis patients by race. The developer noted that race interacts with age, but that a model including age but not race/ethnicity was not sufficient. The developer reported that the identification of patients who died had been validated in prior studies. The Committee agreed that race/ethnicity should be in the model.</p> <p>2c. Disparities: H-; M-; L-; I- Rationale: The measure takes into account race/ethnicity as discussed regarding the risk model. However, mortality rates are not reported separately by race.</p>
<p>3. Usability: H-15; M-6; L-0; I-0 (Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</p> <p>Rationale:</p>
<p>4. Feasibility: H-20; M-1; L-0; I-0 (4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</p> <p>Rationale:</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: <u>Y-21; N-0; A-0</u> (All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</p> <p>Comments:</p> <p>If applicable, Questions for Committee:</p> <p>If applicable, Conditions/Questions for Developer:</p> <p>Developer Response:</p> <p>Steering Committee Follow-up:</p>
<p>5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)</p> <p>Comments:</p>

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0369 Dialysis Facility Risk-adjusted Standardized Mortality Ratio (32) Level

Steering Committee Recommendation for Endorsement:

Rationale:

Mineral Metabolism

<p>1655 ESRD patients with PTH >400pg/mL and not treated with a calcimimetic or vitamin D analog.</p> <p>Description: Percentage of end stage renal disease (ESRD) patients aged 18 years and older with serum intact PTH levels >400pg/mL who are NOT treated with a calcimimetic agent or vitamin D analog to lower the PTH during the 3-month reporting period.</p> <p>Numerator Statement: Number of patients from the denominator with serum intact PTH >400pg/mL who are NOT being treated with a calcimimetic agent or vitamin D analog to lower the PTH.</p> <p>Denominator Statement: All hemodialysis and peritoneal dialysis patients aged 18 years and older at the dialysis facility for at least 30 days who have been on dialysis for greater than 90 days and who have not been discharged from the facility prior to the last day of the most recent month of the 3-month reporting period.</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. Not applicable.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory</p> <p>Measure Steward: Amgen Inc.</p>
<p>Importance to Measure and Report (based on decision logic): <u>No</u></p> <p>1a. Impact: H-8; M-12; L-1; I-0; 1b. Performance Gap: H-8; M-13; L-0; I-0</p> <p>Rationale: While CKDbone disease is a high impact problem, the focus of this measure may not be. Provided some evidence that patients with PTH>400 were not being treated with the two drugs (16% in LDO and 25% in DOPPS). A study by De Boer identified that race is a determinant of secondary hyperparathyroidism.</p> <p>1c. Evidence (based on decision logic): <u>No</u> IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-4; M-11; L-2; I-4; Quality: H-1; M-7; L-8; I-5; Consistency: H-0; M-9; L-6; I-6</p> <p>Rationale: There is some evidence of association between high PTH and poor outcomes but no evidence that altering the level affects outcomes. A systematic review and meta-analysis (Palmer) failed to demonstrate a strong or consistent relationship between high PTH and mortality; however, the submitters questioned the validity of the study. The measure implies that two drugs are the right intervention. There is evidence they will lower PTH but no evidence of improved outcomes. No RCTs to demonstrate that reducing PTH improves outcomes. In response to a question about whether a trial could be done, other Committee members said yes. KDIGO concluded that the guideline did not meet standard for performance measure. The measure also raises the question of whether a lab value from one point in time is valid when you need to check PTH multiple times to get stable value. Questions also were raised about what is appropriate threshold and why this should be considered a safety signal. The developer replied it's a safety issue because it's a progressive disease. The Committee noted that different assays provide different results. The developer said all assays are FDA approved and reliability is greater than discussed. In response to a question about evidence from bone biopsy to confirm bone disease, the developer stated that in a study, PTH above 500-600 had confirmed bone disease about half were treated w/VitD and some with calcimimetic. The submitter identified that the harm of treating high PTH with the specified drugs is adynamic bone disease, which is not the most predominant renal osteodystrophy.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): 2a. Reliability: H-; M-; L-; I- 2b. Validity: H-; M-; L-; I-</p> <p>Rationale:</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p>
<p>3. Usability: H-; M-; L-; I-</p> <p><i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale:</p>
<p>4. Feasibility: H-; M-; L-; I-</p> <p><i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale:</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: <u>Y-; N-; A-</u></p> <p><i>(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</i></p> <p>Comments:</p> <p>If applicable, Questions for Committee:</p> <p>If applicable, Conditions/Questions for Developer:</p> <p>Developer Response:</p> <p>Steering Committee Follow-up:</p>
<p>5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)</p>

NQF

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1655 ESRD patients with PTH >400pg/mL and not treated with a calcimimetic or vitamin D analog.
Comments:
Steering Committee Recommendation for Endorsement:
Rationale:

<p>1658 ESRD patients with PTH <130pg/mL and continued treatment with a calcimimetic or vitamin D analog.</p> <p>Description: Percentage of end stage renal disease (ESRD) patients aged 18 years and older with serum intact PTH levels <130pg/mL who continue to be treated with a calcimimetic agent or vitamin D analog during the 3-month reporting period.</p> <p>Numerator Statement: Number of patients from the denominator with serum intact PTH <130pg/mL who continue to be treated with a calcimimetic agent or vitamin D analog.</p> <p>Denominator Statement: All hemodialysis and peritoneal dialysis patients aged 18 years and older at the dialysis facility for at least 30 days who have been on dialysis for greater than 90 days and who have not been discharged from the facility prior to the last day of the most recent month of the 3-month reporting period.</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. Not applicable.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory</p> <p>Measure Steward: Amgen Inc.</p>
<p>Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: H-1; M-20; L-0; I-0; 1b. Performance Gap: H-4; M-15; L-1; I-0</p> <p>Rationale: Performance gap indicated many patients with PTH<130 continue to be treated with drugs. In response to a question about reduction vs. stopping, the developer stated these levels are very low so should be off the drugs. Disparity is more in the racial differences in PTH levels rather than testing and treatment</p> <p>1c. Evidence (based on decision logic): <u>Yes</u> IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-11; M-8; L-1; I-1; Quality: H-1; M-3; L-14; I-3; Consistency: H-2; M-10; L-4; I-0</p> <p>Rationale: Studies show association between low PTH and adynamic bone disease. No studies looked at outcomes when calcitriol or cinacalcet was stopped. Is it appropriate to use one value vs. trends? There is very little if any direct evidence related to any specific PTH level. especially given variability of different assays. KDIGO rating to stop vitamin D or calcimimetics is 'low'. Even though concerns about evidence, seen more as a safety monitoring issue when someone with very suppressed PTH is on VitD/calcimimetic.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>No</u> 2a. Reliability: H-1; M-3; L-16; I-1 2b. Validity: H-; M-3; L-6; I-12</p> <p>Rationale: The submission indicated the data would come from CROWNWeb and developer had initial conversation with CMS about modifying CROWNWeb to capture both VitD and calcimimetics. No reliability testing was performed. The developer stated that it was not necessary because it was electronic data. The Measure Testing guidance indicates that measures based on electronic record data identified and computed using computer programs will be repeatable/reproducible and that if validity testing of data elements is conducted, reliability of data elements does not need to be done. However, the developer did not conduct validity testing of the data elements. Although the developer referred to validity of data elements, it only compared population level estimates between the LDOs and DOPPS data so there is no information about the accuracy of the data elements used in the measure (PTH value, VitD/calcimimetic prescription). Other types of validity are acceptable, but then reliability testing would need to be conducted.</p> <p>Timing is a problem - looking at low PTH and meds in same time period. Could perhaps use low PTH level as index event and then look at prescriptions after that. Because of variability in assays, could consider cutoff of 2x upper limit of normal for that lab assay. Because of need for multiple test to have a stable value, could consider 2 suppressed values. Possible exclusion needed for parathyroidectomy or low VitD3.</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p>
<p>3. Usability: H-; M-; L-; I-</p> <p><i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale:</p>
<p>4. Feasibility: H-; M-; L-; I-</p> <p><i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale:</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: <u>Y-; N-; A-</u></p> <p><i>(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</i></p> <p>Comments:</p> <p>If applicable, Questions for Committee:</p> <p>If applicable, Conditions/Questions for Developer:</p> <p>Developer Response:</p> <p>Steering Committee Follow-up:</p>

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1658 ESRD patients with PTH <130pg/mL and continued treatment with a calcimimetic or vitamin D analog.
5. Related and Competing Measures (<i>5a. Harmonization; 5b. Superior to competing measures</i>) Comments:
Steering Committee Recommendation for Endorsement: Rationale:

Pt. Education/QoL

<p>0320 Patient Education Awareness—Physician Level</p> <p>Description: Percentage of end stage renal disease (ESRD) patients aged 18 years and older with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period.</p> <p>Numerator Statement: Number of patients from the denominator with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period.</p> <p>Denominator Statement: All ESRD patients aged 18 years and older receiving renal replacement therapy.</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. Not applicable.</p> <p>Level of Analysis: Clinician : Individual</p> <p>Type of Measure: Process</p> <p>Data Source: Electronic Clinical Data : Electronic Health Record, Paper Records</p> <p>Measure Steward: Kidney Care Quality Alliance</p>
<p>Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: H-; M-; L-; I-; 1b. Performance Gap: H-; M-; L-; I-</p> <p>Rationale: Although there are tremendous educational deficiencies among CKD and ESRD patients, it is not clear that this measure can address them. Data on impact is about pre-dialysis vs. this measure focused on dialysis patients. It was noted that it is good to repeat the education even after begin dialysis because patients forget or may be too overwhelmed when first given information. Limited data on performance from testing indicates no patients received testing on ALL modalities. Does the performance gap indicate lack of documentation vs. what education the patient reports received. In response to a question, it was clarified that education must be given every year and documented. Assessment of performance gap was before patient education on modalities became a condition of coverage. Big leap from giving information to understanding and effective decisionmaking.</p> <p>1c. Evidence (based on decision logic): <u>Yes</u> IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-; M-; L-; I-; Quality: H-; M-; L-; I-; Consistency: H-; M-; L-; I-</p> <p>Rationale: Some of the evidence referred to by the developer was obtained in pre-dialysis CKD patients and not in the ESRD population. The Right Start and Impact programs occur in first 90 days on dialysis so they are applicable to the population in this measure. The RightStart program involves multiple levels of intervention with education only one of several components. Thus, positive outcomes associated with the RightStart program cannot be attributed purely to the educational component. The developer also noted a new study on patient education on modality options (June 2011 AM J Kidney Disease). The Steering Committee decided to consider the measure further as an exception to evidence criterion.</p> <p>Exception to evidence: Y-18; N-3</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): 2a. Reliability: H-; M-; L-; I- 2b. Validity: H-; M-; L-; I-</p> <p>Rationale: Although the developer submitted that the data will be obtained through CROWNWeb, it was noted that CROWNWeb currently does not include patient education. The developer stated that it has had a conversation with CMS who expressed interest in including in CROWNWeb. Reliability testing was conducted in 4 physician practices - interabstractor reliability of data between two study abstractors was high (0.8474). Measure requires checkbox not quality or effectiveness of education.</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p>
<p>3. Usability: H-; M-; L-; I-</p> <p>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</p> <p>Rationale:</p>
<p>4. Feasibility: H-; M-; L-; I-</p> <p>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</p> <p>Rationale:</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: <u>Y-; N-; A-</u></p> <p>(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</p> <p>Comments:</p> <p>If applicable, Questions for Committee:</p> <p>If applicable, Conditions/Questions for Developer:</p>

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0320 Patient Education Awareness—Physician Level
Developer Response:
Steering Committee Follow-up:
5. Related and Competing Measures (<i>5a. Harmonization; 5b. Superior to competing measures</i>)
Comments:
Steering Committee Recommendation for Endorsement:
Rationale:

<p>0324 Patient Education Awareness—Facility Level</p> <p>Description: Percentage of a physician’s end stage renal disease (ESRD) patients aged 18 years and older with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period.</p> <p>Numerator Statement: Number of patients from the denominator with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period.</p> <p>Denominator Statement: All ESRD patients aged 18 years and older.</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. Not applicable.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Electronic Clinical Data : Electronic Health Record, Paper Records</p> <p>Measure Steward: Kidney Care Quality Alliance</p>
<p>Importance to Measure and Report (based on decision logic): Yes</p> <p>1a. Impact: H-11; M-9; L-1; I-0; 1b. Performance Gap: H-4; M-10; L-1; I-6</p> <p>Rationale: Although there are tremendous educational deficiencies among CKD and ESRD patients, it is not clear that this measure can address them. Data on impact is about pre-dialysis vs. this measure focused on dialysis patients. It was noted that it is good to repeat the education even after begin dialysis because patients forget or may be too overwhelmed when first given information. Limited data on performance from testing indicates no patients received testing on ALL modalities. Does the performance gap indicate lack of documentation vs. what education the patient reports received. In response to a question, it was clarified that education must be given every year and documented. Assessment of performance gap was before patient education on modalities became a condition of coverage. Big leap from giving information to understanding and effective decisionmaking.</p> <p>1c. Evidence (based on decision logic): Yes IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-; M-2; L-6; I-13; Quality: H-1; M-3; L-4; I-13; Consistency: H-; M-1; L-4; I-16</p> <p>Rationale: Some of the evidence referred to by the developer was obtained in pre-dialysis CKD patients and not in the ESRD population. The Right Start and Impact programs occur in first 90 days on dialysis so they are applicable to the population in this measure. The RightStart program involves multiple levels of intervention with education only one of several components. Thus, positive outcomes associated with the RightStart program cannot be attributed purely to the educational component. The developer also noted a new study on patient education on modality options (June 2011 AM J Kidney Disease). The Steering Committee decided to consider the measure further as an exception to evidence criterion.</p> <p>Exception to evidence: Y-18; N-3</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): 2a. Reliability: H-0; M-11; L-8; I-2 2b. Validity: H-; M-; L-; I-</p> <p>Rationale: Although the developer submitted that the data will be obtained through CROWNWeb, it was noted that CROWNWeb currently does not include patient education. The developer stated that has had a conversation with CMS who expressed interest in including in CROWNWeb. Reliability testing was conducted in facilities - interabstractor reliability of data between facility abstractor and study abstractor. The kappa for the measure score was reported as (-0.0026). More errors were missed information resulting in under-reporting. The kappa for the same measure in physician office testing with interabstractor reliability between two study abstractors was high (0.8474) indicating that the measure can be reliable and that the conditions of coverage will increase attention to documentation. Measure requires checkbox not quality or effectiveness of education. It's good that the measure stipulates that regardless of whether the facility offers the various modalities.</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p>
<p>3. Usability: H-; M-; L-; I-</p> <p>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</p> <p>Rationale:</p>
<p>4. Feasibility: H-; M-; L-; I-</p> <p>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</p> <p>Rationale:</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-; N-; A-</p> <p>(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</p> <p>Comments:</p>

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0324 Patient Education Awareness—Facility Level
If applicable, Questions for Committee:
If applicable, Conditions/Questions for Developer:
Developer Response:
Steering Committee Follow-up:
5. Related and Competing Measures (<i>5a. Harmonization; 5b. Superior to competing measures</i>)
Comments:
Steering Committee Recommendation for Endorsement:
Rationale:

<p>0260 Assessment of Health-related Quality of Life in Dialysis Patients</p> <p>Description: Percentage of dialysis patients who receive a health-related quality of life assessment using the KDQOL-36 (36-question survey that assesses patients' functioning and well-being) at least once per year.</p> <p>Numerator Statement: Number of patients who complete a KDQOL-36 with or without assistance at least once per year</p> <p>Denominator Statement: Number of eligible prevalent dialysis patients (peritoneal dialysis, in-center hemodialysis, home hemodialysis) in the facility during the year minus exclusions.</p> <p>Exclusions: < Age 18 Unable to complete due to cognitive impairment, dementia, or active psychosis Non-English speaking/reading (no native language translation or interpreter available) Patients under the facility's care for <3 months Patients who refuse to complete</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Patient Reported Data/Survey</p> <p>Measure Steward: RAND</p>
<p>Importance to Measure and Report (<i>based on decision logic</i>):</p> <p>1a. Impact: H-; M-; L-; I-; 1b. Performance Gap: H-; M-; L-; I- <u>Rationale:</u></p> <p>1c. Evidence (<i>based on decision logic</i>): IF a Health Outcome, rationale supports: NA Quantity: H-; M-; L-; I-; Quality: H-; M-; L-; I-; Consistency: H-; M-; L-; I- <u>Rationale:</u></p>
<p>2. Scientific Acceptability of Measure Properties (<i>based on decision logic</i>): 2a. Reliability: H-; M-; L-; I- 2b. Validity: H-; M-; L-; I- <u>Rationale:</u></p> <p>2c. Disparities: H-; M-; L-; I- <u>Rationale:</u></p>
<p>3. Usability: H-; M-; L-; I- (<i>Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement</i>) <u>Rationale:</u></p>
<p>4. Feasibility: H-; M-; L-; I- (4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented) <u>Rationale:</u></p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: No (All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures) <u>Comments:</u> No data on reliability and validity testing was provided. A Committee member identified that the process of administering the KDQoL is now a condition of coverage and facilities are also required to use the information for quality improvement. Therefore, a process performance measure is not a high priority. There is a need for research and development for an outcome measure using patient-reported outcome data such as form the KDQoL. If applicable, Questions for Committee: If applicable, Conditions/Questions for Developer: <u>Developer Response:</u> Steering Committee Follow-up:</p>
<p>5. Related and Competing Measures (<i>5a. Harmonization; 5b. Superior to competing measures</i>) <u>Comments:</u></p>
<p>Steering Committee Recommendation for Endorsement: <u>Rationale:</u></p>

Vascular Access

<p>0251 Vascular Access—Functional AVF or Evaluation by Vascular Surgeon for Placement</p> <p>Description: Percentage of end stage renal disease (ESRD) patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis >90 days who:</p> <p>(1) have an functional (defined as two needles used) autogenous arteriovenous fistula (AVF); or</p> <p>(2) do not have such a fistula but have been seen/evaluated by a vascular surgeon or other surgeon qualified in the area of vascular access for a functional autogenous AVF at least once during the 12-month reporting period.</p> <p>Numerator Statement: Number of patients from the denominator who:</p> <p>(1) Have a functional (defined as two needles used) autogenous AVF; or</p> <p>(2) Do not have such a fistula but have been seen/evaluated by a vascular surgeon or other surgeon qualified in the area of vascular access for a functional autogenous AVF at least once during the 12-month reporting period.</p> <p>Denominator Statement: All ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis for greater than 90 days.</p> <p>This measure includes both in-center and home hemodialysis patients.</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. Not applicable.</p> <p>Level of Analysis: Clinician : Individual</p> <p>Type of Measure: Outcome</p> <p>Data Source: Electronic Clinical Data : Electronic Health Record, Paper Records</p> <p>Measure Steward: Kidney Care Quality Alliance</p> <p>Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: H-20; M-0; L-0; I-0; 1b. Performance Gap: H-3; M-17; L-0; I-1</p> <p>Rationale: This is a physician-level measure; there is a separate facility-level CMS measure (0257). Data on performance gap is from data collected in testing (from facility and physician records) indicated a mean physician performance rate of 72%; no distribution reported. Should this be interpreted as a gap from 100%? In question about improvement, the developer stated that the measure was originally endorsed under time-limited status and this is the testing information completed in 2010.</p> <p>1c. Evidence (based on decision logic): <u>Yes</u> IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-0; M-20; L-0; I-0; Quality: H-0; M-19; L-2; I-0; Consistency: H-7; M-14; L-0; I-0</p> <p>Rationale: No RCTs. Evidence supports that fistula have lower rates of complications. Evidence not directly about evaluation by surgeon. Not a strong case that evaluation mandated in measure will affect outcomes.</p> <p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>No</u> 2a. Reliability: H-0; M-17; L-4; I-0 2b. Validity: H-0; M-8; L-13; I-0</p> <p>Rationale: Although specified for data from CROWNWeb, information on evaluation for AVF not currently in CROWNWeb. It was clarified there is no exclusion for hospice patients. Documentation - nephrologist, surgeon, staff note and if decide not to place an AVF reason must be documented. In response to the question of how "other qualified surgeon" is defined, the developer noted that in some rural areas may not have vascular surgeon and some other surgeon places AVF. The term "qualified" infers a judgment call that is hard to capture in measure. Not just surgeons - could be interventional nephrologist. Also there are different skill levels so a fistula from one surgeon may fail that another surgeon is able to place. Practices vary so may be better to just say "evaluated by vascular surgeon or other physician for an AVF." Definition of functioning fistula requires only one occurrence of 2 needles - is that sufficient? Tested using facility records and physician records - interrater reliability of data was high for the resulting score. For patients who have graft that's functioning well, that person would not need evaluation for fistula - could lead to overuse of yearly evaluation for approximately 15% of patients with functioning graft. What about patients who have been evaluated as not being a candidate for AVF? Representativeness of study sample isn't demonstration of validity of the data or the measure. Face validity was assumed because of prior endorsement, but no systematic assessment. The NQF measure testing TF did not consider that in its guidance. The developer stated the expert group who developed the measure is in the additional information section. Is evaluation every year warranted if patient has functioning graft? Developer stated it was amenable to redirecting to functional permanent access. What about when catheter is only option, e.g., congenital heart disease, behavior/cognitive problems don't tolerate 2 needles. An unintended consequence of fistula first was to ignore patient choice and stratification by need. In the FHN study, home patients use catheters and complications have not been as big a problem. Evaluation may indicate AVF not appropriate. For example vein mapping might be done before would refer to surgeon and could change whether even refer to surgeon. A Committee member suggested that all the potential exceptions identified will be minimal and may not need to be in the measure. Performance on the measure does not have to be 100% and if potential exclusions don't vary substantially across physicians then should not be an issue for comparing performance. Regarding patient choice/readiness,</p>

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<p>0251 Vascular Access—Functional AVF or Evaluation by Vascular Surgeon for Placement</p> <p>don't want to institutionalize a system to just let it go - need to bring up again.</p> <p>2c. Disparities: <u>H-</u>; <u>M-</u>; <u>L-</u>; <u>I-</u> <u>Rationale:</u></p> <p>3. Usability: <u>H-</u>; <u>M-</u>; <u>L-</u>; <u>I-</u> <i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i> <u>Rationale:</u></p> <p>4. Feasibility: <u>H-</u>; <u>M-</u>; <u>L-</u>; <u>I-</u> <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i> <u>Rationale:</u></p> <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: <u>Y-</u>; <u>N-</u>; <u>A-</u> (All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures) <u>Comments:</u> Ask the developer to consider: functioning grafts, potential exclusions hospice, elderly, patient choice, patient doesn't follow through. Definition of functioning fistula only requires one occurrence of 2 needles - is that sufficient? If applicable, Questions for Committee: If applicable, Conditions/Questions for Developer: Ask the developer to consider: functioning grafts, potential exclusions: hospice, elderly, patient choice, patient doesn't follow through. Definition of functioning fistula only requires one occurrence of 2 needles - is that sufficient? Developer Response: KCQA appreciates the opportunity to respond to the suggestions of the NQF Steering Committee in regards to Measure 0251: Vascular Access—Functional AVF or Evaluation by Vascular Surgeon for Placement. Our responses are as follows:</p> <ul style="list-style-type: none"> • Functioning Grafts: The KCQA Steering Committee agrees to incorporate functional arteriovenous grafts in the numerator statement to allow physicians to receive credit for patients with this safe and effective permanent access type. We note, however, that the measure was originally specified so as to align with <i>NQF 0257 Maximizing Placement of AVF (CMS)</i> and so have concern about harmonization issues if that measure is not similarly changed and seek NQF's guidance on how best to address this matter. • Hospice Exclusion: The KCQA Steering Committee agrees that this modification is reasonable and would bring the specifications into alignment with the other KCQA vascular access measure (<i>NQF 0262</i>), which <u>does</u> exclude hospice patients. However, KCQA agrees to adopt the exclusion only if the CMS AVF (<i>NQF 0257</i>) and catheter (<i>NQF 0256</i>) measures related to vascular access also incorporate this exclusion, so that all relevant NQF-endorsed measures are harmonized. If the CMS measures do not incorporate this exclusion, KCQA seeks NQF's guidance on how best to address the issue of measure harmonization. We note that only 2 of 1,057 patients were in hospice status during KCQA's testing. • Elderly Patient Exclusion: KCQA does not agree to incorporate an exclusion for elderly patients on the grounds that there is ample evidence indicating that AVFs and AV grafts are safe and effective vascular access options for the majority of patients of advanced age. KCQA believes that this exclusion would be a disincentive to ensuring that all eligible patients are appropriately evaluated for permanent access placement and thus compromise the quality of care provided to elderly ESRD patients. • Patient Choice and Patient Failure to Follow Up Exclusions: KCQA does not agree to incorporate an exclusion for patient choice or patient failure to follow up on the grounds that such exclusions would compromise the measure's intent to incentivize evaluation for permanent access (and concomitant education on the significant benefits of AVFs and AV grafts over catheters during that evaluation), and would make the measure susceptible to gaming. • Functional AVF Definition: The KCQA Steering Committee has concern that revising the definition of "functioning AVF" would compromise harmonization with the NQF-endorsed CMS AVF measure, which also defines functional AVFs in this manner. Moreover, we note that as currently specified, the KCQA measure <u>does not</u> require only one occurrence of two needles. Rather, the measure requires that all hemodialysis patients receive a vascular access status assessment on a yearly basis if they do not have a functioning AVF (and now AV graft). Thus if a previously functioning AVF is no longer functioning (i.e., two needles used), that patient must be evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional radiologist at least once during the 12-month reporting period for permanent access placement. <p>Physicians Eligible to Conduct Vascular Access Evaluation: Though not noted above, the NQF Steering Committee suggested during the meeting that KCQA refine the definition of what types of physicians are eligible to conduct the evaluation for permanent access placement. The current specifications read "vascular surgeon or other qualified surgeon." The NQF</p>
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0251 Vascular Access—Functional AVF or Evaluation by Vascular Surgeon for Placement
Committee noted that interventional radiologists would be excluded under the current construct. We acknowledge that interventional radiologists are qualified to perform this assessment and thus agree to amend the numerator statement to “evaluation by a vascular surgeon, other qualified surgeon, or interventional radiologist.”
Steering Committee Follow-up:
5. Related and Competing Measures (<i>5a. Harmonization; 5b. Superior to competing measures</i>)
Comments:
Steering Committee Recommendation for Endorsement:
Rationale:

<p>0259 Hemodialysis Vascular Access - Decision-making by Surgeon to Maximize Placement of Autogenous Arterial Venous Fistula</p> <p>Description: Percentage of patients with advanced chronic disease (CKD4 or 5) or end-stage renal disease (ESRD) undergoing open surgical implantation of permanent hemodialysis access who receive an autogenous arteriovenous fistula (AVF).</p> <p>Numerator Statement: CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented by surgeon to have received autogenous AV fistula</p> <p>OR</p> <p>Fistula not Performed for Medical Reasons</p> <p>OR</p> <p>Fistula not Performed for Patient Reasons.</p> <p>NOTE: This measure will be reported as the total of the three categories of numerators and also as the three numerators reported separately.</p> <p>Denominator Statement: Patients with CKD4, CKD5 or End-stage renal disease who undergo open surgical placement of permanent hemodialysis access</p> <p>ICD-9 585.3, 585.4, 585.5, 585.6 or 996.73</p> <p>AND</p> <p>CPT 36818, 36819, 36820, 36821, 36825, or 36830</p> <p>Exclusions:</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims</p> <p>Measure Steward: Society for Vascular Surgery</p>
<p>Importance to Measure and Report (<i>based on decision logic</i>): No</p> <p>1a. Impact: H-17; M-3; L-1; I-0; 1b. Performance Gap: H-0; M-0; L-2; I-18</p> <p>Rationale: Without data to review on this measure as specified it is not possible to know if there is a performance gap. If the surgeon excludes patients who aren't candidates for AVF as specified in the measure, then generally the result will be 100% unless the measure focuses on success rate of a functioning fistula (so it won't distinguish performance). Large prospective randomized study (JAMA 2008) shows 60% failure rate - fistulas were in but not usable. The developer thinks the exclusions are necessary to prevent a perverse incentive to place a fistula even if not an appropriate candidate. Developer said the PQRI data probably shows high performance but because that doesn't include all surgeons, it won't be definitive answer on performance gap. The SC agrees there is room for improvement in placing fistulas, but the concern is whether this metric will identify that gap.</p> <p>1c. Evidence (<i>based on decision logic</i>): IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-; M-; L-; I-; Quality: H-; M-; L-; I-; Consistency: H-; M-; L-; I-</p> <p>Rationale:</p>
<p>2. Scientific Acceptability of Measure Properties (<i>based on decision logic</i>): 2a. Reliability: H-; M-; L-; I- 2b. Validity: H-; M-; L-; I-</p> <p>Rationale:</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p>
<p>3. Usability: H-; M-; L-; I-</p> <p>(<i>Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement</i>)</p> <p>Rationale:</p>
<p>4. Feasibility: H-; M-; L-; I-</p> <p>(<i>4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented</i>)</p> <p>Rationale:</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: No</p> <p>(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</p> <p>Comments: What is the performance on this measure as specified?</p> <p>If applicable, Questions for Committee:</p> <p>If applicable, Conditions/Questions for Developer: What is the performance on this measure <u>as specified</u>?</p> <p>Developer Response:</p>

NQF

NATIONAL QUALITY FORUM

0259 Hemodialysis Vascular Access - Decision-making by Surgeon to Maximize Placement of Autogenous Arterial Venous Fistula
Steering Committee Follow-up:
5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)
Comments:
Steering Committee Recommendation for Endorsement:
Rationale:

NEXT STEPS

Conditions for recommendation and any additional questions will be sent to the measure developers for responses. The Steering Committee will review all its recommendations, measure developer responses, and harmonization and competing measures on a series of follow-up conference calls. The Committee will revote on measures with conditional recommendations and other measures as needed (e.g., competing measures, conditions related to harmonization, etc.). The Committee also will continue to discuss gaps in quality performance measures.