CBE ID

1662

Title

Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

Project

Advanced Illness and Post-Acute Care

Endorsement Status

Endorsed with Conditions

E&M Committee Rationale/Justification

- Evaluate why the measure is not widely used and develop implementation guidance to support use of the measure.
- Conduct empirical validity testing at the entity level for both reliability and validity.

Is Under Review

No

Next Maintenance Cycle

Fall 2028

Previous Endorsement Cycle

Fall 2023

Initial Endorsement

Tue, 09/01/2015 - 00:00

Steward

Renal Physicians Association

1.0 New or Maintenance

Maintenance

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.

This measure is NQF Measure 1662/MIPS Measure 489.

1.7 Composite Measure

No

1.7 Measure Type

Process

1.8 Level of Analysis

Clinician: Individual

1.9 Care Setting

Clinician Office/Clinic

1.10 Measure Rationale

This measure is aimed at increasing the number of patients with CKD and proteinuria who are prescribed ACE inhibitor or ARB therapy. ACE inhibitors and ARBs are preferred agents for diabetic kidney disease and nondiabetic kidney diseases with proteinuria (albuminuria), even in the absence of hypertension. In these diseases, ACE inhibitors and ARBs lower blood pressure, reduce proteinuria (albuminuria), slow the progression of kidney disease, and likely reduce cardiovascular disease risk by mechanisms in addition to lowering blood pressure. These benefits have been shown across high quality, multi-center, randomized controlled trials such as RENAAL (Reduction of Endpoints in NIDDM with the Angiotensin II Antagonist Losartan) (Brenner et al., New England Journal of Medicine, 2001). A meta-analysis of randomized trials showed that ACEi/ARB therapy lowered the odds of kidney failure (also known as end-stage renal disease [ESRD]) by 30-39 percent and of cardiovascular disease events by 18 percent-24 percent (Xie et al., Am J Kidney Dis, 2016). In a meta-analysis including primarily diabetic patients with proteinuria, use of ACEi/ARB therapy had a 0.36 to 0.78 odds of incident kidney failure (Cai et al., Nephrology, dialysis, transplantation, 2018). Similarly, in a Cochrane meta-analysis, patients with early (stage 1 to 3) non-diabetic CKD who were treated versus not treated with ACEi/ARB had 31 percent lower risk of kidney failure (Jafar et al., Annals of internal medicine, 2001). Based upon this robust evidence, ACE inhibitors and ARBs are recommended for patients with CKD and proteinuria by the Kidney Disease: Improving Global Outcomes (KDIGO) international guidelines and the Kidney Disease Outcomes Quality Initiative.

CKD is a major public health problem; a total of 37 million Americans have CKD. There is a clear performance gap in ACE inhibitor and ARB usage among patients with CKD, with only 40 percent of CKD patients receiving an ACEi/ARB in NHANES data (Murphy et al., JASN, 2019). Population health efforts to increase the use of ACEi/ARB in American Indians and Alaska Natives have been associated with a decrease in incident kidney failure related to diabetic kidney disease (Bullock et al., MMWR Morbidity and mortality weekly report, 2017). In summary, this measure is a central component of high-quality nephrology care, as ACE inhibitors and ARBs decrease the rate of kidney failure, cardiovascular outcomes, and mortality in patients with CKD and proteinuria.

References:

Brenner BM, Cooper ME, de Zeeuw D, Keane WF, Mitch WE, Parving HH, Remuzzi G, Snapinn SM, Zhang Z, Shahinfar S, et al. Effects of losartan on renal and cardiovascular outcomes in patients with type 2 diabetes and nephropathy. N Engl J Med. 2001;345(12):861–9.

Xie X, Liu Y, Perkovic V, Li X, Ninomiya T, Hou W, Zhao N, Liu L, Lv J, Zhang H, Wang H. Renin-Angiotensin System Inhibitors and Kidney and Cardiovascular Outcomes in Patients With CKD: A Bayesian Network Meta-analysis of Randomized Clinical Trials. Am J Kidney Dis. 2016 May;67(5):728-41. doi: 10.1053/j.ajkd.2015.10.011. Epub 2015 Nov 18. PMID: 26597926.

Cai J, Huang X, Zheng Z, Lin Q, Peng M, Shen D. Comparative efficacy of individual renin–angiotensin system inhibitors on major renal outcomes in diabetic kidney disease: a network meta-analysis. Nephrol Dial Transplant. 2018; 33(11):1968–1976. doi: 10.1093/ndt/gfy001

Jafar TH, Schmid CH, Landa M, et al. Angiotensin-Converting Enzyme Inhibitors and Progression of Nondiabetic Renal Disease: A Meta-Analysis of Patient-Level Data. Ann Intern Med. 2001;135:73-87. [Epub 17 July 2001]. doi:10.7326/0003-4819-135-2-200107170-00007

Murphy DP, Drawz PE, Foley RN. Trends in Angiotensin-Converting Enzyme Inhibitor and Angiotensin II Receptor Blocker Use among Those with Impaired Kidney Function in the United States. J Am Soc Nephrol. 2019 Jul;30(7):1314-1321. doi: 10.1681/ASN.2018100971.

Bullock A, Burrows NR, Narva AS, et al. Vital Signs: Decrease in Incidence of Diabetes-Related End-Stage Renal Disease among American Indians/Alaska Natives — United States, 1996–2013. MMWR Morb Mortal Wkly Rep 2017;66:26-32. DOI: 10.15585/mmwr.mm6601e1.

1.11 Measure Webpage

https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2023_M...

1.13 Data Dictionary

Not attached. I attest that all information will be provided where codes and/or value sets are needed (1.14a - 1.15c).

1.14 Numerator

Patients who were prescribed ACE inhibitor or ARB therapy within a 12-month period. Definition: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.

1.14a Numerator Details

Patients who were prescribed ACE inhibitor or ARB therapy within a 12-month period

Definition:
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.

Numerator Options:
Performance Met: ACE Inhibitor (ACE-I) or ARB therapy prescribed during the measurement period (M1200)
OR
Denominator Exception: Documentation of medical reason(s) for not prescribing ACE inhibitor (ACE-I) or ARB therapy during the measurement period (e.g., pregnancy, history of angioedema to ACE-I, other allergy to ACE-I and ARB, hyperkalemia or history of hyperkalemia while on ACE-I or ARB therapy, acute kidney injury due to ACE-I or ARB therapy, other medical reasons.) (M1201)
OR
Denominator Exception: Documentation of patient reason(s) for not prescribing ACE inhibitor or ARB therapy during the measurement period (e.g., patient declined, other patient reasons). (M1202)
OR
Performance Not Met:
ACE inhibitor or ARB therapy not prescribed during the measurement period, reason not given. (M1203)

1.15 Denominator

All patients aged 18 years and older with the diagnosis of CKD (Stages 1-5, not receiving RRT) and proteinuria. Definitions:Proteinuria: 1. >300mg of albumin in the urine per 24 hours OR 2. Urine albumin-to-creatinine ratio (ACR) >300 mg/g OR 3. Urine protein-to-creatinine ratio (PCR) > 0.3 g/g Renal Replacement Therapy (RRT) – For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation.

1.15a Denominator Details

All patients aged 18 years and older with the diagnosis of CKD (CKD Stages 1-5, not receiving RRT) and proteinuria.

Definitions:

Proteinuria:
1. >300mg of albumin in the urine per 24 hours OR
2. Urine albumin-to-creatinine ratio (ACR) >300 mg/g OR
3. Urine protein-to-creatinine ratio (PCR) > 0.3 g/g

Renal Replacement Therapy (RRT) – For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation.

Patients receiving RRT –
The following codes would be sufficient to define the Denominator Exclusion (M1199) of receiving RRT: 90951, 90952, 90953, 90954, 90955, 90956, 90957, 90958, 90959, 90960, 90961, 90962, 90963, 90964, 90965, 90966, 90967, 90968, 90969, 90970, I70.1, N18.6, Z49.31, Z49.32, Z99.2

Denominator Criteria (Eligible Cases):
All patients aged 18 years and older on the date of the encounter.

AND
Diagnosis of CKD (Stages 1-5) (ICD-10-CM): E11.22, N18.1, N18.2, N18.30, N18.31, N18.32, N18.4, N18.5, N18.9
AND
Diagnosis of Proteinuria (ICD-10-CM): R80.1, R80.8, R80.9
AND
Patient encounter during the performance period (CPT): 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350
AND NOT

DENOMINATOR EXCLUSION:
Patients receiving RRT: M1199

1.15b Denominator Exclusions

Patients receiving RRT: M1199.

The following codes would be sufficient to define the Denominator Exclusion (M1199) of receiving RRT: 90951, 90952, 90953, 90954, 90955, 90956, 90957, 90958, 90959, 90960, 90961, 90962, 90963, 90964, 90965, 90966, 90967, 90968, 90969, 90970, I70.1, N18.6, Z49.31, Z49.32, Z99.2.

1.15c Denominator Exclusions Details

The following codes would be sufficient to define the Denominator Exclusion (M1199) of receiving RRT: 90951, 90952, 90953, 90954, 90955, 90956, 90957, 90958, 90959, 90960, 90961, 90962, 90963, 90964, 90965, 90966, 90967, 90968, 90969, 90970, I70.1, N18.6, Z49.31, Z49.32, Z99.2.

1.16 Type of Score

Rate/proportion

1.17 Measure Score Interpretation

Better performance = Higher score

1.18 Calculation of Measure Score

1. Start with Denominator.
2. Check All patients aged 18 years and older on the date of the encounter:
   a. If All patients aged 18 years and older on the date of the encounter equals No, do not include in Eligible Population/Denominator. Stop processing.
   b. If All patients aged 18 years and older on the date of encounter equals Yes, proceed to check Diagnosis of CKD (Stages 1-5) as listed in Denominator.
3. Check Diagnosis of CKD (Stages 1-5) as listed in Denominator:
   a. If Diagnosis of CKD (Stages 1-5) as listed in Denominator equals No, do not include in Eligible Population/Denominator. Stop processing.
   b. If Diagnosis of CKD (Stages 1-5) as listed in Denominator equals Yes, proceed to check Diagnosis of Proteinuria.

4. Check Diagnosis of Proteinuria:
   a. If Diagnosis of Proteinuria equals No, do not include in Eligible Population/Denominator. Stop processing.
   b. If Diagnosis of Proteinuria equals Yes, proceed to check Patient encounter during the performance period as listed in Denominator.

5. Check Patient encounter during the performance period as listed in Denominator:
   a. If Patient encounter during the performance period as listed in Denominator equals No, do not include in Eligible Population/Denominator. Stop processing.
   b. If Patient encounter during the performance period as listed in Denominator equals Yes, proceed to check Patients receiving RRT.

6. Check Patients receiving RRT:
   a. If Patients receiving RRT equals Yes, do not include in Eligible Population/Denominator. Stop processing.
   b. If Patients receiving RRT equals No, include in Eligible Population/Denominator.

7. Denominator Population: Denominator Population is all Eligible Patients in the Denominator. Denominator is represented as Denominator in the Sample Calculation (attached). Letter d equals 80 patients in the Sample Calculation.

8. Start Numerator

9. Check ACE Inhibitor (ACE-I) or ARB therapy prescribed during the measurement period:
   a. If ACE Inhibitor (ACE-I) or ARB therapy prescribed during the measurement period equals Yes, include in Data Completeness Met and Performance Met. Data Completeness Met and Performance Met letter is represented as Data Completeness and Performance Rate in the Sample Calculation (attached). Letter a equals 40 patients in the Sample

Calculation.
b. If ACE Inhibitor (ACE-I) or ARB therapy prescribed during the measurement period equals No, proceed to check Documentation of medical reason(s) for not prescribing ACE inhibitor (ACE-I) or ARB therapy during the measurement period.
10. Check Documentation of medical reason(s) for not prescribing ACE inhibitor (ACE-I) or ARB therapy during the measurement period:
a. If Documentation of medical reason(s) for not prescribing ACE inhibitor (ACE-I) or ARB therapy during the measurement period equals Yes, include in Data Completeness Met and Denominator Exception. Data Completeness Met and Denominator Exception letter is represented as Data Completeness and Performance Rate in the Sample Calculation l. Letter b1 equals 10 patients in the Sample Calculation.

b. If Documentation of medical reason(s) for not prescribing ACE inhibitor (ACE-I) or ARB therapy during the measurement period equals No, proceed to check Documentation of patient reason(s) for not prescribing ACE inhibitor or ARB therapy during the measurement period.

11. Check Documentation of patient reason(s) for not prescribing ACE inhibitor or ARB therapy during the measurement period:

a. If Documentation of patient reason(s) for not prescribing ACE inhibitor or ARB therapy during the measurement period equals Yes, include in Data Completeness Met and Denominator Exception. Data Completeness Met and Denominator Exception letter is represented as Data Completeness and Performance Rate in the Sample Calculation. Letter b2 equals 0 patients in the Sample Calculation.
b. If Documentation of patient reason(s) for not prescribing ACE inhibitor or ARB therapy during the measurement period equals No, proceed to check ACE inhibitor or ARB therapy not prescribed during the measurement period, reason not given.

12. Check ACE inhibitor or ARB therapy not prescribed during the measurement period, reason not given:
a. If ACE inhibitor or ARB therapy not prescribed during the measurement period, reason not given equals Yes, include in Data Completeness Not Met and Performance Not Met. Data Completeness Met and Performance Not Met letter is represented as Data Completeness in the Sample Calculation listed at the end of this document. Letter c equals 20 patients in the Sample Calculation.

b. If ACE inhibitor or ARB therapy not prescribed during the measurement period, reason not given equals No, proceed to check Data Completeness Not Met.

13. Check Data Completeness Not Met: If Data Completeness Not Met, the Quality Data Code or equivalent was not submitted. 10 patients have been subtracted from the Data Completeness Numerator in the Sample Calculation.

Sample Calculations

- Data Completeness equals Performance Met (a equals 40 patients) plus Denominator Exception (b1 + b2 = 10 patients) plus Performance Not Met (c equals 20 patients) divided by Eligible Population / Denominator (d equals 80 patients). All equals 70 patients divided by 80 patients. All equals 87.50 percent.
- Performance Rate equals Performance Met (a equals 40 patients) divided by Data Completeness Numerator (70 patients) minus Denominator Exception (b1 + b2 = 10 patients). All equals 40 patients divided by 60 patients. All equals 66.67 percent.

1.18a Attach measure score calculation diagram

Adult Kidney Disease_ Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy diagram.pdf

1.19 Measure Stratification Details

This measure is not stratified.

1.20 Types of Data Sources

Claims Data, Electronic Health Records

1.25 Data Source Details

Data is contained in patient chart; no specialized collection instrument is needed. Entity will review CPT codes, ICD-10 codes and lab values to calculate the measure.

1.26 Minimum Sample Size

The CMS MIPS program requires performance data for at least 70% of the denominator eligible cases for each quality measure in order to achieve data completeness.

2.1 Attach Logic Model

ACEi ARB measure logic model_0.docx

2.2 Evidence of Measure Importance

Clinical practice guidelines support the use of ACE and ARB in CKD patients not on RRT.

The Kidney Disease Improving Global Outcomes (KDIGO) 2012 guidelines for the evaluation and management of CKD recommend that “an ARB or ACE-I be used in both diabetic and non-diabetic adults with CKD and urine albumin excretion >300 mg/24 hours (or equivalent)” (Recommendation 3.1.7, 1B). Guideline available at https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf

The KDIGO 2021 Clinical Practice Guideline on the Management of Blood Pressure (BP) in CKD recommends “starting renin-angiotensin-system inhibitors (RASi) (ACEi or ARB) for people with high BP, CKD, and severely increased albuminuria (G1–G4, A3) without diabetes” and “for people with high BP, CKD, and moderately-to-severely increased albuminuria (G1–G4, A2 and A3) with diabetes” (Recommendations 3.2.1 and 3.2.3, 1B). Guideline available at https://kdigo.org/wp-content/uploads/2016/10/KDIGO-2021-BP-GL.pdf.

This measure was rated as **HIGH** for Overall Measure Validity in Mendu ML, Tummalapalli SL, Lentine KL, Erickson KF, Lew SQ, Liu F, Gould E, Somers M, Garimella PS, O'Neil T, White DL, Meyer R, Bieber SD, Weiner DE. Measuring Quality in Kidney Care: An Evaluation of Existing Quality Metrics and Approach to Facilitating Improvements in Care Delivery. J Am Soc Nephrol. 2020 Mar;31(3):602-614. doi: 10.1681/ASN.2019090869. Epub 2020 Feb 13. PMID: 32054692; PMCID: PMC7062216.

Table 1. Performance Scores by Decile

Performance Gap

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Mean Performance Score	see note above												
N of Entities	see note above												
N of Persons / Encounters / Episodes	see note above												

2.6 Meaningfulness to Target Population

Members of the American Society of Nephrology (ASN) Quality Committee performed an environmental scan of existing kidney quality metrics. To assess the measures’ validity, we conducted two rounds of structured metric evaluation, on the basis of the American College of Physicians criteria: importance, appropriate care, clinical evidence base, clarity of measure specifications, and feasibility and applicability. ASN examined 60 quality metrics, including seven for CKD prevention, two for slowing CKD progression, two for CKD management, one for advanced CKD and kidney replacement planning, 28 for dialysis management, 18 for broad measures, and two patient-reported outcome measures. The ACEi/ARB measure was the only measure related to evidence-based medications that prevent kidney failure, cardiovascular events, and death in patients with CKD. There are no other metrics related to ACEi/ARB use for the CKD population currently in the CMS Measures Inventory Tool.

This measure was rated as **HIGH** for Overall Measure Validity in Mendu ML, Tummalapalli SL, Lentine KL, Erickson KF, Lew SQ, Liu F, Gould E, Somers M, Garimella PS, O'Neil T, White DL, Meyer R, Bieber SD, Weiner DE. Measuring Quality in Kidney Care: An Evaluation of Existing Quality Metrics and Approach to Facilitating Improvements in Care Delivery. J Am Soc Nephrol. 2020 Mar;31(3):602-614. doi: 10.1681/ASN.2019090869. Epub 2020 Feb 13. PMID: 32054692; PMCID: PMC7062216.

3.1 Contributions Towards Closing Care Gaps

Chronic kidney disease (CKD) is a major public health problem; a total of 37 million Americans have CKD. There is a clear performance gap in ACE inhibitor and ARB usage among patients with CKD, with only 40% of CKD patients receiving an ACEi/ARB in NHANES data (Murphy et al., JASN, 2019) [4]. Population health efforts to increase the use of ACEi/ARB in American Indians and Alaska Natives have been associated with a decrease in incident kidney failure related to diabetic kidney disease (Bullock et al., MMWR Morbidity and mortality weekly report, 2017) [5]. In summary, this measure is a central component of high-quality nephrology care, as ACE inhibitors and ARBs decrease the rate of kidney failure, cardiovascular outcomes, and mortality in patients with CKD and proteinuria.

1. Xie X, Liu Y, Perkovic V, et al. Renin-Angiotensin System Inhibitors and Kidney and Cardiovascular Outcomes in Patients With CKD: A Bayesian Network Meta-analysis of Randomized Clinical Trials. Am J Kidney Dis 2016;67:728-41.
2. Cai J, Huang X, Zheng Z, Lin Q, Peng M, Shen D. Comparative efficacy of individual renin-angiotensin system inhibitors on major renal outcomes in diabetic kidney disease: a network meta-analysis. Nephrology, dialysis, transplantation : official publication of the European Dialysis and Transplant Association - European Renal Association 2018;33:1968-76.
3. Jafar TH, Schmid CH, Landa M, et al. Angiotensin-converting enzyme inhibitors and progression of nondiabetic renal disease. A meta-analysis of patient-level data. Annals of internal medicine 2001;135:73-87.
4. Murphy DP, Drawz PE, Foley RN. Trends in angiotensin-converting enzyme inhibitor and angiotensin II receptor blocker use among those with impaired kidney function in the United States. Journal of the American Society of Nephrology. 2019 Jul 1;30(7):1314-21.
5. Bullock A, Burrows NR, Narva AS, et al. Vital Signs: Decrease in Incidence of Diabetes-Related End-Stage Renal Disease among American Indians/Alaska Natives - United States, 1996-2013. MMWR Morbidity and mortality weekly report 2017;66:26-32. PMC5687264.

African-Americans have the highest reported prevalence and incidence of treated ESRD. Overall, African-Americans are four times more likely to progress to ESRD compared to whites (988 vs. 254 patients per million) and at a higher-than-average risk for developing ESRD in the Southeastern US. Diabetes Mellitus (DM) is the leading cause of ESRD in all racial and ethnic groups, but occurs at a much higher rate among African-Americans, Hispanics and Native Americans (422,382.9, and 307.2 vs. 115 per million, respectively) compared to whites. In addition, African-Americans have the highest rate of hypertension-related ESRD, which far exceeds other racial and ethnic groups. As a result, hypertension remains a close second to DM as the leading cause of ESRD in the African-American community.(1)

In individuals with early CKD, African American women (odds ratio [OR], 1.47; 95% confidence interval [CI], 1.14 to 1.88), white men (OR, 1.85; 95% CI, 1.39 to 2.46), and white women (OR, 1.69; 95% CI, 1.28 to 2.22) had greater odds of hypertension control (blood pressure <130/80 mm Hg) than African American men. In individuals with late CKD, white men (OR, 1.66; 95% CI, 1.10 to 2.52) and white women (OR, 1.67; 95% CI, 1.13 to 2.46) had greater odds of hypertension control than African American men. No differences were seen between African American men and women with late CKD.[6]

In the United States, the incidence of ESRD from hypertensive CKD in African American men is 5 times that in white men and 1.4 times that in African American women.[7]

6. Alves TP, Lewis, J. Racial differences in chronic kidney disease (CKD) and end-stage renal disease (ESRD) in the United States: a social and economic dilemma. Clinical Nephrology.2010;74(1):S72-S77.
7. Duru OK, Li S, Jurkovitz C, Bakris G, et al. Race and Sex Differences in Hypertension Control in CKD: Results From the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2008 February;51(2):192-198.

4.1 Feasibility Assessment

Not applicable during the Fall 2023 cycle.

4.3 Feasibility Informed Final Measure

The measure was not changed as a result of the feasibility assessment as it was found to be feasible as specified.

4.4 Proprietary Information

Proprietary measure or components (e.g., risk model, codes), without fees

4.4a Fees, Licensing, or Other Requirements

No fees are charged by the Renal Physicians Association for use of this measure.

CPT codes in the measure are copyright of the American Medical Association.

5.1.1 Data Used for Testing

The measure was developed by the Renal Physicians Association (RPA) and the American Medical Association (AMA)-convened Physician Consortium for Performance Improvement (Consortium). The AMA requested that the Iowa Foundation for

Medical Care (IFMC) perform on-site validity and feasibility testing of the measure. In addition, IFMC was asked to compare the claims information submitted for the Physician Quality Reporting Initiative (PQRI) to the medical record documentation in support of each measure submitted for PQRI payment. The objective of the feasibility and implementation testing was to assess the feasibility of the collection, the measurement, and reporting of the data while also monitoring the costs of doing so. Reliability testing was also performed to determine whether the specifications, including the data definitions prepared by us in collaboration with RPA/AMA, resulted in consistent measurements. In addition, IFMC tested the reliability of PQRI submissions on claims when compared to medical record documentation. Another objective was to perform testing in a variety of environments, i.e., electronic health record (EHR), paper medical record and administrative/claims data-based measurement.

A measure testing protocol was drafted by IFMC and vetted through the AMA. For reliability testing of the measures two IFMC staff performed on-site manual data collection on the same medical records to determine if the measures could be collected reliably. To explore whether electronic capture of all necessary data elements to compute each measure was inherent in the EHR-based sites, a follow up grid was sent to each EHR site requesting this detailed information. Information obtained for each element included whether the data element was located in a discrete field in the EHR and whether that field was in a standard codified format.

A sample of patients > 18 years of age was to be pulled by each site of the first 35 patients seen in each category using a start date of July 1, 2007. Each sample was oversampled by five patients in an effort to ensure a remaining sample of 30 patients in each category from each site.

Four nephrology practice sites representing various types, locations and sizes were identified to participate in testing the measures:

- The number of physicians per site ranged from 5-62 physicians
- The sites were located in four different regions: Midwestern, Western, Eastern, and Southern
- Patient visit volume ranged from 60-2250 CKD patients seen per month

Sample size per physician organization ranged from 24-30 (as shown below) for a total of 112 CKD patients

- Site 1: 24 CKD patients
- Site 2 : 29 CKD patients
- Site 3 : 29 CKD patients
- Site 4 : 30 ESRD patients (30 PD patients, 30 HD patients)
- Sample selection: Data were collected from the medical records of the first up to 35 CKD patients on each type of dialysis seen at each site after July 1, 2007. The measurement period was July 1, 2007-June 30, 2008.

- Data abstraction was performed in 2008.

Sampling Method

- To arrive at a sample of 30 records per condition/per site, we will over-sample for 35 records.
- For practices participating in CMS' Physician Quality Reporting Initiative (PQRI), the sample will be drawn from a population of patients for whom: 1) a CPT II code was submitted on a claim in 2008, AND 2) the patients had at least 2 office visits with the nephrologist in the 2007 calendar year.
- For sites that are not participating in PQRI, the sample with be drawn from a patient population in which patients had at least 2 office visits with the nephrologist in the 2007 calendar year.
- IFMC will provide one of the following sampling methodologies to the practice sites:
  - Identify records for 35 patients (with CKD , not on RRT) whose Social Security number ends in a specific number, i.e., 2 and 4

OR

- Identify records for the first 35 patients seen during the first month of the timeframe used for testing (this method would help assure that the sampled patients would potentially have 12 months of data for review).

The nephrology office sites were visited by a two-person abstractor team to conduct feasibility and reliability testing. The two abstractors individually abstracted each medical record, compared the results, and evaluated the mismatches.

5.1.2 Differences in Data

The same sample was used for all testing.

5.1.3 Characteristics of Measured Entities

The RPA, AMA and IFMC members of the team mutually agreed that the testing site model would consist of a nephrology practice alpha site local to IFMC and three sites distributed geographically across the United States of various practice sizes and medical record types (electronic vs. paper). Potential nephrology practice sites were contacted by an IFMC representative for the purpose of soliciting participation in measure testing activities. The criteria above were paramount; however, selection was subject to willingness by the practice to

participate.

RPA provided a list of their Practice Managers Committee containing names and contact information. From this list, three clinics were chosen based on the criteria discussed above. The desired geographic mix was attained. The alpha site was located in the upper Midwest, one test site in the East, one in the South, and one in the Western United States.

Four nephrology practice sites representing various types, locations and sizes were identified to participate in testing the measures:

- The number of nephrologists per site ranged from 5-62 physicians.
- The sites were located in four different regions: Midwestern, Western, Eastern, and Southern.
- Patient visit volume ranged from 60-2250 CKD patients seen per month.

Sample selection: Data were collected from the medical records of the first up to 35 CKD patients on each type of dialysis seen at each site after July 1, 2007. The measurement period was July 1, 2007-June 30, 2008.

Sample size per physician organization ranged from 24-30 for a total of 112 CKD patients.

5.1.4 Characteristics of Units of the Eligible Population

This measure is not stratified. Data testing included gender, age and CKD stage.

5.2.1 Level(s) of Reliability Testing Conducted

Person or encounter level (i.e., data element) (e.g., inter–abstractor reliability)

5.2.2 Method(s) of Reliability Testing

Data abstracted from patient records were used to calculate inter-rater reliability for the measure.

Patients were randomly selected from visits for CKD.

Data analysis included:

- Percent agreement
- Kappa statistic with 95% confidence interval to adjust for chance agreement

Cohen's kappa coefficient is a statistical measure of inter-rater agreement or inter-annotator agreement for qualitative (categorical) items. It is generally thought to be a more robust measure than simple percent agreement calculation since κ takes into account the agreement occurring by chance.

5.2.3 Reliability Testing Results

The statistical results from reliability testing:
Measure (N, % Agreement, Kappa (95% Confidence Interval))

ACE Inhibitor or ARB Therapy Measure (73, 93.15%, 0.8047 (0.6395- 0.9699).

5.2.4 Interpretation of Reliability Results

This measure is highly reliable, as shown in results from the inter-abstrator analysis.

5.3.1 Level(s) of Validity Testing Conducted

Person or encounter level (i.e., data element) (e.g., sensitivity and specificity)

5.3.3 Method(s) of Validity Testing

Face Validity

An expert panel was used to assess face validity of the measure. This panel consisted of 21 members, with representation from the following specialties: nephrology, pediatric nephrology, endocrinology, nursing, methodology, internal medicine, preventive medicine and family medicine.

Face validity of the measure score as an indicator of quality was systematically assessed as follows:
After the measure was fully specified, the expert panel was asked to rate their agreement with the following statement:

Please rate your agreement with the following statement for each measure- the scores obtained from the measure as specified will accurately differentiate quality across providers.

Scale 1-5, where 1=Strongly Disagree; 3=Neither Disagree nor Agree; 5=Strongly Agree

Additional Review

In 2019, the American Society of Nephrology's (ASN) Quality Committee performed a systematic compilation and evaluation of national kidney metrics. To assess the measures' validity, the ASN Quality Committee conducted two rounds of structured metric evaluation, on the basis of the American College of Physicians criteria: importance, appropriate care, clinical evidence base, clarity of measure specifications, and feasibility and applicability. Quality metrics were included if they met the following criteria: (1) had defined numerator, denominator, and exclusion criteria; (2) were physician-directed measures relevant to the care of kidney disease patients or were classified as a kidney disease metric by the organization; and (3) were published or endorsed by an organization recognized nationally for quality metrics, as opposed to single health system or organization-specific metrics. ASN did not include clinical practice guidelines without specified numerator and denominator parameters. We organized these metrics on the basis of applicability across the spectrum of kidney disease care delivery: CKD prevention, slowing CKD progression, CKD management, advanced CKD and kidney replacement planning, and dialysis management. ASN also classified broad measures as applying across the spectrum of kidney disease care and metrics that were patient reported outcome measures (PROMs).

Ratings were completed similar to the approach outlined by the ACP Performance Measurement Committee, utilizing the RAND Corporation/University of California, Los Angeles (UCLA) method of evaluating a medical intervention. As a part of their effort to review existing performance measures, the Performance Measurement Committee of the ACP developed and applied five criteria to evaluate measures included in the Quality Payment Program.

1. *Importance:* The metric will lead to measurable and meaningful improvement in clinical outcome or there is an opportunity for improvement.
2. *Appropriate care:* The metric will stem overuse or underuse of a test or treatment.
3. *Clinical evidence base:* The metric is on the basis of high-quality and high-quantity evidence, and has consistent data representing clinical knowledge.
4. *Measure specifications:* The metric has clarity (a clearly defined numerator and denominator), validity, reliability, and appropriate risk adjustment.
5. *Feasibility and applicability:* The metric is under the influence of the individual or entity being assessed, attribution level is appropriate, data collection is feasible and burden acceptable, and results will help improve care.

ACP criteria as well as consideration of unintended consequences were applied to all measures to evaluate validity. Validity is defined by this methodology as "the measure is correctly assessing what it is designed to measure, adequately distinguishing good and poor quality." Two rounds of metric evaluation were conducted by 11 members of the ASN Quality Committee. In the first round, members evaluated the measures independently in spring of 2019; the second round of ratings was conducted during an in-person meeting in July 2019, using a formal group process,

with a senior committee member (D.E.W.) serving as moderator. After a group discussion of each measure, members rated the ACP criteria on a 9-point scale, with 1 to 3 indicating “does not meet criteria,” 4 to 6 “meets some criteria,” and 7 to 9 “meets criteria.” Each measure also received an overall high/medium/low rating. The overall metric ratings were unchanged from round one to two, and there was strong correlation between domain criteria ratings and overall ratings (see Supplemental Figure 1). Intraclass correlation coefficients (ICCs) showed a moderate correlation among overall ratings (ICC=0.68) and ACP domain ratings (ICC range: 0.59–0.82) (see Supplemental Figure 2 and Supplemental Table 2). Individual comments were collected from the first round of ratings, and group comments were collected from the second round. After the individual metrics were rated for validity, a subset of the committee (M.L.M., S.L.T., D.E.W., and S.D.B.) organized them into subcategories and globally assessed the scope and attribution of the metrics. Please see Supplemental Figures and full article from the Journal of the American Society of Nephrology (JASN) available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7062216/.

5.3.4 Validity Testing Results

Face Validity

The statistical results of validity testing were:

The results of the expert panel rating of the validity statement were as follows:

N = 19; Mean rating = 4.47

Frequency Distribution of Ratings

1 - 0 (Strongly Disagree)

2 - 0

3 - 0 (Neither Disagree nor Agree)

4 - 10

5 - 9 (Strongly Agree)

Additional Review by ASN Quality Committee

Median and interquartile ranges (IQR) of ACP domain ratings.

ACP 1: Importance Median [IQR]: 9 [9-9]

ACP 2: Appropriateness Median [IQR]: 9 [8-9]

ACP 3: Clinical Evidence Median [IQR]: 8 [7-9]

ACP 4: Specifications Median [IQR]: 5 [4-6]

ACP 5: Feasibility Median [IQR]: 6 [5-8]

This measure was rated as **HIGH** for Overall Measure Validity by the ASN Quality Committee.

5.3.5 Interpretation of Validity Results

These results indicate that face validity of the measure score as an indicator of quality was consistent.

5.3.2 Type of Accountable Entity Level Validity Testing Conducted (derived)

Systematic assessment of face validity of the measure's performance score as an indicator of quality or resource use

5.4.1 Methods Used to Address Risk Factors

No risk adjustment or stratification

5.4.1b Rationale For No Adjustment or Stratification

This is a process measure. It is not risk adjusted.

5.4.4 Risk/Case-Mix Adjustment Modeling and/or Stratification Results

This measure is not risk stratified.

6.1.3 Current Use(s)

Public Reporting, Payment Program

6.1.3 Program Details

Name of the program and sponsor
Merit-based Incentive Payment System (MIPS) - Centers for Medicare and Medicaid (CMS)

URL of the program
https://qpp.cms.gov/mips/reporting-options-overview
Purpose of the program
The Merit-based Incentive Payment System (MIPS) is one way to participate in the Quality Payment Program (QPP).
Geographic area and percentage of accountable entities and patients included
Medicare Part B patients in the United States.
Applicable level of analysis and care setting

Eligible clinicians may participate as an individual, group, virtual group or alternative payment model (APM) Entity.

Individual
Clinicians can collect and report data representing their individual performance. Clinicians that are MIPS eligible at the individual level will receive a payment adjustment based on their individual final score unless they have a higher final score from group or APM Entity participation.

Group
A practice can choose to collect and report aggregated data at the group level on behalf of all its clinicians. The clinicians in the practice that are MIPS eligible at the group level will receive a payment adjustment based on the group's final score. The clinicians in the practice that are MIPS eligible at the individual level will receive a payment adjustment based on the group's final score unless they have a higher final score from individual or APM Entity participation.

Virtual Group
Clinicians can elect to form a virtual group. CMS-approved virtual groups collect and report aggregated data on behalf of all their clinicians. The MIPS eligible clinicians in the virtual group will receive a payment adjustment based on the virtual group's final score, even if they voluntarily participate as an individual, group or APM Entity.

APM Entity
An APM Entity can choose to collect and report aggregated data at the Entity level on behalf of its MIPS eligible clinicians. The clinicians in the APM Entity that are MIPS eligible at the individual or group level will receive a payment adjustment based on the APM Entity's final score unless they have a higher final score from individual or group participation. (Note that clinicians in a virtual group always receive the virtual group's final score.)

6.2.1 Actions of Measured Entities to Improve Performance

Entities must review lab results of all CKD patients for the presence of proteinuria, identify

relevant patients without contraindications, discuss the value of taking ACEi/ARBs with the patients for whom it is indicated and prescribe ACEi/ARBs to those patients. Once patients are on the medication, dosage needs to be reviewed and up-titrated to achieve maximal benefit. Improvement requires patient monitoring and review.

6.2.2 Feedback on Measure Performance

Feedback received from the ASN Quality Committee included:

- Strong evidence for ACEi/ARB use in delaying CKD progression; evidence stronger with higher proteinuria and earlier CKD stages.
- May cause increased rates of hyperkalemia and/or creatinine elevation, particularly in advanced CKD stages, and requires monitoring.

6.2.3 Consideration of Measure Feedback

The RPA agrees that patients must be monitored for increased rates of hyperkalemia and/or creatinine elevation. However, RPA believes this to be part of high quality patient care and does not require changes to the measure specifications.

6.2.4 Progress on Improvement

RPA awaits the release of MIPS data regarding this measure to be able to benchmark progress. Review of the 2022 USRDS report does not show significant change in the use of ACEi/ARBs in CKD patients (based on 2020 data). It is hoped that the inclusion of the measure in the MIPS program may spur improvement in the use of these medications that can slow the progression of CKD.

6.2.5 Unexpected Findings

It is possible for the measure to be satisfied by prescribing a low dose of ACEi/ARB without an effort to up-titrate to the maximal dose, which is what is needed to achieve maximal benefit. The “unintended” consequence is suboptimal treatment with patients placed on very low doses of RAS blockade rather than having the dose properly titrated. In order to overcome this, it may be valuable for providers to link the measure to an electronic clinical reminder to review dosage.

Developer POC email

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Measure Developer POC

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United States

Measured/accountable entity (reliability and/or validity) methodology and results (if available)

Measured entity (reliability and validity) methodology and results (if available), Person or encounter-level (reliability and validity) methodology and results (if available)

Responder for Survey

Patient

The measure developer is different from the measure steward

No

Steward Address

United States

Steward Organization

Renal Physicians Association