NATIONAL QUALITY FORUM

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Click to go to the link. ALT + LEFT ARROW to return

Purple text represents the responses from measure developers.

Red text denotes developer information that has changed since the last measure evaluation review.

Brief Measure Information

NQF #: 0541

Corresponding Measures:

De.2. Measure Title: Proportion of Days Covered (PDC): 3 Rates by Therapeutic Category

Co.1.1. Measure Steward: Pharmacy Quality Alliance

De.3. Brief Description of Measure: The percentage of individuals 18 years and older who met the Proportion of Days Covered (PDC) threshold of 80 percent during the measurement year.

Report a rate for each of the following:

- Diabetes All Class (PDC-DR)
- Renin Angiotensin System Antagonists (PDC-RASA)
- Statins (PDC-STA)

A higher rate indicates better performance.

1b.1. Developer Rationale: This measure, Proportion of Days Covered (PDC): 3 Rates by Therapeutic Category, evaluates adherence to three therapeutic categories of medications aligned with three common chronic conditions: diabetes agents for diabetes, renin-angiotensin system antagonists (RASA) for hypertension, and statins for hyperlipidemia. Medication therapy is recommended as a mainstay of treatment for these conditions and clinical guidelines emphasize the importance of adherence to medications to achieve optimal outcomes.

More than 26 million American adults (9.8%) have diabetes.(1) For type 2 diabetes, the most common form, pharmacologic treatment can improve clinical outcomes, including reducing chronic kidney disease (CKD) progression, major cardiovascular events, and cardiovascular mortality.(2) Approximately 46% of American adults have hypertension(1) and RASA are recommended as initial therapy for many patients for cardiovascular risk reduction, particularly those with diabetes or CKD.(3,4) Approximately 30% of American adults have elevated LDL cholesterol(1) and statin therapy is recommended for treating hyperlipidemia and also for primary prevention of cardiovascular disease in several treatment guidelines.(2,5-7)

Recent studies support the body of evidence showing that medication adherence is correlated with improved clinical outcomes and decreased healthcare costs.(8) Medication adherence for diabetes, hypertension, and hyperlipidemia remains suboptimal(9) and multiple interventions may be used to improve adherence.(10,11)

1. Benjamin EJ, Muntner P, Alonso A, et al; American Heart Association Council on Epidemiology and Prevention Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics-2019

Update: A Report From the American Heart Association. Circulation. 2019;139(10):e56-e528. doi: 10.1161/CIR.0000000000000659. PMID: 30700139.

2. American Diabetes Association. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes-2019. Diabetes Care. 2019;42(Suppl 1):S90-S102. PMID: 30559235.

3. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Soc Hypertens. 2018;12:579.e1-579.e73. PMID: 30219548.

4. American Diabetes Association. 10. Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes-2019. Diabetes Care. 2019;42(Suppl 1):S103-S123. PMID: 30559236.

5. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol. Circulation. 2018 Nov 10:CIR0000000000000625. PMID: 30586774.

6. Jellinger PS, Handelsman Y, Rosenblit PD, et al. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY GUIDELINES FOR MANAGEMENT OF DYSLIPIDEMIA AND PREVENTION OF CARDIOVASCULAR DISEASE. Endocr Pract. 2017; 23(Suppl 2):1-87. PMID: 28437620.

7. US Preventive Services Task Force, Bibbins-Domingo K, Grossman DC, Curry SJ, et al. Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: US Preventive Services Task Force Recommendation Statement. JAMA. 2016; 316(19):1997-2007. PMID: 27838723.

8. Lloyd JT, Maresh S, Powers CA, Shrank WH, Alley DE. How Much Does Medication Nonadherence Cost the Medicare Fee-for-Service Program? Med Care. 2019;57:218-24. PMID: 30676355.

9. Ritchey M, Chang A, Powers C, et al. Vital Signs: Disparities in Antihypertensive Medication Nonadherence Among Medicare Part D Beneficiaries - United States, 2014. MMWR Morb Mortal Wkly Rep. 2016;65:967-76. PMID: 27632693.

10. Kini V, Ho PM. Interventions to Improve Medication Adherence: A Review. JAMA. 2018;320:2461-73. PMID: 30561486.

11. Viswanathan M, Golin CE, Jones CD, et al. Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review. Ann Intern Med. 2012;157:785-95. PMID: 22964778.

S.4. Numerator Statement: The number of individuals who met the PDC threshold of 80 percent during the measurement year.

S.6. Denominator Statement: Individuals age 18 years and older as of the first day of the measurement year, with at least two prescription claims for medication(s) within a specific therapeutic category (Diabetes; RASA; Statins) on different dates of service during the treatment period and are continuously enrolled during the treatment period, which begins on the index prescription start date (IPSD) and extends through whichever comes first: the last day of the measurement year, death or disenrollment. The IPSD should occur at least 91 days before the end of the enrollment period.

Note: The IPSD is the earliest date of service for a target medication during the measurement year

Exclusions for the Diabetes rate:

- Individuals with one or more prescription claims for insulin during the treatment period (See Medication Table PDC-H: Insulin Exclusion)
- Individuals in hospice or with End-Stage Renal Disease

Exclusions for the RASA rate:

- Individuals with one or more prescription claims for the medication, sacubitril/valsartan during the treatment period (See Medication Table PDC-RASA-B: Sacubitril/Valsartan Exclusion)
- Individuals in hospice or with End-Stage Renal Disease

Exclusions for the Statins rate:

- Individuals in hospice or with End-Stage Renal Disease

S.8. Denominator Exclusions: Exclusions for the Diabetes rate:

- Individuals with one or more prescription claims for insulin during the treatment period (See Medication Table PDC-H: Insulin Exclusion)
- Individuals in hospice or with end-stage renal disease during the measurement year

Exclusions for the RASA rate:

- Individuals with one or more prescription claims for the medication, sacubitril/valsartan during the treatment period (See Medication Table PDC-RASA-B: Sacubitril/Valsartan Exclusion)
- Individuals in hospice or with End-Stage Renal Disease

Exclusions for the Statins rate:

- Individuals in hospice or with End-Stage Renal Disease

De.1. Measure Type: Process

S.17. Data Source: Claims, Enrollment Data

S.20. Level of Analysis: Health Plan

IF Endorsement Maintenance – Original Endorsement Date: Aug 05, 2009 **Most Recent Endorsement Date:** Nov 10, 2014

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? The measure is not paired/grouped

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement endorsed measures are evaluated periodically to ensure that the measures still meets the NQF endorsement criteria ("maintenance"). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

Criteria 1: Importance to Measure and Report

1a. Evidence

Maintenance measures – less emphasis on evidence unless there is new information or change in evidence since the prior evaluation.

1a. Evidence. The evidence requirements for a *structure, process or intermediate outcome* measure is that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also

should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following evidence for this measure:

- **Systematic Review of the evidence specific to this measure?** ☐ **Yes** ☒ **No**
- **Quality, Quantity and Consistency of evidence provided?** ☐ **Yes** ☒ **No**
- **Evidence graded?** ☐ **Yes** ☒ **No**

Summary of prior review in 2014

- The developer previously provided a summary of the links between diabetes/hypertension/hyperlipidemia to treatment with medications with over 80% medication adherence for proportion of day covered which can lead to outcomes of health outcomes such as decreased A1C, decrease major cardiovascular events; as well as lowered healthcare costs (i.e. decreased ED visits and hospitalizations).
- The developer previously presented evidence supporting conceptual relationship between adherence to the medication and the patient outcomes of fewer hospitalizations, few deaths and low costs of care. It was noted that the evidence is not medication specific previously by the NQF Committee in 2014.

Changes to evidence from last review

☐ **The developer attests that there have been no changes in the evidence since the measure was last evaluated.**

☒ **The developer provided updated evidence for this measure:**

Updates:

- Brief background: This is a measure of medication adherence in patients 18+ years of age who are taking either oral antidiabetic medications, RASAs or statins.
- The developer provided the following recent studies to continue to demonstrate relationship of medication adherence with clinical and economic outcomes:
    - Adherence to statin (PDC ≥80%) was associated with 23% decreased incidence of ischemic stroke compared to nonadherence (Korhonen et al, 2016).
    - PDC ≥80% of statins was also associated with fewer inpatient visits and lower inpatient and total healthcare costs in the commercial population (Chinthammit et al, 2019).
    - PDC ≥80% was also associated with lower all-cause acute care and outpatient costs in older adults enrolled in Medicare with type 2 diabetes (Boye et al, 2016).
    - PDC ≥80% was also associated with fewer inpatient visits; and lower inpatient and total healthcare costs in the commercial population (Campbell et al, 2019).
    - PDC ≥80% of renin angiotensin system antagonists (RASA) was also associated with fewer inpatient visits and outpatient visits; and lower inpatient and total healthcare costs in the commercial population (Axon et al, 2019).
    - In Lloyd et al, 2019, for the Medicare fee-for-service beneficiaries with diabetes, heart failure, and hyperlipidemia, it is estimated the avoidable health care costs that could be saved if nonadherent beneficiaries with diabetes became adherent was $4.5 billion (over $5,000 per beneficiary) annually. Similar levels of avoidable health care costs were found among nonadherent beneficiaries with hyperlipidemia and heart failure. If nonadherent beneficiaries with hypertension became adherent, the authors estimated Medicare could save $13.7 billion annually.
- There was no Quality, Quantity, and Consistency nor grading of the studies provided by the developer for the studies.

Questions for the Committee:

If the developer provided updated evidence for this measure:

- The evidence provided by the developer is updated, directionally the same compared to that for the previous NQF review. Does the Committee agree there is no need for repeat discussion and vote on Evidence?
- For structure, process, and intermediate outcome measures:
    - What is the relationship of this measure to patient outcomes?
    - How strong is the evidence for this relationship?
    - Is the evidence directly applicable to the process of care being measured?

Guidance from the Evidence Algorithm

Process measure with no systematic review or grading (Box 7) → empirical evidence summarizes studies (Box 8) →evidence indicates substantial net benefit (Box 9) → Moderate

The highest possible rating is "Moderate" for Evidence.

Preliminary rating for evidence: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

Maintenance measures – increased emphasis on gap and variation

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- The developer provided data from the Centers for Medicare & Medicaid Services (CMS) Medicare Part D Star Ratings Program to evaluate prescription drug plans (both Medicare Advantage plans [MA-PDs] and stand-alone prescription drug plans [PDPs]). Separate analyses were provided for diabetes medications, RASA, and statins for MA-PDs and PDPs. Although performance rates have improved since 2013, there is still an opportunity for improvement.

PDC Diabetes Medications:

- The mean rate has increased steadily over the last 5 reporting years (2013-2017), indicating overall improvement across plans.
    - For MA-PDs, the mean rate improved from 76.8% in 2013 to 81.5% in 2017.
    - For PDPs, the mean rate improved from 79.3% in 2013 to 83.4% in 2017.
- The standard deviation has decreased modestly over the last 5 reporting years (2013-2017), indicating that the difference in rates between high and low performing plans has narrowed slightly.
    - For MA-PDs, the standard deviation decreased from 5.9% in 2013 to 4.6% in 2017.
    - For PDPs, the standard deviation decreased from 4.8% in 2013 to 3.6% in 2017.

PDC RASA Medications (for hypertension):

- The mean rate has increased steadily over the last 5 reporting years (2013-2017), indicating overall improvement across plans.
    - For MA-PDs, the mean rate improved from 78.3% in 2013 to 83.4% in 2017.
    - For PDPs, the mean rate improved from 81.1% in 2013 to 85.8% in 2017.
- The standard deviation has decreased modestly over the last 5 reporting years (2013-2017), indicating that the difference in rates between high and low performing plans has narrowed slightly.
    - For MA-PDs, the standard deviation decreased from 5.5% in 2013 to 4.3% in 2017.
    - For PDPs, the standard deviation decreased from 4.5% in 2013 to 2.5% in 2017.

PDC Statin Medications (for hyperlipidemia):

- The mean rate has increased steadily over the last 5 reporting years (2013-2017), indicating overall improvement across plans.
    - For MA-PDs, the mean rate improved from 74.0% in 2013 to 80.2% in 2017.
    - For PDPs, the mean rate improved from 76.6% in 2013 to 82.7% in 2017.
- The standard deviation has decreased modestly over the last 5 reporting years (2013-2017), indicating that the difference in rates between high and low performing plans has narrowed slightly.
    - For MA-PDs, the standard deviation decreased from 7.1% in 2013 to 5.8% in 2017.
    - For PDPs, the standard deviation decreased from 5.1% in 2013 to 4.3% in 2017.

Disparities

- The developer used data from the 2016 Medicare Research Identifiable Files (RIF) 5% national sample data and the 2017 Medicare Prescription Drug Event (PDE) 100% data.
- In general, younger beneficiaries were less likely to be adherent compared to older beneficiaries; individuals identified as White or Asian were more likely to be adherent compared to Blacks or Hispanics; individuals with low income subsidy (LIS)/dual eligibility status were less likely to be adherent compared to those without LIS/dual eligibility status; and individuals with disability as the reason for Medicare entitlement were less likely to be adherent compared to those with other reasons for Medicare entitlement.

Questions for the Committee:

- Specific questions on information provided for gap in care.
- Is there a gap in care that warrants a national performance measure?
- If no disparities information is provided, are you aware of evidence that disparities exist in this area of healthcare?

Preliminary rating for opportunity for improvement: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence to Support Measure Focus: For all measures (structure, process, outcome, patient-reported structure/process), empirical data are required. How does the evidence relate to the specific structure, process, or outcome being measured? Does it apply directly or is it tangential? How does the structure, process, or outcome relate to desired outcomes? For maintenance measures –are you aware of any new studies/information that changes the evidence base for this measure that has not been cited in the submission?

- evidence relates well with retrospective data and applies directly, the evidence for this measure is based on 10 years of use in Medicare
- The evidence provided is mainly from studies showing a link between adherence to medications and improved outcomes, not specifically that this measure improved outcomes. The evidence is strong that medication adherence is a good thing, but I think it remains a stretch as to whether the way they measure adherence translates to similar outcomes.
- New studies provided and continue to support the measure

1b. Performance Gap: Was current performance data on the measure provided? How does it demonstrate a gap in care (variability or overall less than optimal performance) to warrant a national performance measure? Disparities: Was data on the measure by population subgroups provided? How does it demonstrate disparities in the care?

- within the United States there is a gap in care as it relates to adherence to medications for diabetes, RASA blood pressure medications and statin medication. Yes stratifications by age and gender (all medicare beneficiary eligibility subgroup) all have gap in adherence. Yes low PDC leads to non-adherence in all subgroups and therefore lead to increase in health care costs that could be avoidable.

- For all subgroups, there remains opportunity for improvement. There is data about disparities.
- The compliance rate for these measures are improving. However, they do not appear to be topped out. There continues to be a need to improve compliance with these medications to drive better patient outcomes.

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications **and** Testing

2b. Validity: Testing**;** Exclusions**;** Risk-Adjustment**;** Meaningful Differences**;** Comparability**;** Missing Data

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Complex measure evaluated by Scientific Methods Panel? ☒ **Yes** ☐ **No**

Evaluators: NQF Scientific Methods Panel Subgroup

Methods Panel Review (Combined)

Evaluation of Reliability and Validity:

Scientific Methods Panel Votes: Measure passes

- Reliability: H-1, M-3, L-1, I-0
- Validity: H-1, M-3, L-1, I-0

This measure was reviewed by the Scientific Methods Panel. A summary of the measure is provided below:

Reliability

- Reliability testing was performed for measure score
- Measure Score
    - Measure Score testing conducted via a beta-binomial model, which was used to calculate plan-specific reliability scores based on the method outlined by Adams (2009).
        - The mean reliability score for the Medicare plan-contract (with median) were 0.8492 (0.9316) for Diabetes, 0.8953 (0.9724) for RASA, and 0.9171 (0.9793) for Statins.
        - The mean reliability score for the Medicaid plans (with median) were 0.9174 (0.9655) for Diabetes, 0.9340 (0.9798) for RASA, and 0.9305 (0.9781) for Statins.
    - The results indicate that the PDC measure is reliable though the risk-adjusted measure was not as strongly reliable. The measure developer postulates that one potential reason for low split half scores for diabetes medications and RASA are due to the fact that only 5% of the

Medicare population was used for testing of this measure. One panel member suggested that since the authors are in possession of the data, they could have tested this hypothesis by increasing the sample size in subsequent iterations.
    - The developer responded to the Methods Panel concern by providing updated testing of the risk-adjusted measures using the 2017 100% CMS Medicare Prescription Drug Event (PDE) data. Using the 100% Medicare dataset, reliability improved substantially, ranging from 0.73 (RASA) to 0.88 (Statins), and by conventional interpretation, all three measures are considered to have good reliability.
  - The SMP had the suggestion that the measure steward revisit this specification to limit the exclusion cases where hospice and ESRD are present at the onset of the measurement period

Validity

- Validity testing was performed for measure score
- Measure Score
  - Measure Score testing conducted both empirically and via a face validity assessment
    - Construct validity was tested. Correlation was examined using the Pearson correlation statistics between each of the therapeutic categories and other performance measures used in the Star Ratings program.
      - The measure developer provided a rationale for choosing the measures as follows:
        - For Diabetes, we examined whether the measure rate is correlated with the Diabetes Care – Blood Sugar Controlled measure used in the CMS Part C Star Ratings program. We hypothesized that organizations that perform well on the PDC Diabetes measure should perform well on the Diabetes Care – Blood Sugar Controlled measure as both focus on diabetes care, and adherence to anti-hyperglycemic agents can lower blood sugar and decrease complications such as visual loss and renal failure.
        - For RASA, convergent validity was tested by exploring whether the measure rate is correlated with the Controlling Blood Pressure measure used in the CMS Part C Star Ratings program. We hypothesized that organizations that perform well on the PDC RASA measure should perform well on the Controlling Blood Pressure measure.
        - For Statins, convergent validity was tested by exploring whether the measure rate is correlated with the Statin Use in Persons with Diabetes measure used in the CMS Part D Display measures. We hypothesized that organizations that perform well on the PDC Statins measure should perform well on the Statin Use in Persons with Diabetes measure.
      - All three therapeutic categories showed statistically significant positive correlation with their respective corresponding Star Ratings measure.
      - Oral antidiabetic, RASAs and statin meds had correlation coefficients of 0.47, 0.52, and 0.35 respectively when compared to a corresponding Star measure.
    - Face validity was tested through multiple PQA committees. It was not clear from the submission how this was conducted, and several panel members asked for additional clarity. Recommendation to measure developer to further clarify how face validity is assessed in the course of the PQA measure development process in future submissions; submission was considered vague.

        - The SMP noted that the MIF specifications of exclusions (i.e. S.9, p. 10-11) notes hospice & ESRD cases are excluded if hospice or ESRD services are received anytime during the treatment period. The SMP expressed concern that a fairly significant portion of patients by plan were excluded because of ESRD status. Panel members suggested that it seems more logical to only exclude such cases when hospice or ESRD is present at the onset of the measurement; that the development for the need for hospice or ESRD during the treatment year may be a reflection of poor quality care.
    - The comment from the one dissenting SMP member: "Empiric testing of validity was noted by several weak—tested correlation with other process measures—stated purpose of metric is to improve clinical outcomes. Because the measure proponents have the access to the claims data which contains the needed information regarding outcome (mortality, hospital admission, overall cost of care, etc.) much more meaningful empiric testing would have been to demonstrate the association of high performance with improved clinical outcome."
    - The SMP expressed concern that the measure developer didn't summarize the c- statistic results, which were 0.583 to 0.597 [Table 14 on p27], which is poor. 0.5 indicates the model is "no better than random prediction".

Standing Committee Action Item(s):

- The Standing Committee can discuss reliability and/or validity or accept the Scientific Methods Panel ratings.

Questions for the Committee regarding reliability:

- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?
- The Scientific Methods Panel is satisfied with the reliability testing for the measure. Does the Committee think there is a need to discuss and/or vote on reliability?

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The Scientific Methods Panel is satisfied with the validity analyses for the measure. Does the Committee think there is a need to discuss and/or vote on validity?

Preliminary rating for reliability: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Preliminary rating for validity: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Methods Panel Evaluation (Combined): Scientific Acceptability

Measure Number: 0541

Measure Title: Proportion of days covered (PDC):) –): 3 rates by therapeutic category

Type of measure:

☒ **Process** ☐ **Process: Appropriate Use** ☐ **Structure** ☐ **Efficiency** ☐ **Cost/Resource Use**

☐ **Outcome** ☐ **Outcome: PRO-PM** ☐ **Outcome: Intermediate Clinical Outcome** ☐ **Composite**

Data Source:

☒ **Claims** ☐ **Electronic Health Data** ☐ **Electronic Health Records** ☐ **Management Data**

☐ **Assessment Data** ☐ **Paper Medical Records** ☐ **Instrument-Based Data** ☐ **Registry Data**

☒ **Enrollment Data** ☐ **Other**

Level of Analysis:

☐ **Clinician: Group/Practice** ☐ **Clinician: Individual** ☐ **Facility** ☒ **Health Plan**

☐ **Population: Community, County or City** ☐ **Population: Regional and State**

☐ **Integrated Delivery System** ☐ **Other**

Measure is:

☐ **New** ☒ **Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?** ☒ **Yes** ☒ **No**

   Submission document: "MIF_xxxx" document, items S.1-S.22

   NOTE*: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.*

2. **Briefly summarize any concerns about the measure specifications.**

   Panel member 1: No concern – This is a well-known measure that CMS has been using for years to provide Star ratings to drug plans.

   Panel member 2:

   a. Numerator is unclear: As currently described, the measure is extremely unclear as to whether the PDC involves three separate and independent rating or a composite of the three. As described in the Measure Information form it appears as though rating is on a patient level and coverage in any one of the areas would qualify for coverage in the numerator. However, all the testing was done on the basis of individual metrics. Either approach is problematic, as a patient prone to be compliant with one medication is more likely to be compliant with another and vice versa. In any event, if a patient has been identified in the denominator by two prescriptions for diabetic medication and two for RAS medication and is subsequently has 100% of his days in the assessment period covered by diabetic medication and zero days covered by RAS medication, is his score 100%, 50% or 0%? Or does he have two scores, one 100% for diabetes and one 0% for RAS?

   b. Numerator penalizes therapeutic success. If patient is being treated for diabetes and hypertension and successfully loses weight (or has gastric bypass surgery) and now no longer is hypertensive nor glucose intolerant and comes off medication he stays in the denominator, but score goes down as "nonadherent" In the numerator.

   c. Denominator defines disease categories by two prescriptions for the class of medication. Therefore, if patient has diabetes, is not being treated he/she in reality is not being covered with medication but is invisible to this measure.

   d. If you are found to be statin intolerant you might well have one prescription for a statin, found to have muscle symptoms, and then tried on another statin, thereby entering the denominator for the statin group, and then taken off of all statins and started on extimibe or other alternative medication—you would thereafter have a 0% despite appropriate medical therapy.

   e. Although more of a problem of face validity and evidence base rather than definition, but the rationale for the measure is medication adherence. Measure assumes that filling a prescription=medication adherence. Measure sponsors provide no evidence to substantiate that assumption (or to quantify degree to which the two can and cannot be equated)

Panel member 3: It is unclear how many unique patients appear in numerator and denominator. Further, the integration of data from Medicare and IHA appears to lead to exclusion of patients/organizations but the magnitude is unclear.

Panel member 4: None

Panel member 5: While the medication names are listed that meet the numerator definition (i.e. response to S.5 on MIF) there is no list of codes for such medications provided (e.g. NDC), which is what I assume is used to actually identify the given medication when computing measure results.

RELIABILITY: TESTING

Submission document: "MIF_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

3. **Reliability testing level** ☒ **Measure score** ☐ **Data element** ☐ **Neither**

   Panel member 2: As noted above in response to #2a, all testing was done on the basis of measure as determined by category of medication. If the three measures are intended to function completely independently such that a given patient might have completely different scores in each of the three areas, then the reliability testing performed makes sense. Otherwise, it does not.

4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure**
   ☒ **Yes** ☒ **No**

   Panel member 4: All testing was conducted using the same datasets for each line of business except the following:

   • missing data and unadjusted reliability testing for Medicare: used the 100% CMS Medicare PDE data from 2014

5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of patient-level data conducted?

   ☐ **Yes** ☐ **No**

   Panel member 5: Score level testing conducted

6. **Assess the method(s) used for reliability testing**

   Submission document: Testing attachment, section 2a2.2

   Panel member 1: Appropriate method (signal to noise ratio) was used to assess reliability of the proposed PDC measure for Medicare and Medicaid data separately.

   Panel member 3: Split half reliability was performed at the plan level by insurance type and medication class and is appropriate.

   Panel member 2: Beta binomial model that appeared appropriate for unadjusted data. Split-half approach for risk-adjusted data.

   Panel member 4: For unadjusted scores, the developer uses the Beta-binomial model (Adams 2009) to estimate signal-to-noise

   For adjusted scores, the developer reports split-half correlations with randomly selected subsets of patients

   Panel member 5: "Reliability testing was conducted for the unadjusted measure scores for Medicare and Medicaid, and the risk-adjusted measure scores for Medicare…." [p7]

   "…For the Medicare and Medicaid unadjusted measure rates, the reliability of the computed measure scores was measured as the ratio of signal-to-noise. The signal is the proportion of the variability in measured performance that can be explained by true differences in plan (or contract) performance." [p7]

"A beta-binomial model was used to calculate plan-specific reliability scores based on the method outlined by Adams.[1] The reliability score is defined as the ratio of the plan-to-plan variance to the sum of the plan-to-plan variance and the plan-specific error. The plan-to-plan variance is an estimate of the variance of the true rates. The plan-specific error variance is the sampling or measurement error.

$$reliability = \frac{\sigma^2_{plan-to-plan}}{\sigma^2_{plan-to-plan} + \sigma^2_{plan-specific-error}}$$

Risk adjustment was applied at the measure score level. As such, the Adams beta binomial methodology described above could not be used to assess reliability of the risk-adjusted measure scores. To assess reliability of the risk-adjusted measure scores for Medicare, we employed a split-half approach where plan-contract performance was measured using a random sample of beneficiaries, and then measured again using a second random sample. The two groups are independent samples, with each sample including half of the population within each plan-contract. This means that each plan-contract is measured twice, but each measurement is made using an entirely distinct set of beneficiaries. As a metric of agreement, we calculated the intra-class correlation coefficient (ICC)[2] and assessed the values according to conventional standards.[3] " [p8]

[ ] Test types appears reasonable

7. **Assess the results of reliability testing**

Submission document: Testing attachment, section 2a2.3

Panel member 1: The results indicate that the PDC measure is reliable though the risk-adjusted measure is less than enthusiastic. The measure developer postulates that one potential reason for low ICC scores for diabetes medications and RASA are due to the fact that only 5% of the Medicare population was used for testing of this measure. Since the authors are in possession of the data, they could have easily tested this hypothesis by increasing the sample size in subsequent iterations.

Panel member 4: The unadjusted scores demonstrate high reliability; the adjusted scores is indeterminate

Panel member 2: Beta binomial model suggested high reliability. Split half approach was much more moderate with ICC of 0.354, 0.3513 and 0.5022 for Diabetes, RASA and Statins respectively

Panel member 3: While the unadjusted reliability coefficients exceed 0.85, the risk-adjusted scores are low for diabetes and RASA, and moderate for Statins. The developer attributes this finding to the 5% sample of the Medicare population that may have differentially affected smaller health plans, accounting for the low ICCs in the split half analysis.

Panel member 5:

"Unadjusted Measure Scores

Using the parameter estimates from the beta-binomial model, we computed individual plan/contract reliability scores. Table 5 shows the distribution of the plan/contract level scores for Medicare and Medicaid.

[table on p8 omitted]

The mean reliability score for the Medicare plan-contract (with median) were 0.8492 (0.9316) for Diabetes, 0.8953 (0.9724) for RASA, and 0.9171 (0.9793) for Statins.

The mean reliability score for the Medicaid plans (with median) were 0.9174 (0.9655) for Diabetes, 0.9340 (0.9798) for RASA, and 0.9305 (0.9781) for Statins.

Risk-Adjusted Measure Scores for Medicare

The intra-class correlation between the two risk standardized scores among the two samples was 0.3548 for Diabetes, 0.3513 for RASA and 0.5022 for Statins. " [p8-9]

"Unadjusted Measure Scores

A reliability score of 0.7 is considered the minimum threshold for reliability. Based on the mean reliability scores between 0.85 (Diabetes) and 0.92 (Statins) for Medicare and 0.92 (Diabetes) and 0.93 (RASA and Statins) for Medicaid, the measure scores for the three therapeutic categories are considered reliable.

Risk-Adjusted Measure Scores for Medicare

The ICC scores for Diabetes and RASA are considered low, while the ICC score for Statins is considered moderate according to conventional interpretation.[1] However, it is important to note that the analysis was conducted using the 5% sample of the Medicare population, and sample size is one of the drivers of reliability.

Smaller plan-contracts may negatively impact the ICC as the random split is more likely to introduce noise, since the two halves may not be equally balanced, unlike large plan-contracts where we expect both samples to be normally distributed due to the law of large numbers. Thus, we anticipate the reliability would improve when applied to the total Medicare population. This is evident in the high reliability for the unadjusted measure scores for Medicare, which was conducted using the 100% CMS PDE data. " [p9]

Notes:

[ ] It was stated that a signal to noise ratio test was employed. However, such results are not provided.

[ ] Results were provided for a simple calculation of mean & median scores. I don't perceive this is statement of the reliability of the measure.

[ ] ICC low for diabetes & RASA

[ ] ICC moderate for statins

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

   ☐ **No**

   ☐ **Not applicable** (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

   ☐ **No**

   ☒ **Not applicable** (data element testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and all testing results):

    ☒ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

    ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has not been conducted)

    ☒ **Low** (NOTE: Should rate LOW if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

    ☐ **Insufficient** (NOTE: Should rate INSUFFICIENT if you believe you do not have the information you need to make a rating decision)

11. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**

    Panel member 1: See my rational offered in 7 and 8 above.

Panel member 5:

Regarding ambiguous specifications: See my response to question #2 above.

Regarding other comments / concerns on reliability, see my response to question #7 above.

Panel member 4: The submission is close to a best practice in the reporting of reliability.

Panel member 2: Results of ICC for risk-adjusted data are concerning.

Panel member 3: Risk adjustment appeared to have a substantial impact on reliability.

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. **Please describe any concerns you have with measure exclusions.**

Submission document: Testing attachment, section 2b2.

Panel member 1: None

Panel member 3: Exclusion of ESRD patients and patients on insulin (effectively all patients with Type 1 diabetes) excluded up to ~25% of patients in plan-contracts, and 7-8% of the population for each variable.

Panel member 2: Exclusion for patients taking Entresto, although somewhat logical in that that medication is indicated for treatment of congestive heart failure and not hypertension, if a patient has hypertension and congestive heart failure (which is an extremely common scenario, and is started on an RAS and switched to Entresto he would be dropped from denominator even though he may actually be being provided with a medication to treat the condition for which he was entered into the RAS category to start with. However, impact of dropping patient from analysis rather than "crediting" the plan for treating with RAS would likely be very small.

Panel member 4: None

Panel member 5: The MIF specifications of exclusions (i.e. S.9, p. 10-11) notes hospice & ESRD cases are excluded if hospice or ESRD services are received anytime during the treatment period. It seems more logical to only exclude such cases when hospice or ESRD is present at the onset of the measurement. The development for the need for hospice or ESRD during the treatment year may be a reflection of poor quality care. Of course, quality of care is what we are measuring.

Suggest the measure steward revisit this specification to limit the exclusion cases where hospice or ESRD are present at the onset of the measurement period only.

13. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

Submission document: Testing attachment, section 2b4.

Panel member 1: None

Panel member 3: Although differences between therapeutic categories were small, because the risk-adjusted standard deviations were also small, the differences were statistically significant.

Panel member 2: Provided each of the three categories is assessed separately, it appears as though potentially meaningful differences can be identified.

Panel member 4: None

Panel member 5: "For the Medicare population, for Diabetes, the mean rate (with standard deviation [SD]) was 82.1% (5.5%), for RASA the mean rate (SD) was 85.7% (5.0%) and for Statins the mean rate (SD) was 80.6% (5.9%)." [p32]

[ ] No concerns. There is reasonable variation.

14. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**

Submission document: Testing attachment, section 2b5.

Panel member 1: None
Panel member 3: N/A
Panel member 4: None
Panel member 5: NA

15. **Please describe any concerns you have regarding missing data.**

Submission document: Testing attachment, section 2b6.

Panel member 1: None

Panel member 4: None

Panel member 3: Missing data on race (20%) resulted in exclusion of the race variable from risk adjustment. However, models seen with and without race were comparable.

Panel member 5: [ ] No concerns.

16. **Risk Adjustment**

16a. **Risk-adjustment method** ☐ **None** ☒ **Statistical model** ☐ **Stratification**

16b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☐ Yes ☐ No ☒ Not applicable

16c. **Social risk adjustment:**

16c.1 Are social risk factors included in risk model? ☒ Yes ☐ No ☐ Not applicable

16c.2 Conceptual rationale for social risk factors included? ☐ Yes ☐ No

16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☐ Yes ☐ No

16d.**Risk adjustment summary:**

16d.1 All of the risk-adjustment variables present at the start of care? ☒ Yes ☐ No

16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☐ Yes ☐ No **Panel member 5**: NA - factors are present at the start of care

16d.3 Is the risk adjustment approach appropriately developed and assessed? ☒ Yes ☐ No

16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration)
☒ Yes ☒ No **Panel member 5**: See my "notes" below to question #16e.

16d.5.Appropriate risk-adjustment strategy included in the measure? ☒ Yes ☐ No

16e**. Assess the risk-adjustment approach**

Panel member 1: As documented in the Section 2b.3. of the testing document, the measure developer provides detailed rationale for risk-adjustment (which was informed by the PQA Risk Adjustment Advisory Panel or RAAP), and I have no additional concern with their methodology.
Panel member 5: "A comparison of agreement between the two risk adjustment methodologies showed almost perfect agreement, with kappa = 0.99 for Diabetes, 0.98 for RASA and 0.97 for Statins. This was much higher than the unadjusted vs. random effects models (0.69-0.80). This showed that SDS risk adjustment was more appropriate for evaluating performance scores compared to the unadjusted measure scores. In addition, as shown in Tables 19-21, we observed significant shifts in deciles post risk-adjustment, with over 50% of plan-contracts changing deciles.

The c-statistic is used to assess model discrimination, and ranges from 0.5 to 1.0 with 0.5 indicating the model is no better than random prediction and 1.0 showing perfect prediction. In research, a c-statistic of 0.7 or greater indicate acceptable discrimination. However, with performance measurement, the purpose of risk adjustment is to reduce bias due to patient characteristics present at the start of care, not to completely explain variations in outcomes, and therefore does not include variables related to quality of care.

It is important to note that the variables included in this analysis have been found to have an impact on outcome measures in other studies. This suggests that although the covariates used for risk adjustment in this

study are important, there may be other covariates that could improve the model, such as clinical variables for diagnoses, disease severity, etc. As with any risk adjustment modeling, the model can only account for measurable and available covariates. Therefore, if any unmeasured factors are not randomly distributed within contracts, the risk adjustment methodology may not adequately mitigate the impact of these unmeasured factors.

Finally, the risk decile plots show that the higher deciles of the predicted outcomes were associated with higher observed outcomes. In addition, within each decile, there is no meaningful discrepancy between the observed PDC score in a decile and that predicted by the model, which shows good discrimination and predictive ability of the models." [p29]

Notes:

[ ] The response to the question 2b3.10 neglects to summarize the c- statistic results which were 0.583 to 0.597 [Table 14 on p27], which is very poor. 0.5 indicates the model is "no better than random prediction".

Panel member 4: Given that this is a process measure the rationale for risk adjustment is not entirely clear**.**

Panel member 3: Risk adjustment appeared to move plans' ranks by at least one decile for 75% of the plans. However the absolute decile change was relatively small ($\overline{x}$ ~1.5%). Risk adjustment was performed with individual and community level variables.

VALIDITY: TESTING

17. **Validity testing level: ☒ Measure score ☐ Data element ☐ Both**
18. **Method of establishing validity of the measure score:**
    - ☒ **Face validity**
    - ☒ **Empirical validity testing of the measure score**
    - ☐ **N/A (score-level testing not conducted)**
19. **Assess the method(s) for establishing validity**

    Submission document: Testing attachment, section 2b2.2

Panel member 1: Both the methods of convergent validity and face validity in the context of this measure has been explained well, I have no concerns.

Panel member 5: "Convergent Validity Convergent validity was tested for each therapeutic category for the Medicare population using the publicly available CMS Medicare Part C & D Star Ratings data.[1] Correlation was examined using the Pearson correlation statistics between each of the therapeutic categories and other performance measures used in the Star Ratings program.

For Diabetes, we examined whether the measure rate is correlated with the *Diabetes Care – Blood Sugar Controlled* measure used in the CMS Part C Star Ratings program. We hypothesized that organizations that perform well on the PDC Diabetes measure should perform well on the *Diabetes Care – Blood Sugar Controlled* measure as both focus on diabetes care, and adherence to anti-hyperglycemic agents can lower blood sugar and decrease complications such as visual loss and renal failure.[2,3]

For RASA, convergent validity was tested by exploring whether the measure rate is correlated with the *Controlling Blood Pressure* measure used in the CMS Part C Star Ratings program. We hypothesized that organizations that perform well on the PDC RASA measure should perform well on the *Controlling Blood Pressure measure*. According to the 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA hypertension guidelines and the 2018 American Diabetes Association guidelines, medication nonadherence is a major contributor to poor control of hypertension and a key barrier to reducing mortality.[4,5] Moreover, studies have shown improved clinical outcomes for individuals who are adherent to their medications.[6]

For Statins, convergent validity was tested by exploring whether the measure rate is correlated with the *Statin Use in Persons with Diabetes* measure used in the CMS Part D Display measures. We hypothesized that

organizations that perform well on the PDC Statins measure should perform well on the *Statin Use in Persons with Diabetes* measure. Atherosclerotic cardiovascular disease (ASCVD) is the leading cause of morbidity and mortality for individuals with diabetes in addition to being the largest contributor to costs of diabetes care.[4] Individuals with diabetes who are 40-75 years old are at a markedly increased lifetime risk for the development of ASCVD, experience greater morbidity, and are at a decreased likelihood of survival following the onset of ASCVD. HMG-CoA reductase inhibitors, also known as statins, are recommended for management of dyslipidemia and/or primary prevention of cardiovascular disease (CVD) in several treatment guidelines.[7-11] By lowering LDL cholesterol, statins decrease the risk of CVD morbidity and mortality." [p10]

"Face Validity PQA uses a systematic, transparent, consensus-based measure development, testing, and endorsement process. That process was used in 2008 to develop this measure. The measure was assessed for face validity (i.e., whether it appears to measure what it intends to measure) through review by workgroup participants that developed the measure (PQA Adherence Workgroup), the PQA Quality Metrics Expert Panel (QMEP), and PQA's full membership.

The 2018 PQA Measure Update Panel and QMEP most recently reviewed this measure. These panels include individuals with expertise and experience in pharmacy, medicine, research, and clinical or other technical expertise related to quality improvement and measure development." [p11]

Notes:

[ ] Convergent validity: Seems like a reasonable approach.

[ ] Convergent validity: One issue is the comparator of the CMS star ratings is Medicare only cases. Meanwhile, the measure being assessed includes both Medicare & Medicaid cases. Thus, we're neglecting checking this form of validity for the Medicaid population.

[ ] Convergent validity: One question is it's not made clear that the time periods match regarding: a) results from this measure under review & b) the Medicare star rating. Re "a": the time period is unstated. Re "b" on p12 [under table 6] it states "*Correlation analyses conducted using the CMS Medicare Part C & D Star Ratings Data from January – December 2016.*"

[ ] Face validity: This is a very vague & obtuse explanation of the face validity process. Suggest the measure steward provide more specifics of the process employed to enable others to access face validity.

Panel member 4: The developer examines the Pearson correlation among related measures.

Panel member 2: Face validity from previous submission as well as submitted (and more recent nonsubmitted) literature provide strong support for face validity

Empiric testing of validity was weak—tested correlation with other process measures—stated purpose of metric is to improve clinical outcomes. Since the measure proponents have the access to the claims data which contains the needed information regarding outcome (mortality, hospital admission, overall cost of care, etc.) much more meaningful empiric testing would have been to demonstrate the association of high performance with improved clinical outcome.

20. **Assess the results(s) for establishing validity**

Submission document: Testing attachment, section 2b2.3

Panel member 1:I agree with the results of convergent validity (albeit small correlation for statin PDC measure). The measure has also been considered to have face validity by the members of the workgroup participants that developed the measure (PQA Adherence Workgroup), the PQA Quality Metrics Expert Panel (QMEP), and PQA's full membership, and therefore I have no further concerns.

Panel member 5: "Table 6. Convergent Validity Testing for Medicare…

Therapeutic Category	Comparison	Correlation Coefficient	*p*-Value
Diabetes	C15: Diabetes Care - Blood Sugar Controlled	0.465	<0.0001
RASA	C16: Controlling Blood Pressure	0.517	<0.0001
Statins	DMD15: Statin Use in Persons with Diabetes	0.346	<0.0001

RASA: renin-angiotensin system antagonists

Note: Correlation analyses conducted using the CMS Medicare Part C & D Star Ratings Data from January – December 2016." [p12]

"Based upon the systematic, consensus-based PQA measure development process designed to assure face validity, the measure has been determined to have face validity." [p12]

Notes:

[ ] Convergent validity evidences a modest correlation.

[ ] Face validity: In response to question #21 above I noted "This is a very vague & obtuse explanation of the face validity process." Regarding the results presented (immediately above), the explanation of the face validity findings are equally vague & non-specific. The measure steward could provide more detailed findings form the face validity process beyond stating "*the measure has been determined to have face validity*."

Panel member 3: The association of each therapeutic measure with disease control reflected in the relevant CMS Star Ratings provided evidence of convergent validity. However, error bars and mean values (vs. rankings provided in Figures 1-3) would have added evidence for discriminant validity.

Panel member 2: As noted, face validity was strong; empiric testing suboptimal

Panel member 4: The developer reports low (weak) validity at the measured entity level.

Panel member 3: Both consensus-based face validity and convergent validity were assessed. Convergent validity of each therapeutic category with CMS Part C&D Star Ratings showed significant correlations, as expected since use of medications and disease control should be associated.

21. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**

    Submission document: Testing attachment, section 2b1.

    ☒ **Yes**

    ☒ **No**

    ☐ **Not applicable** (score-level testing was not performed)

Panel member 5: [ ] Face validity: In response to question #21 above I noted "This is a very vague & obtuse explanation of the face validity process."

22. **Was the method described and appropriate for assessing the accuracy of ALL critical data elements?** *NOTE that data element validation from the literature is acceptable.*

    Submission document*: Testing attachment, section 2b1.*

    ☒ **Yes**

    ☐ **No**

    ☒ **Not applicable** (data element testing was not performed)

23. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

    ☒ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

☒ **Low** (NOTE: Should rate LOW if you believe that there are threats to validity and/or relevant threats to validity were not assessed OR if testing methods/results are not adequate)

☐ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level is required; if not conducted, should rate as INSUFFICIENT.)

24. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.**

Panel member 1: See my rationale for "High" rating in 21 and 22 above.

Panel member 5:

Notes (repeated response from question #21 above):

[ ] Convergent validity: Seems like a reasonable approach.

[ ] Convergent validity: One issue is the comparator of the CMS star ratings is Medicare only cases. Meanwhile, the measure being assessed includes both Medicare & Medicaid cases. Thus, we're neglecting checking this form of validity for the Medicaid population.

[ ] Convergent validity: One question is it's not made clear that the time periods match regarding: a) results from this measure under review & b) the Medicare star rating. Re "a": the time period is unstated. Re "b" on p12 [under table 6] it states "*Correlation analyses conducted using the CMS Medicare Part C & D Star Ratings Data from January – December 2016.*"

[ ] Face validity: This is a very vague & obtuse explanation of the face validity process. Suggest the measure steward provide more specifics of the process employed to enable others to access face validity.

Notes (repeated from question response #22):

[ ] Convergent validity evidences a modest correlation.

[ ] Face validity: In response to question #21 above I noted "This is a very vague & obtuse explanation of the face validity process." Regarding the results presented (immediately above), the explanation of the face validity findings are equally vague & non-specific. The measure steward could provide more detailed findings form the face validity process beyond stating "*the measure has been determined to have face validity*."

Panel member 4: A demonstration of an implicit quality construct is the lowest level of acceptable empirical validity testing. To demonstrate a moderate level, the developer must show an empirical association between the implicit quality construct and the material outcome.

Panel member 2: Updating of cited literature with empiric testing of measure association with clinical outcome would have provided very strong evidence of validity. Face validity is sufficient to at least rate validity as moderate. This measure is somewhere between moderate "plus" and high "minus"

Panel member 3: See #22

ADDITIONAL RECOMMENDATIONS

25. **If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.**

Committee Pre-evaluation Comments:
Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Reliability-Specifications: Which data elements, if any, are not clearly defined? Which codes with descriptors, if any, are not provided? Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? What concerns do you have about the likelihood that this measure can be consistently implemented?

- PDC Proportion of Days Covered is defined well now in literature and preferred method of medication adherence calculations for health plans, both commercial and medicare/medicaid.
- The reliability improved with the increased sample size.
- no concerns

2a2. Reliability - Testing: Do you have any concerns about the reliability of the measure?

- No it has 10 years of use in Medicare
- No
- same as above- •no concerns

2b1. Validity -Testing: Do you have any concerns with the testing results?

- they compared the rates to other measures in 750 Medicare plans, validated the risk adjustment piece and performed a correlation analysis with a moderate result.
- I think reliability and face validity is weak, and is perhaps one of the stronger arguments for discussion on this measure. Although there were positive correlations, they were not remarkable.
- accept the Scientific Methods rating

2b4-7. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data)2b4. Meaningful Differences: How do analyses indicate this measure identifies meaningful differences about quality? 2b5. Comparability of performance scores: If multiple sets of specifications: Do analyses indicate they produce comparable results? 2b6. Missing data/no response: Does missing data constitute a threat to the validity of this measure?

- The missing data was with race but it does not effect the validity as the beneficary level eligibility includes the appropriate inclusion without needing race. NOTE: participate may or may not chose to include their race at the prescriptin claims level.
- No
- same as above •accept the Scientific Methods rating

2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment)2b2. Exclusions: Are the exclusions consistent with the evidence? Are any patients or patient groups inappropriately excluded from the measure?2b3. Risk Adjustment: If outcome (intermediate, health, or PRO-based) or resource use performance measure: Is there a conceptual relationship between potential social risk factor variables and the measure focus? How well do social risk factor variables that were available and analyzed align with the conceptual description provided? Are all of the risk-adjustment variables present at the start of care (if not, do you agree with the rationale provided)? Was the risk adjustment (case-mix adjustment) appropriately developed and tested? Do analyses indicate acceptable results? Is an appropriate risk-adjustment strategy included in the measure?

- Race being an incomplete data point is a nuisance but does not have an impact becaus non-adherence occurs across on beneficiary levels
- I do think consideration for hospice, ESRD or other end of life diagnoses are extremely relevant, especially for statin medications.
- Accpetable results

Criterion 3. Feasibility

Maintenance measures – no change in emphasis – implementation issues may be more prominent

3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

Data Specifications and Elements

- The measure is generated from prescription claims and enrollment data
- ALL data elements are in defined fields in electronic claims
- This measure is not an eMeasure.

Data Collection Strategy

- Per developer, no extra burden or cost in the collection of the data.
- Users of measure must obtain permission from PQA and license. For commercial use, this involves the payment of a licensure fee. The licensing fee may be structured as a fixed annual amount or as a variable amount that is dependent on the volume of utilization of the measures.

Questions for the Committee:

- Are the required data elements routinely generated and used during care delivery?
- Are the required data elements available in electronic form, e.g., EHR or other electronic sources?
- Is the data collection strategy ready to be put into operational use?

Preliminary rating for feasibility: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

RATIONALE:

Committee Pre-evaluation Comments:
Criteria 3: Feasibility

3. Feasibility: Which of the required data elements are not routinely generated and used during care delivery? Which of the required data elements are not available in electronic form (e.g., EHR or other electronic sources)? What are your concerns about how the data collection strategy can be put into operational use?

- no concern as it was with retrospective data
- N/A
- Yes the measure is feasible as measure is claims based. However, some collection burden related to accessing the specifications

Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported? ☒ **Yes** ☐ **No**

Current use in an accountability program? ☒ **Yes** ☐ **No** ☐ **UNCLEAR**

OR

Planned use in an accountability program? ☐ **Yes** ☐ **No**

Accountability program details

Public Reporting and Payment Programs:

- The measure is used by the Centers for Medicare and Medicaid Services in their Part C and Part D quality and performance measurement system (Star Ratings). Its drug benefit program to evaluate Medicare prescription drug plans, both PDPs and MA-PDs. As such, it is used by a pay-for-performance program, driving quality bonus payments, as well as public reporting.

Quality Improvement Program:

- Integrated Healthcare Association (IHA) is a California multi-stakeholder, non-profit association that promotes quality improvement, accountability and affordability of health care in California. This program collects data and reports results on behalf of 12 health plans covering approximately 11.8 million members in California.

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- CMS provides the measure scores and ratings on the PDC 3 Rates measure through the Medicare Part D Star Ratings program. Plans receive their scores and ratings twice annually
- PQA receives feedback from measure users via a web form or email. Comments then are reviewed by PQA staff and brought to the Measure Update Panel (MUP), which then determines whether refinements or clarifications to the specifications are needed.
- Additionally, high performing plans are invited to present during PQA´s Annual Meeting and during PQA´s Quality Forum webinars, to highlight their quality improvement interventions that have been effective in showing improvement in PQA measures used in the Part D Star Ratings, including the PDC 3 Rates measure.

Additional Feedback:

Some of the feedback received from measured entities included:

- Health plans recommended the following changes to the PDC 3 Rates measure:
    - Exclude individuals in hospice care from all three measure rates;
    - Exclude individuals with end-stage renal disease from all three measure rates;
    - Exclude individuals with 1 or more prescription claims for sacubitril/valsartan for the PDC-RASA rate;
    - Revise the enrollment criteria to not allow any gaps in enrollment for all three measure rates; and
    - Consider sociodemographic (SDS) risk adjustment for all three measure rates.
- Feedback from others:

- PQA's Patient and Caregiver Advisory Panel (PCAP) recommended that individuals in hospice care be excluded from all three measure rates.
- PQA's Patient and Caregiver Advisory Panel (PCAP) recommended individuals with end-stage renal disease and those in hospice care be excluded from all three measure rates.

- The five changes listed above, now are reflected in the PDC 3 Rates measure specifications.

***Questions for the Committee**:*

- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?
- How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use: ☒ Pass ☐ No Pass

RATIONALE: This is a maintenance measure and is currently in a public reporting and accreditation program.

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- The developer provided data from the Centers for Medicare & Medicaid Services (CMS) Medicare Part D Star Ratings Program to evaluate prescription drug plans (both Medicare Advantage plans [MA-PDs] and stand-alone prescription drug plans [PDPs]). The developer provided separate analyses for diabetes medications, RASA, and statins for MA-PDs and PDPs. Although performance rates have improved since 2013, there is still an opportunity for improvement.

PDC Diabetes Medications:

- The mean rate has increased steadily over the last 5 reporting years (2013-2017), indicating overall improvement across plans.
  - For MA-PDs, the mean rate improved from 76.8% in 2013 to 81.5% in 2017.
  - For PDPs, the mean rate improved from 79.3% in 2013 to 83.4% in 2017.
- The standard deviation has decreased modestly over the last 5 reporting years (2013-2017), indicating that the difference in rates between high and low performing plans has narrowed slightly.
  - For MA-PDs, the standard deviation decreased from 5.9% in 2013 to 4.6% in 2017.
  - For PDPs, the standard deviation decreased from 4.8% in 2013 to 3.6% in 2017.

PDC RASA Medications (for hypertension):

- The mean rate has increased steadily over the last 5 reporting years (2013-2017), indicating overall improvement across plans.
  - For MA-PDs, the mean rate improved from 78.3% in 2013 to 83.4% in 2017.
  - For PDPs, the mean rate improved from 81.1% in 2013 to 85.8% in 2017.
- The standard deviation has decreased modestly over the last 5 reporting years (2013-2017), indicating that the difference in rates between high and low performing plans has narrowed slightly.
  - For MA-PDs, the standard deviation decreased from 5.5% in 2013 to 4.3% in 2017.
  - For PDPs, the standard deviation decreased from 4.5% in 2013 to 2.5% in 2017.

PDC Statin Medications (for hyperlipidemia):

- The mean rate has increased steadily over the last 5 reporting years (2013-2017), indicating overall improvement across plans.
    - For MA-PDs, the mean rate improved from 74.0% in 2013 to 80.2% in 2017.
    - For PDPs, the mean rate improved from 76.6% in 2013 to 82.7% in 2017.
- The standard deviation has decreased modestly over the last 5 reporting years (2013-2017), indicating that the difference in rates between high and low performing plans has narrowed slightly.
    - For MA-PDs, the standard deviation decreased from 7.1% in 2013 to 5.8% in 2017.
    - For PDPs, the standard deviation decreased from 5.1% in 2013 to 4.3% in 2017.

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

- Per developer, in the CMS 2018 Impact Assessment Report, patient impact analyses and cost estimates were conducted for the PDC-3 Rates measure for PDPs and MA-PDs (2011–2015). Health care costs avoided based on patient impacts were estimated at $4.2 billion-$26.9 billion.

Potential harms There are no harms identified by the developer.

Additional Feedback: N/A

Questions for the Committee:

- How can the performance results be used to further the goal of high-quality, efficient healthcare?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability and use: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 4: Usability and Use

4a1. Use - Accountability and Transparency: How is the measure being publicly reported? Are the performance results disclosed and available outside of the organizations or practices whose performance is measured? For maintenance measures - which accountability applications is the measure being used for? For new measures - if not in use at the time of initial endorsement, is a credible plan for implementation provided?4a2. Use - Feedback on the measure: Have those being measured been given performance results or data, as well as assistance with interpreting the measure results and data? Have those being measured or other users been given an opportunity to provide feedback on the measure performance or implementation? Has this feedback has been considered when changes are incorporated into the measure?

- 750 Medicare Contract Plans receive feedback every 3 months. Yes year round feedback and perfomance measurement of the PDC. Yes
- Recommendations to include hospice and ESRD appear to have been incoroporated into the measure.
- Yes, via open comments, panel discussions and used in CMS programs

4b1. Usability – Improvement: How can the performance results be used to further the goal of high-quality, efficient healthcare? If not in use for performance improvement at the time of initial endorsement, is a credible rationale provided that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations?4b2. Usability – Benefits vs. harms: Describe any actual unintended consequences and note how you think the benefits of the measure outweigh them.

- the benefit is identifying non-adherence in plan population to improve drug adherence and improve person centered outcomes and lower health care costs.
- This has led to some improvements, but I do think has led to some unintended consequences in terms of duplication of efforts to promote compliance with the measure. (insurers, physicians, etc). This is a questionable use of resources for uncertain benefit.

- "5. Usable measure, there are opportunities to use this measure in other programs to drive improved outcomes. "

Criterion 5: Related and Competing Measures

Related measures

- 1879 : Adherence to Antipsychotic Medications for Individuals with Schizophrenia
- 1880 : Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder

Harmonization

- As noted by the developer, the measures address adherence using the same methodology (i.e., proportion of days covered [PDC]), however they have different areas of focus and different target populations.

Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures

5. Related and Competing: Are there any related and competing measures? If so, are any specifications that are not harmonized? Are there any additional steps needed for the measures to be harmonized?

- this measure is specific for person taking medications for diabetes, RASA for blood presure and statin thereapy
- NA
- "6. Yes, the methodology is used across multiple measure but the focus on these disease states is needed and appropriate for continued monitoring"

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 06/12/2019

- **No NQF Members have submitted support/non-support choices as of this date.**

1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. ***Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

Evidence_Submission_Form_PQA_PDC_040819_FV.docx

1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

1a. Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** 0541

Measure Title: Proportion of Days Covered (PDC): 3 Rates by Therapeutic Category

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

Date of Submission: 4/8/2019

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

Outcome

☐ Outcome:

☐ Patient-reported outcome (PRO):

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

☐ Intermediate clinical outcome (*e.g., lab value*):

☒ Process: Adherence to medications leads to improved clinical outcomes and lower healthcare costs

☐ Appropriate use measure:

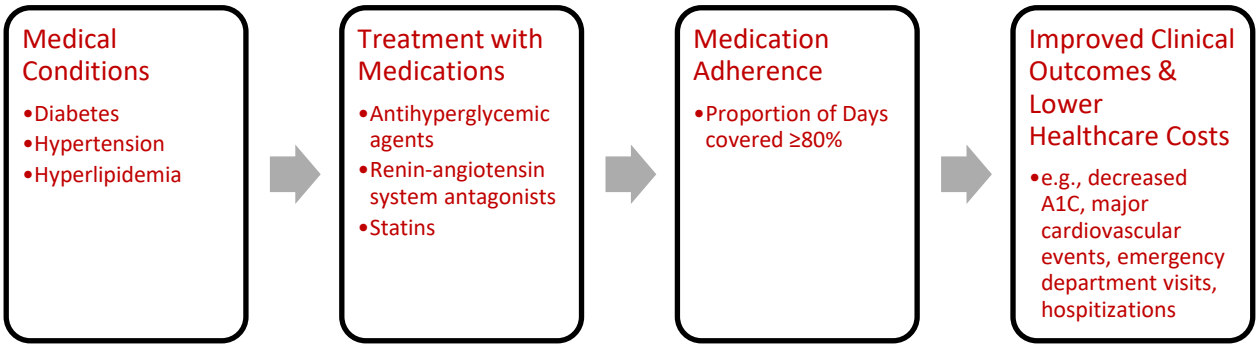
☐ Structure:

☐ Composite:

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

This measure evaluates adherence to three therapeutic categories of medications aligned with three common chronic conditions: diabetes agents for diabetes, renin-angiotensin system antagonists for hypertension, and statins for hyperlipidemia. Medication adherence for these conditions remains suboptimal[1-3] and multiple interventions may be used to improve adherence.[4,5] Recent evidence continues to demonstrate the

relationship of medication adherence with improved clinical outcomes and reduced healthcare costs.[1]



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5. Kini V, Ho PM. Interventions to Improve Medication Adherence: A Review. JAMA. 2018;320:2461-73. PMID: 30561486.

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

N/A

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

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

N/A

1a.3. SYSTEMATIC REVIEW(S) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

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

☐ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

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

☒ Other

Source of Systematic Review: • **Title** • **Author** • **Date** • **Citation, including page number** • **URL**	
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	
Provide all other grades and definitions from the evidence grading system	
Grade assigned to the **recommendation** with definition of the grade	
Provide all other grades and definitions from the recommendation grading system	
Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	
Estimates of benefit and consistency across studies	
What harms were identified?	
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	

1a.4 OTHER SOURCE OF EVIDENCE

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

The evidence supporting this measure is from published studies.

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

Each medication class included in this measure aligns with a common chronic medical condition: diabetes agents for diabetes, renin-angiotensin system antagonists (RASA) for hypertension, and statins for hyperlipidemia. Medication therapy is recommended as a mainstay of treatment for these conditions and clinical guidelines emphasize the importance of adherence to medications to achieve optimal outcomes.[1-6] Evidence correlates medication adherence, most commonly evaluated using the proportion of days covered (PDC) methodology, to improved clinical outcomes and decreased healthcare costs (see evidence summarized below). Adherence to diabetes medications, RASA, and statins remains suboptimal, with demonstrable opportunity for improvement.[7-9]

Proportion of Days Covered Methodology for Medication Adherence

The PDC and medication possession ratio (MPR) are the two most commonly used methodologies to characterize medication adherence in the published literature.[10] Compared to other adherence estimates, the

MPR and PDC methodologies have the greatest predictive validity (C-statistic, 0.701) in predicting diabetes-specific hospitalizations.[11]

There have been several criticisms of the MPR methodology, most notably the tendency for this approach to overestimate adherence. A comparison of 11 medication adherence methodologies by Hess et al.[12] found MPR and a modified MPR overestimated adherence rates compared to PDC. Furthermore, in a literature review conducted by Raebel et al.[10] to evaluate adherence methodologies, MPR was found to have multiple calculation methods (i.e., lack of standardization) and is inflated when medication switching within the same class occurs.

Conversely, the PDC methodology provides a more conservative estimate of adherence in instances of frequent medication switches and concomitant therapy with multiple drugs within a class.[10] The International Society of Pharmacoeconomics and Outcomes Research (ISPOR) published a guidance document on medication adherence studies and notes the PDC methodology has an advantage of simultaneously reflecting both compliance and persistence.[13]

This measure evaluates adherence as a dichotomous variable at a threshold of 80% PDC. The preponderance of studies evaluating medication adherence utilizes a threshold of 80%. A systematic review of adherence studies conducted by Andrade et al.[14] found over 90% of published adherence studies used an 80% threshold to classify adherence. This threshold has also been correlated to improvements in clinical outcomes, healthcare resource utilization and costs (as summarized below).

Medication Adherence Impact on Clinical Outcomes and Healthcare Costs

Studies included in the 2014 submission are noted in [purple] font, and more recent studies through March 2019, which were added for the spring 2019 endorsement maintenance submission, are noted in red font.

In 2002, Wei et al.[15] conducted a retrospective cohort study to evaluate the effect of adherence to statins on recurrence of MI and all-cause mortality (N=5,590). Compared with those not taking statins, those who had ≥80% adherence to statin treatment had an adjusted relative risk (aRR) of recurrent MI of 0.19 (95% confidence interval [CI], 0.08-0.47) and all-cause mortality of 0.47 (95% CI, 0.22-0.99). There was no significant reduction in either endpoint for those who were less <80% adherent to statins.

In 2004, Lau and Nau[16] conducted a retrospective study to examine the association between adherence to oral diabetes medications and subsequent hospitalization the following year among patients with type 2 diabetes (N=900). Compared with patients who were adherent (MPR ≥80%) to oral antihyperglycemic medications, those who were nonadherent were much more likely to have a hospitalization the following year (Odds Ratio [OR], 2.53; 95% Confidence Interval [CI], 1.38-4.64).

In 2005, Sokol et al.[17] conducted a retrospective cohort study to evaluate the impact of medication adherence (PDC ≥80%) on healthcare utilization and cost for diabetes, hypertension, hyperlipidemia, and CHF (N=137,277). For all four conditions, hospitalization rates were significantly lower for adherent patients (P<0.0001). Medication adherence was also associated with lower medical costs for diabetes, hypertension, and hyperlipidemia (P<0.05).

In 2006, Ho et al.[18] conducted a retrospective study to evaluate the effects of medication nonadherence to cardioprotective medications on hospitalization and mortality among patients with diabetes mellitus and ischemic heart disease (N=3,998). In multivariable analysis, receipt of any angiotensin-converting enzyme (ACE)/angiotensin 2 receptor blockers (ARBs), beta-blockers, or statins was associated with lower all-cause mortality (OR, 0.65; 95% CI, 0.43-0.99). Medication adherence (PDC ≥80%) to any cardioprotective medications was associated with lower all-cause mortality (OR, 0.52; 95% CI, 0.39-0.69) compared with non-adherence. In contrast, there was no mortality difference between patients receiving cardioprotective medications who were non-adherent compared with patients not receiving any medications (OR, 1.01; 95% CI, 0.64–1.61).

In 2011, Roebuck et al.[19] conducted a retrospective analysis to evaluate the relationship between medication adherence (MPR ≥80%) and the utilization and cost of health services in patients with CHF (N=16,353), hypertension (N=112,757), diabetes (N=42,080), or hyperlipidemia (N=53,041). Across all conditions,

adherence (MPR ≥80%) was associated with significantly lower annual inpatient hospital days and emergency department visits. The additional annual pharmacy spending was offset by the decrease in medical spending.

In 2014, Choudhry et al.[20] conducted a retrospective analysis to evaluate the relationship between medication adherence (PDC ≥80%) and post-myocardial infarction adverse coronary events (N=4,117). Compared with patients randomized to usual care, patients who were adherent to statins, beta-blockers, and ACE/ARBs were significantly less likely to experience first major vascular event or revascularization (hazard ratio [HR] range, 0.64-0.81). In contrast, nonadherent patients showed no benefit (HR range, 0.98-1.04; P≤0.01 for the difference in HRs between adherent and nonadherent patients).

Recent evidence continues to demonstrate the relationship of medication adherence with clinical and economic outcomes.

A 2016 study by Korhonen et al.[21] evaluated the relationship between statin adherence (PDC ≥80%) and ischemic stroke in patients with diabetes (N=52,868). Adherence to statins was associated with a 23% decreased incidence of ischemic stroke (95% CI, 14–32%) compared to nonadherence.

Boye et al.[22] examined the relationship of medication adherence thresholds with clinical outcomes and cost among older adults enrolled in Medicare with type 2 diabetes (N=123,235). A PDC ≥80% was associated with a lower probability of hospitalization (37.4% vs. 56.2%), emergency department visits (54.2% vs. 72.1%), and acute complications (13.0% vs 24.1%) compared to PDC <20% (P<0.001). PDC ≥80% was also associated with lower all-cause acute care and outpatient costs. The mean outpatient and acute-care costs were $17,298 and $13,373 with a PDC ≥80% compared with $28,086 and $32,340 with a PDC <20% (P<0.05), respectively.

These findings are not limited to the Medicare population. A 2018 study by Roebuck et al.[23] assessed the impact of medication adherence within seven chronic conditions on health services utilization among Medicaid enrollees (N=656,646 blind/disabled adults; N=704,368 other adults). Full adherence (PDC ≥80%) was associated with 8%–26% fewer hospitalizations and 3%–12% fewer emergency department visits among those with CHF, hypertension, diabetes, and schizophrenia/bipolar. In all analyses, full adherence was associated with up to 15% fewer outpatient physician/clinic visits.

Analyses in commercial populations report similar findings. A 2019 study by Campbell et al.[24] investigated the association of diabetes adherence (PDC ≥ 80%) with healthcare utilization and expenditures among commercially-insured adults (N=1,576,112). Adherence was associated with fewer inpatient visits (risk ratio [RR]=0.834, 95% CI, 0.819-0.850) and lower inpatient (cost ratio [CR]=0.833, 95% CI, 0.829-0.836) and total (CR=0.958, 95% CI, 0.954-0.962) healthcare costs.

Similar findings were observed with statin adherence. Chinthammit et al.[25] evaluated the association of statin adherence (PDC ≥ 80%) with healthcare utilization and expenditures among commercially-insured adults (N= 4,450,308). Adherence was associated with fewer inpatient visits (RR=0.746, 95% CI=0.739-0.753) and lower inpatient (CR=0.780, 95% CI=0.779-0.782) and total (CR=0.975, 95% CI=0.973-0.977) healthcare costs.

Axon et al.[26] analyzed the association of RASA adherence (PDC ≥ 80%) with healthcare utilization and expenditures among commercially-insured adults (N= 4,842,058). Adherence was associated with fewer inpatient (RR=0.612, 95% CI=0.607-0.617) and outpatient visits (RR=0.995, 95% CI=0.994, 0.997); and lower inpatient (CR=0.614, 95% CI=0.613-0.615) and total (CR=0.876, 95% CI=0.874-0.878) healthcare costs.

In 2019, Lloyd et al.[7] estimated the cost of medication nonadherence (PDC <80%) among Medicare fee-for-service beneficiaries with diabetes, heart failure, hypertension, and hyperlipidemia (N=14,657,735). Medication nonadherence ranged from 23% for heart failure, 25% for hypertension, 35% for diabetes, to 38% for hyperlipidemia. The authors estimated the avoidable health care costs that could be saved if nonadherent beneficiaries with diabetes became adherent was $4.5 billion (over $5,000 per beneficiary) annually. Similar levels of avoidable health care costs were found among nonadherent beneficiaries with hyperlipidemia and heart failure. If nonadherent beneficiaries with hypertension became adherent, the authors estimated Medicare could save $13.7 billion annually.

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

A primary literature search was conducted via PubMed for clinical guidelines, clinical trials, systematic reviews, and observational studies (through March 2019).

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

References

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1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure *(e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*

If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

This measure, Proportion of Days Covered (PDC): 3 Rates by Therapeutic Category, evaluates adherence to three therapeutic categories of medications aligned with three common chronic conditions: diabetes agents for diabetes, renin-angiotensin system antagonists (RASA) for hypertension, and statins for hyperlipidemia. Medication therapy is recommended as a mainstay of treatment for these conditions and clinical guidelines emphasize the importance of adherence to medications to achieve optimal outcomes.

More than 26 million American adults (9.8%) have diabetes.(1) For type 2 diabetes, the most common form, pharmacologic treatment can improve clinical outcomes, including reducing chronic kidney disease (CKD) progression, major cardiovascular events, and cardiovascular mortality.(2) Approximately 46% of American adults have hypertension(1) and RASA are recommended as initial therapy for many patients for cardiovascular risk reduction, particularly those with diabetes or CKD.(3,4) Approximately 30% of American adults have elevated LDL cholesterol(1) and statin therapy is recommended for treating hyperlipidemia and also for primary prevention of cardiovascular disease in several treatment guidelines.(2,5-7)

Recent studies support the body of evidence showing that medication adherence is correlated with improved clinical outcomes and decreased healthcare costs.(8) Medication adherence for diabetes, hypertension, and hyperlipidemia remains suboptimal(9) and multiple interventions may be used to improve adherence.(10,11)

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1b.2. Provide performance scores on the measure as specified (<u>current and over time</u>) at the specified level of analysis. *(<u>This is required for maintenance of endorsement</u>. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients;*

dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

The PDC-3 Rates measure is used by the Centers for Medicare & Medicaid Services (CMS) in the Medicare Part D Star Ratings Program to evaluate prescription drug plans (both Medicare Advantage plans [MA-PDs] and stand-alone prescription drug plans [PDPs]). CMS has reported considerable variation in the measure rates among plans during the last 5 reporting years (2013-2017). This variation, as described below, demonstrates the performance gap and opportunity for health plans to improve adherence rates for the diabetes medications, renin angiotensin system antagonists (RASA), and statins.

PDC-Diabetes:

The mean rate has increased steadily over the last 5 reporting years (2013-2017), indicating overall improvement across plans.

- For MA-PDs, the mean rate improved from 76.8% in 2013 to 81.5% in 2017.
- For PDPs, the mean rate improved from 79.3% in 2013 to 83.4% in 2017.

The standard deviation has decreased modestly over the last 5 reporting years (2013-2017), indicating that the difference in rates between high and low performing plans has narrowed slightly.

- For MA-PDs, the standard deviation decreased from 5.9% in 2013 to 4.6% in 2017.
- For PDPs, the standard deviation decreased from 4.8% in 2013 to 3.6% in 2017.

The distribution of rates for 2013-2017 are summarized in the table below.

MA-PD

Values	**2013**	**2014**	**2015**	**2016**	**2017**
n	433	408	394	404	397
stddev	5.9%	6.1%	5.2%	5.0%	4.6%
mean	76.8%	77.4%	78.6%	80.1%	81.5%
min	56.0%	23.0%	48.0%	61.0%	61.0%
p10	69.0%	70.0%	72.0%	74.0%	75.0%
p20	72.0%	73.0%	74.0%	76.0%	78.0%
p25	73.0%	74.0%	75.0%	77.0%	79.0%
p30	74.0%	75.0%	76.0%	78.0%	80.0%
p40	76.0%	77.0%	78.0%	79.0%	81.0%
p50	77.0%	78.0%	79.0%	80.0%	82.0%
p60	78.0%	79.0%	81.0%	81.0%	83.0%
p70	80.0%	81.0%	81.0%	83.0%	84.0%
p75	80.0%	81.0%	82.0%	83.0%	85.0%
p80	82.0%	82.0%	83.0%	84.0%	85.0%
p90	84.0%	84.0%	84.0%	86.0%	87.0%
max	91.0%	94.0%	93.0%	98.0%	94.0%
IQR	7.0%	7.0%	7.0%	6.0%	6.0%

PDP

Values	**2013**	**2014**	**2015**	**2016**	**2017**
n	63	60	56	55	54
stddev	4.8%	4.7%	4.5%	3.9%	3.6%
mean	79.3%	79.7%	80.9%	81.9%	83.4%
min	66.0%	65.0%	68.0%	71.0%	72.0%

Values	2013	2014	2015	2016	2017
p10	74.0%	74.0%	75.0%	77.0%	80.0%
p20	76.0%	77.0%	79.0%	79.5%	81.0%
p25	77.0%	77.5%	79.5%	80.0%	82.0%
p30	77.0%	78.0%	80.0%	81.0%	82.0%
p40	79.0%	79.5%	80.0%	82.0%	82.0%
p50	80.0%	80.0%	81.0%	82.0%	83.0%
p60	81.0%	81.0%	81.0%	82.0%	84.0%
p70	82.0%	82.0%	83.0%	84.0%	84.0%
p75	83.0%	82.0%	83.0%	84.0%	85.0%
p80	83.0%	83.0%	84.0%	84.5%	86.0%
p90	84.0%	85.0%	86.0%	87.0%	89.0%
max	93.0%	95.0%	94.0%	91.0%	94.0%
IQR	6.0%	4.5%	3.5%	4.0%	3.0%

PDC-RASA:

The mean rate has increased steadily over the last 5 reporting years (2013-2017), indicating overall improvement across plans.

- For MA-PDs, the mean rate improved from 78.3% in 2013 to 83.4% in 2017.
- For PDPs, the mean rate improved from 81.1% in 2013 to 85.8% in 2017.

The standard deviation has decreased modestly over the last 5 reporting years (2013-2017), indicating that the difference in rates between high and low performing plans has narrowed slightly.

- For MA-PDs, the standard deviation decreased from 5.5% in 2013 to 4.3% in 2017.
- For PDPs, the standard deviation decreased from 4.5% in 2013 to 3.5% in 2017.

The distribution of rates for 2013-2017 are summarized in the table below.

MA-PD

Values	2013	2014	2015	2016	2017
n	447	425	406	415	415
stddev	5.5%	5.7%	4.9%	4.5%	4.3%
mean	78.3%	79.3%	80.6%	82.0%	83.4%
min	62.0%	34.0%	59.0%	67.0%	68.0%
p10	70.0%	72.0%	74.0%	76.0%	77.0%
p20	73.0%	75.0%	77.0%	78.0%	80.0%
p25	75.0%	76.0%	78.0%	79.0%	81.0%
p30	76.0%	77.0%	79.0%	80.0%	82.0%
p40	78.0%	79.0%	80.0%	82.0%	83.0%
p50	79.0%	80.0%	81.0%	83.0%	84.0%
p60	80.0%	81.0%	83.0%	83.0%	85.0%
p70	82.0%	83.0%	84.0%	85.0%	86.0%
p75	82.0%	83.0%	84.0%	85.0%	87.0%
p80	83.0%	84.0%	85.0%	86.0%	87.0%
p90	85.0%	85.0%	86.0%	87.0%	88.0%
max	92.0%	94.0%	90.0%	95.0%	93.0%
IQR	7.0%	7.0%	6.0%	6.0%	6.0%

PDP

Values	2013	2014	2015	2016	2017
n	64	61	58	57	54
stddev	4.5%	4.1%	3.7%	3.8%	2.5%
mean	81.1%	81.6%	82.8%	84.1%	85.8%
min	68.0%	70.0%	72.0%	73.0%	80.0%
p10	75.0%	76.0%	77.0%	79.0%	82.0%
p20	77.0%	78.0%	81.0%	81.0%	84.0%
p25	79.0%	80.0%	82.0%	82.0%	84.0%
p30	80.0%	80.0%	82.0%	83.0%	85.0%
p40	81.0%	81.0%	82.0%	84.0%	85.0%
p50	82.0%	82.0%	83.0%	85.0%	86.0%
p60	83.0%	83.0%	84.0%	85.0%	86.0%
p70	84.0%	84.0%	85.0%	86.0%	87.0%
p75	84.0%	84.0%	85.0%	87.0%	88.0%
p80	85.0%	85.0%	86.0%	87.0%	88.0%
p90	86.0%	86.0%	88.0%	89.0%	89.0%
max	89.0%	91.0%	89.0%	90.0%	90.0%
IQR	5.0%	4.0%	3.0%	5.0%	4.0%

PDC-Statins:

The mean rate has increased steadily over the last 5 reporting years (2013-2017), indicating overall improvement across plans.

- For MA-PDs, the mean rate improved from 74.0% in 2013 to 80.2% in 2017.
- For PDPs, the mean rate improved from 76.6% in 2013 to 82.7% in 2017.

The standard deviation has decreased modestly over the last 5 reporting years (2013-2017), indicating that the difference in rates between high and low performing plans has narrowed slightly.

- For MA-PDs, the standard deviation decreased from 7.1% in 2013 to 5.8% in 2017.
- For PDPs, the standard deviation decreased from 5.1% in 2013 to 4.3% in 2017.

The distribution of rates for 2013-2017 are summarized in the table below.

MA-PD

Values	2013	2014	2015	2016	2017
n	446	426	408	417	416
stddev	7.1%	7.0%	6.4%	5.8%	5.8%
mean	74.0%	75.1%	76.7%	78.5%	80.2%
min	40.0%	21.0%	38.0%	51.0%	50.0%
p10	66.0%	67.0%	69.0%	71.0%	73.0%
p20	69.0%	71.0%	72.0%	74.0%	77.0%
p25	71.0%	72.0%	73.0%	76.0%	78.0%
p30	72.0%	73.0%	74.0%	76.0%	79.0%
p40	74.0%	75.0%	76.0%	78.0%	80.0%
p50	75.0%	76.0%	78.0%	79.0%	81.0%
p60	76.0%	78.0%	79.0%	81.0%	82.0%
p70	78.0%	79.0%	80.0%	82.0%	83.0%

Values	2013	2014	2015	2016	2017
p75	78.0%	80.0%	81.0%	82.0%	84.0%
p80	79.0%	81.0%	82.0%	83.0%	85.0%
p90	81.0%	82.0%	83.0%	85.0%	86.0%
max	92.0%	88.0%	94.0%	92.0%	92.0%
IQR	7.0%	8.0%	8.0%	6.0%	6.0%

PDP

Values	2013	2014	2015	2016	2017
n	64	61	58	56	54
stddev	5.1%	5.1%	4.9%	4.4%	4.3%
mean	76.6%	77.7%	79.5%	80.8%	82.7%
min	53.0%	49.0%	54.0%	61.0%	59.0%
p10	72.0%	74.0%	75.0%	77.0%	79.0%
p20	74.0%	75.0%	77.0%	78.0%	81.0%
p25	75.0%	76.0%	78.0%	79.0%	81.0%
p30	75.0%	77.0%	78.0%	79.0%	82.0%
p40	77.0%	77.0%	79.0%	80.0%	82.0%
p50	77.5%	78.0%	80.0%	81.0%	83.0%
p60	78.0%	79.0%	81.0%	82.0%	83.0%
p70	79.0%	80.0%	82.0%	83.0%	84.0%
p75	80.0%	80.0%	82.0%	83.5%	85.0%
p80	80.0%	81.0%	83.0%	84.0%	86.0%
p90	81.0%	82.0%	85.0%	86.0%	87.0%
max	84.0%	86.0%	87.0%	88.0%	89.0%
IQR	5.0%	4.0%	4.0%	4.5%	4.0%

[IQR = interquartile range]

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

N/A

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. *(This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

Data used for testing included the 2016 Medicare Research Identifiable Files (RIF) 5% national sample data and the 2017 Medicare Prescription Drug Event (PDE) 100% data.

- Medicare Research Identifiable Files (RIF) 5% national sample data (January 1 – December 31, 2016): This is a nationally representative 5% sample of the Medicare population, and includes data from 554 Medicare Advantage Prescription Drug (MAPD) plans and stand-alone Prescription Drug Plans (PDPs) covering all states. Of beneficiaries aged 18 years and older, the population included 2,203,754 individuals. After

applying all inclusion and exclusion criteria, the Diabetes population included 268,737 individuals, the RASA population included 775,226 individuals and the Statins population included 872,736 individuals.

- Medicare Prescription Drug Event (PDE) 100% data (January 1 – December 31, 2017): This includes 100% of the Medicare population, and includes data from 705 MAPD and PDP plans, covering all states. Of beneficiaries aged 18 years and older, the population included 43,402,012 individuals. After applying all inclusion and exclusion criteria, the Diabetes population included 5,723,718 individuals, the RASA population included 17,547,859 individuals and the Statins population included 19,017,664 individuals.

In general, younger beneficiaries were less likely to be adherent compared to older beneficiaries; individuals identified as White or Asian were more likely to be adherent compared to Blacks or Hispanics; individuals with low income subsidy (LIS)/dual eligibility status were less likely to be adherent compared to those without LIS/dual eligibility status; and individuals with disability as the reason for Medicare entitlement were less likely to be adherent compared to those with other reasons for Medicare entitlement.

Diabetes Disparities Data

A comparison of measure rates by age groups - Diabetes

Age	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
<65 years	75.9%	74.6%	78.6%	76.1%
65+ years	82.8%	83.5%	84.0%	84.1%

A comparison of measure rates by gender - Diabetes

Gender	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
Male	82.8%	83.7%	83.9%	84.2%
Female	80.9%	80.9%	82.5%	81.4%

A comparison of measure rates by race- Diabetes

Race	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
White	83.3%	83.9%	84.5%	84.2%
Black	75.1%	72.9%	76.4%	73.6%
Asian	85.2%	83.9%	87.1%	84.9%
Hispanic	78.7%	73.8%	81.5%	75.2%
Other/Unknown	83.4%	81.5%	84.5%	83.1%

A comparison of measure rates by LIS/dual eligibility status - Diabetes

LIS/Dual Status	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
LIS and/or Dual	80.3%	78.7%	81.2%	78.4%
Non-LIS/Non-Dual	82.4%	83.8%	83.9%	82.7%

A comparison of measure rates by Disability as a reason for Medicare entitlement status - Diabetes

Disability Status	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
Disability	78.0%	77.4%	77.0%	74.1%
Other	83.2%	83.8%	84.0%	84.1%

RASA Disparities Data

A comparison of measure rates by age groups - RASA

Age	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
<65 years	77.5%	75.3%	81.9%	79.3%
65+ years	85.2%	85.7%	87.8%	87.4%

A comparison of measure rates by gender - RASA

Gender	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
Male	84.1%	84.5%	87.0%	86.4%
Female	84.4%	84.5%	86.9%	86.1%

A comparison of measure rates by race- RASA

Race	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
White	85.6%	85.9%	88.1%	87.4%
Black	78.1%	75.9%	80.9%	77.9%
Asian	85.1%	83.4%	88.3%	85.4%
Hispanic	80.3%	75.3%	83.8%	78.0%
Other/Unknown	82.5%	80.1%	87.6%	85.2%

A comparison of measure rates by LIS/dual eligibility status - RASA

LIS/Dual Status	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
LIS and/or Dual	80.9%	79.3%	83.1%	80.3%
Non-LIS/Non-Dual	85.4%	86.4%	88.2%	88.4%

A comparison of measure rates by Disability as a reason for Medicare entitlement status - RASA

Disability Status	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
Disability	79.6%	78.4%	80.2%	76.9%
Other	85.6%	86.0%	87.8%	87.4%

Statins Disparities Data

A comparison of measure rates by age groups - Statins

Age	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
<65 years	75.1%	74.9%	77.3%	76.3%
65+ years	81.9%	82.8%	83.2%	82.4%

A comparison of measure rates by gender - Statins

Gender	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
Male	82.3%	83.2%	83.6%	82.9%
Female	80.1%	80.8%	81.4%	80.5%

A comparison of measure rates by race- Statins

Race	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
White	82.8%	83.3%	83.7%	82.8%
Black	73.2%	71.3%	75.2%	71.9%
Asian	81.6%	80.3%	84.0%	80.8%
Hispanic	73.1%	69.8%	75.9%	70.8%
Other/Unknown	81.1%	80.2%	82.9%	80.9%

A comparison of measure rates by LIS/dual eligibility status - Statins

LIS/Dual Status	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
LIS and/or Dual	78.1%	78.0%	78.5%	76.8%
Non-LIS/Non-Dual	82.0%	83.3%	83.6%	83.2%

A comparison of measure rates by Disability as a reason for Medicare entitlement status - Statins

Disability Status	2017 MAPD	2017 PDP	2016 MAPD	2016 PDP
Disability	77.1%	77.7%	75.6%	74.0%
Other	82.2%	82.9%	83.2%	82.5%

In addition to the above results, the CMS 2018 National Impact Assessment Quality Measures Report(1) examined disparities by income and race/ethnicity using 2015 PDP and MA-PD data for Statins, RASA, and Diabetes medications.

Comparison of measure rates by income (income determined using the median household income for the ZIP Code Tabulation Area): Medication adherence rates for low-income beneficiaries were lower than for the high income group for Statins and Diabetes.

Comparison of measure rates by income group - Diabetes & Statins

Income group	Diabetes - MAPD	Diabetes - PDP	Statins - MAPD	Statins - PDP
High	80.8%	82.7%	78.6%	81.6%
Med-High	79.6%	81.8%	78.0%	80.4%
Med-Low	78.9%	80.9%	76.8%	80.1%
Low	76.7%	79.1%	74.8%	77.1%

Comparison of measure rates by race/ethnicity: For all three therapeutics categories, all groups except Asians had lower rates of adherence than Whites.

Comparison of measure rates by race/ethnicity - Diabetes

Race/Ethnicity	MAPD	PDP
White	80.2%	82.0%
Black/African American	71.4%	70.0%
Hispanic/Latino	73.0%	70.5%
Asian	79.8%	82.6%
Am Indian/Alaska native	73.1%	71.1%

Comparison of measure rates by race/ethnicity - RASA

Race/Ethnicity	MAPD	PDP
White	82.0%	83.8%
Black/African American	74.8%	75.7%
Hispanic/Latino	74.9%	74.9%
Asian	81.8%	84.4%
Am Indian/Alaska native	76.8%	73.9%

Comparison of measure rates by race/ethnicity - Statins

Race/Ethnicity	MAPD	PDP
White	78.5%	80.7%
Black/African American	69.1%	68.9%
Hispanic/Latino	69.9%	70.6%
Asian	77.0%	77.5%
Am Indian/Alaska native	74.3%	72.2%

1. 2018 National Impact Assessment of the Centers for Medicare & Medicaid Services (CMS) Quality Measures Report. Baltimore, MD: US Department of Health and Human Services, Centers for Medicare & Medicaid Services; February 28, 2018. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/National-Impact-Assessment-of-the-Centers-for-Medicare-and-Medicaid-Services-CMS-Quality-Measures-Reports.html

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

N/A

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ***Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area *(check all the areas that apply):*

Cardiovascular : Coronary Artery Disease, Cardiovascular : Hyperlipidemia, Cardiovascular : Hypertension, Endocrine : Diabetes

De.6. Non-Condition Specific*(check all the areas that apply):*

Safety, Safety : Medication

De.7. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*

S.1. Measure-specific Web Page *(Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)*

https://www.pqaalliance.org/adherence-measures Note: We do not have a measure-specific web page; however, this URL provides general information about PQA´s PDC measures and additional information can be requested using a link at the bottom of the page.

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure **Attachment:**

S.2b. Data Dictionary, Code Table, or Value Sets *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*

Attachment **Attachment:** 2019_PQA_ESRD_ICD_Codes_20190221.xlsx

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

Yes

S.3.2. For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

2019 Spring Cycle - Endorsement Maintenance

- Value Sets (S.2b): Uploaded an updated value set file for the End-Stage Renal Disease exclusion.
- Testing form: Added a recommendation to apply sociodemographic risk adjustment to the PDC 3 Rates for use in the Medicare Part D quality program.

2018 Annual Update:

- Value Sets (S.2b): Created new value sets for the End-Stage Renal Disease exclusion.
- Denominator (S.6, S.7, S.8, S.9):
- Hospice and end-stage renal disease exclusions added to the three PDC measure rates.
- Sacubitril/valsartan exclusion added to the PDC-RASA rate only.
- Stratification (S.10): Added new stratification clarification (Commercial, Medicaid, Medicare (report each product line separately). This is consistent with PQA plan-level measures.
- Calculation Algorithm/Measure Logic (S.14): Updated measure logic to reflect addition of end-stage renal disease and hospice exclusions for the three PDC measure rates.

S.4. Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.*

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

The number of individuals who met the PDC threshold of 80 percent during the measurement year.

S.5. Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

The number of individuals who met the PDC threshold of 80 percent for medications within the specific therapeutic category (see Tables PDC-DR-A through Table PDC-DR-G: Diabetes Medications for the PDC-DR rate; see Table PDC-RASA-A: Renin Angiotensin System (RAS) Antagonists for the PDC-RASA rate; see Table PCD-STA-A: Statins for the PDC-STA rate) during the measurement year. Follow the steps below for each patient to determine whether the patient meets the PDC threshold.

Step 1: Determine the individual´s treatment period, defined as the Index Prescription Start Date to the end of the measurement year, disenrollment, or death.

Step 2: Within the treatment period, count the days the individual was covered by at least one drug in the class based on the prescription fill date and days of supply. If prescriptions for the same target drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3: Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each individual.

Step 4: Count the number of individuals who had a PDC of 80% or greater. This is the numerator.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a combination product to another combination product where at least one of the target drugs is common.

Table PDC-DR-A through Table PDC-DR-G: Diabetes Medications

metformin (+/- alogliptin, canagliflozin, dapagliloflozin, empagliflozin, ertugliflozin, glipizide, glyburide, linagliptin, pioglitazone, repaglinide, rosiglitazone, saxagliptin, sitagliptin)

chlorpropamide

glimepiride (+/- pioglitazone)

glipizide (+/- metformin)

glyburide (+/- metformin)

tolazamide

tolbutamide

pioglitazone (+/- alogliptin, glimepiride, metformin)

rosiglitazone (+/- metformin)

alogliptin (+/- metformin, pioglitazone)

linagliptin (+/- empagliflozin, metformin)

saxagliptin (+/- metformin, dapagliflozin))

sitagliptin (+/- metformin, ertugliflozin)

albiglutide

dulaglutide

exenatide

liraglutide

lixisenatide

semaglutide

nateglinide

repaglinide (+/- metformin)

canagliflozin (+/- metformin)

dapagliflozin (+/- metformin, saxagliptin)

empagliflozin (+/- metformin, linagliptin)

ertugliflozin (+/- sitagliptin, metformin)

NOTE: Active ingredients are limited to oral formulations only. Excludes nutritional supplement/dietary management combination products.

Table PDC-RASA-A: Renin Angiotensin System (RAS) Antagonists

aliskiren (+/- hydrochlorothiazide)

azilsartan (+/- chlorthalidone)

candesartan (+/- hydrochlorothiazide)

eprosartan (+/- hydrochlorothiazide)

irbesartan (+/- hydrochlorothiazide)

losartan (+/- hydrochlorothiazide)

olmesartan (+/- amlodipine, hydrochlorothiazide)

telmisartan (+/- amlodipine, hydrochlorothiazide)

valsartan (+/- amlodipine, hydrochlorothiazide, nebivolol)

benazepril (+/- amlodipine, hydrochlorothiazide)

captopril (+/- hydrochlorothiazide)

enalapril (+/- hydrochlorothiazide)

fosinopril (+/- hydrochlorothiazide)

lisinopril (+/- hydrochlorothiazide)

moexipril (+/- hydrochlorothiazide)

perindopril (+/- amlodipine)

quinapril (+/- hydrochlorothiazide)

ramipril

trandolapril (+/- verapamil)

NOTE: Active ingredients are limited to oral formulations only. Excludes nutritional supplement/dietary management combination products.

Table PCD-STA-A: Statins

atorvastatin (+/- amlodipine, ezetimibe)

fluvastatin

lovastatin (+/- niacin)

pitavastatin

pravastatin

rosuvastatin

simvastatin (+/-ezetimibe, niacin)

NOTE: Active ingredients are limited to oral formulations only. Excludes nutritional supplement/dietary management combination products.

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*

Individuals age 18 years and older as of the first day of the measurement year, with at least two prescription claims for medication(s) within a specific therapeutic category (Diabetes; RASA; Statins) on different dates of service during the treatment period and are continuously enrolled during the treatment period, which begins on the index prescription start date (IPSD) and extends through whichever comes first: the last day of the measurement year, death or disenrollment. The IPSD should occur at least 91 days before the end of the enrollment period.

Note: The IPSD is the earliest date of service for a target medication during the measurement year

Exclusions for the Diabetes rate:

- Individuals with one or more prescription claims for insulin during the treatment period (See Medication Table PDC-H: Insulin Exclusion)
- Individuals in hospice or with End-Stage Renal Disease

Exclusions for the RASA rate:

- Individuals with one or more prescription claims for the medication, sacubitril/valsartan during the treatment period (See Medication Table PDC-RASA-B: Sacubitril/Valsartan Exclusion)
- Individuals in hospice or with End-Stage Renal Disease

Exclusions for the Statins rate:

- Individuals in hospice or with End-Stage Renal Disease

S.7. Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Individuals age 18 years and older as of the first day of the measurement year, with at least two prescription claims for medication(s) within a specific therapeutic category (see Tables PDC-DR-A through Table PDC-DR-G: Diabetes Medications for the PDC-DR rate; see Table PDC-RASA-A: Renin Angiotensin System (RAS) Antagonists for the PDC-RASA rate; see Table PCD-STA-A: Statins for the PDC-STA rate) on different dates of service during the treatment period and are continuously enrolled during the treatment period, which begins on the index prescription start date (IPSD) and extends through whichever comes first: the last day of the measurement year, death or disenrollment. The IPSD should occur at least 91 days before the end of the enrollment period.

Exclusions for the Diabetes rate:

- Individuals with one or more prescription claims for insulin during the treatment period (See Medication Table PDC-H: Insulin Exclusion)
- Individuals in hospice or with End-Stage Renal Disease

Exclusions for the RASA rate:

- Individuals with one or more prescription claims for the medication, sacubitril/valsartan during the treatment period (See Medication Table PDC-RASA-B: Sacubitril/Valsartan Exclusion)
- Individuals in hospice or with End-Stage Renal Disease

Exclusions for the Statins rate:

- Individuals in hospice or with End-Stage Renal Disease

Table PDC-DR-A through Table PDC-DR-G: Diabetes Medications

metformin (+/- alogliptin, canagliflozin, dapagliloflozin, empagliflozin, ertugliflozin, glipizide, glyburide, linagliptin, pioglitazone, repaglinide, rosiglitazone, saxagliptin, sitagliptin)

chlorpropamide

glimepiride (+/- pioglitazone)

glipizide (+/- metformin)

glyburide (+/- metformin)

tolazamide

tolbutamide

pioglitazone (+/- alogliptin, glimepiride, metformin)

rosiglitazone (+/- metformin)

alogliptin (+/- metformin, pioglitazone)

linagliptin (+/- empagliflozin, metformin)

saxagliptin (+/- metformin, dapagliflozin))

sitagliptin (+/- metformin, ertugliflozin)

albiglutide

dulaglutide

exenatide

liraglutide

lixisenatide

semaglutide

nateglinide

repaglinide (+/- metformin)

canagliflozin (+/- metformin)

dapagliflozin (+/- metformin, saxagliptin)

empagliflozin (+/- metformin, linagliptin)

ertugliflozin (+/- sitagliptin, metformin)

NOTE: Active ingredients are limited to oral formulations only. Excludes nutritional supplement/dietary management combination products.

Table PDC-RASA-A: Renin Angiotensin System (RAS) Antagonists

aliskiren (+/- hydrochlorothiazide)

azilsartan (+/- chlorthalidone)

candesartan (+/- hydrochlorothiazide)

eprosartan (+/- hydrochlorothiazide)

irbesartan (+/- hydrochlorothiazide)

losartan (+/- hydrochlorothiazide)

olmesartan (+/- amlodipine, hydrochlorothiazide)

telmisartan (+/- amlodipine, hydrochlorothiazide)

valsartan (+/- amlodipine, hydrochlorothiazide, nebivolol)

benazepril (+/- amlodipine, hydrochlorothiazide)

captopril (+/- hydrochlorothiazide)

enalapril (+/- hydrochlorothiazide)

fosinopril (+/- hydrochlorothiazide)

lisinopril (+/- hydrochlorothiazide)

moexipril (+/- hydrochlorothiazide)

perindopril (+/- amlodipine)

quinapril (+/- hydrochlorothiazide)

ramipril

trandolapril (+/- verapamil)

NOTE: Active ingredients are limited to oral formulations only. Excludes nutritional supplement/dietary management combination products.

Table PCD-STA-A: Statins

atorvastatin (+/- amlodipine)

fluvastatin

lovastatin (+/- niacin)

pitavastatin

pravastatin

rosuvastatin

simvastatin (+/-ezetimibe, niacin)

NOTE: Active ingredients are limited to oral formulations only. Excludes nutritional supplement/dietary management combination products.

S.8. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*

Exclusions for the Diabetes rate:

- Individuals with one or more prescription claims for insulin during the treatment period (See Medication Table PDC-H: Insulin Exclusion)
- Individuals in hospice or with end-stage renal disease during the measurement year

Exclusions for the RASA rate:

- Individuals with one or more prescription claims for the medication, sacubitril/valsartan during the treatment period (See Medication Table PDC-RASA-B: Sacubitril/Valsartan Exclusion)
- Individuals in hospice or with End-Stage Renal Disease

Exclusions for the Statins rate:

- Individuals in hospice or with End-Stage Renal Disease

S.9. Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

Exclusions for the Diabetes rate:

- Individuals with one or more prescription claims for insulin during the treatment period (See Medication Table PDC-H: Insulin Exclusion)
- Individuals in hospice or with end-stage renal disease during the measurement year

Exclusions for the RASA rate:

- Individuals with one or more prescription claims for the medication, sacubitril/valsartan during the treatment period (See Medication Table PDC-RASA-B: Sacubitril/Valsartan Exclusion)
- Individuals in hospice or with end-stage renal disease during the measurement year

Exclusions for the Statins rate:

- Individuals in hospice or with end-stage renal disease during the measurement year

Hospice exclusion: Applies to PDC-DR, PDC-RASA, and PDC-STA

Individuals in hospice care at any time during the measurement year, identified with a hospice indicator from the enrollment database, where available (e.g., Medicare) or place of service code 34 where a hospice indicator is not available (e.g., Commercial, Medicaid).

End-Stage Renal Disease (ESRD) exclusion: Applies to PDC-DR, PDC-RASA, and PDC-STA

Individuals with an ESRD diagnosis at any time during the measurement year.

- See PQA ICD Value Set, ESRD Exclusion (file name, 2019_PQA_ESRD_ICD_Codes_20190221.xlsx attached in S.2b.)

- An ESRD diagnosis is defined as having at least one claim with any of the listed ESRD diagnoses, including primary diagnosis or any other diagnosis fields during the measurement year.
- Medicare Data (if ICD codes not available): RxHCC 261 - Dialysis Status for Payment Years 2017 or 2018.

Insulin exclusion: Applies to PDC-DR

Individuals with one or more prescription claims for insulin during the treatment period (See Medication Table PDC-H: Insulin Exclusion)

Table PDC-H: Insulin Exclusion

insulin aspart (+/-insulin aspart protamine)

insulin degludec (+/- liraglutide)

insulin detemir

insulin glargine (+/- lixisenatide)

insulin glulisine

insulin isophane (+/- regular insulin)

insulin lispro (+/- insulin lispro protamine)

insulin regular (including inhalation powder)

Note: Active ingredients are limited to inhaled and injectable formulations only.

Sacubitril/valsartan exclusion: Applies to PDC-RASA

Individuals with one or more prescription claims for the medication, sacubitril/valsartan during the treatment period (See Medication Table PDC-RASA-B: Sacubitril/Valsartan Exclusion).

Table PDC-RASA-B: Sacubitril/Valsartan Exclusion

sacubitril/valsartan

S.10. Stratification Information *(Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)*

Commercial, Medicaid, Medicare (report each product line separately).

For Medicare, rates should be stratified by the following to allow health plans to identify disparities and understand how their patient population mix is affecting their risk-adjusted measure rates:

- Age (18-54; 55-64; 65-69; 70-74; 75-79; 80+)
- Gender (Male; Female)
- LIS/Dual Status (LIS and/or Dual eligible; Non-LIS/non-dual)
- Disability status (Disability as reason for Medicare entitlement; Other)

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

Statistical risk model

If other:

S.12. Type of score:

Rate/proportion

If other:

S.13. Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*

Better quality = Higher score

S.14. Calculation Algorithm/Measure Logic (*Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.)*

For EACH PDC rate, identify the Denominator:

Step 1: Identify the eligible population, which includes individuals 18 years and older as of the first day of the measurement year who are continuously enrolled during the treatment period. Exclude patients who dis-enroll and re-enroll in the same plan more than one day later (i.e., >1 day gap in enrollment) after a valid treatment period, but prior to the end of the measurement year.

Step 2: Identify those individuals in Step 1 that have two or more prescription claims for the target class of medication (either Diabetes medication; or RAS Antagonist; or Statin)

Step 3: Exclude any individual in hospice or with end-stage renal disease.

Step 3a: For the PDC-DR rate: Also exclude any individual with one or more prescription claims for insulin during the treatment period.

Step 3b: For the PDC-RASA rate: Also exclude any individual with one or more prescription claims for the medication sacubitril/valsartan during the treatment period.

For EACH PDC rate, calculate the Numerator:

Step 1: Determine the individual´s treatment period, defined as the Index Prescription Start Date to the end of the measurement year, disenrollment or death.

Step 2: Within the treatment period, count the days the individual was covered by at least one drug in the class (Diabetes; RASA; Statins) based on the prescription fill date and days of supply. If prescriptions for the same target drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3: Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each individual.

Step 4: Count the number of individuals who had a PDC of 80% or greater for medications within the specific therapeutic category.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a combination product to another combination product where at least one of the target drugs is common.

Measure Rate:

Report a rate for each of the following:

- Diabetes All Class (PDC-DR)
- Renin Angiotensin System Antagonists (PDC-RASA)
- Statins (PDC-STA)

Divide each numerator by the corresponding denominator and multiply by 100 to calculate each rate as a percentage.

Risk Adjustment (for Medicare- calculated separately for each therapeutic category)

-identify and categorize the variables for risk adjustment:

- Age (18-54; 55-64; 65-69; 70-74; 75-79; 80+)
- Gender (Male; Female)
- LIS/Dual Status (LIS and/or Dual eligible; Non-LIS/non-dual)
- Disability status (Disability as reason for Medicare entitlement; Other)

- Using a random-effects multivariable logistic regression model controlling for the plan-contract (generalized linear mixed model), the patient predicted probability of adherence is calculated after adjusting for the covariates identified above
- for each plan-contract, the expected measure rate is calculated as the average of the patient predicted probability of adherence based on the multivariable logistic regression model
- The risk-adjusted measure rate for each plan-contract is calculated as the ratio of the unadjusted measure scores to the expected score, multiplied by the aggregate unadjusted score for all Part D contracts.

S.15. Sampling *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

N/A

S.16. Survey/Patient-reported data *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*

Specify calculation of response rates to be reported with performance measure results.

N/A

S.17. Data Source *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*

If other, please describe in S.18.

Claims, Enrollment Data

S.18. Data Source or Collection Instrument *(Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)*

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

Administrative claims (i.e., prescription claims), ICD codes, prescription drug hierarchical condition categories (RxHCC), enrollment data

S.19. Data Source or Collection Instrument *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

No data collection instrument provided

S.20. Level of Analysis *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*

Health Plan

S.21. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*

Outpatient Services

If other:

S.22. COMPOSITE Performance Measure - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

N/A

2. Validity – See attached Measure Testing Submission Form

PQA_0541_testing_attachment_7.1_040819_FV.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions. Yes - Updated information is included

Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (*if previously endorsed*)**:** 0541

Measure Title: Proportion of Days Covered: 3 Rates by Therapeutic Category

Date of Submission: 4/9/2019

Type of Measure:

☐ Outcome (*including PRO-PM*)	☐ Composite – ***STOP – use composite testing form***
☐ Intermediate Clinical Outcome	☐ Cost/resource
☒ Process *(including Appropriate Use)*	☐ Efficiency
☐ Structure	

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing,(e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure*. *Testing must be provided for all the sources of data specified and intended for measure implementation.* ***If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.***)

Measure Specified to Use Data From: **(*must be consistent with data sources entered in S.17*)**	**Measure Tested with Data From:**
☐ abstracted from paper record	☐ abstracted from paper record
☒ claims	☒ claims
☐ registry	☐ registry
☐ abstracted from electronic health record	☐ abstracted from electronic health record
☐ eMeasure (HQMF) implemented in EHRs	☐ eMeasure (HQMF) implemented in EHRs
☐ other:	☐ other:

1.2. If an existing dataset was used, identify the specific dataset (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry*).

The Pharmacy Quality Alliance (PQA) proportion of days covered (PDC) 3 rates by therapeutic category (Diabetes, renin-angiotensin system antagonist [RASA], and Statin Medications) measure was tested within two different health plan data sources – the Medicare and the Medicaid populations.

For the Medicare population, data used for testing came from the Medicare Research Identifiable Files (RIFs) 5% national sample data. The Medicare Part D Prescription Drug Event (PDE) claims were used for the identification of prescription drugs. The claims files and Medicare Provider Analysis and Review (MedPAR) files were used to identify end-stage renal disease (ESRD) diagnoses and hospice claims. To identify demographic and eligibility information, the Medicare Beneficiaries Summary Files (MBSF) were used.

For the Medicaid population, the data used for testing came from Medicaid administrative claims in the Medicaid Analytic eXtract (MAX) data. National Medicaid sample data covering 17 states and 291 health plans were included in the testing.

Note: Testing was conducted separately for each therapeutic category (Diabetes, renin-angiotensin system antagonist [RASA], Statins) and each line of business (Medicare, Medicaid).

1.3. What are the dates of the data used in testing? 2014 and 2016

The testing for Medicare included data from January 1, 2016 to December 31, 2016. The testing for Medicaid included data from January 1, 2014 to December 31, 2014. The data from these time periods were the most recent, complete, full year data available to testers at the time of testing.

1.4. What levels of analysis were tested? (*testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

Measure Specified to Measure Performance of: (*must be consistent with levels entered in item S.20*)	Measure Tested at Level of:
☐ individual clinician	☐ individual clinician
☐ group/practice	☐ group/practice
☐ hospital/facility/agency	☐ hospital/facility/agency
☒ health plan	☒ health plan
☐ other:	☐ other:

1.5. How many and which measured entities were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample*)

The Medicare testing was conducted using the Medicare RIF 5% sample data – a nationally representative sample, including data from all states. Of beneficiaries aged 18 years and older as of the first day of the measurement year, the data included 491 Medicare Advantage Prescription Drug (MAPD) contracts and 63 stand-alone Prescription Drug Plans (PDPs). Of the 554 plan-contracts, the mean plan-contract size was 3,978 beneficiaries with a median size of 562 beneficiaries. (see Table 1).

For the Medicaid testing, the analysis included 291 health plans covering 17 states with beneficiaries aged 18 years or older. Of the 291 plans, 17 plans were fee-for-service (FFS), and the remaining 274 plans were Medicaid Managed Care Organizations (MCOs). There was variation in plan size, with mean plan size of 18,415 beneficiaries, and a median plan size of 3,656 beneficiaries. (see Table 1).

Table 1. Plan/Contract Size Distribution for Medicare and Medicaid Populations

Statistic	Medicare	Medicaid
Mean	3,978	18,415
Standard Deviation	19,648	43,222
Minimum	30	30
25th Percentile	190	354
50th Percentile	562	3,656
75th Percentile	2,054	17,560
Maximum	291,999	450,884
Interquartile Range	1,864	17,206

Note: When used in performance programs, plans/contracts with <30 individuals are excluded; as such, all analyses exclude plans/contracts with <30 individuals.

1.6. How many and which patients were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

For the Medicare testing, the initial population ages 18 years and older included 2,203,754 individuals. After applying all inclusion/exclusion criteria, the Diabetes population included 268,737 individuals, the RASA population included 775,226 individuals, and the Statins population included 872,736 individuals. For all therapeutic classes, over 80% of beneficiaries were ages 65 years and older. For all therapeutic classes, over 50% of the population was female, and between 75% (Diabetes) and 81% (Statins) was white, with a little more than 3% of the population's race classified as "other/unknown". In addition, 25-30% of beneficiaries had low-income subsidy (LIS) and/or dual eligibility status, with the Diabetes population having the largest percentage (30.3%). More than 10% of the population were entitled to Medicare due to disability, with the highest percentage in the Diabetes population (13.3%). (see Table 2).

Table 2. Population Characteristics for Medicare – By Therapeutic Category

	Diabetes (n = 268,737)		RASA (n = 775,226)		Statins (n = 872,736)	
Characteristic	**n**	**%**	**n**	**%**	**n**	**%**
Age Group						
18-54	14,131	5.3	33,571	4.3	34,523	4.0
55-64	29,722	11.1	77,487	10.0	83,354	9.6
65-69	72,778	27.1	201,213	26.0	226,016	25.9
70-74	62,332	23.2	174,978	22.6	201,962	23.1
75-79	44,363	16.5	128,778	16.6	149,544	17.1
80+	45,411	16.9	159,199	20.5	177,337	20.3
Gender						
Male	125,356	46.7	344,118	44.4	394,867	45.2
Race						
White	200,254	74.5	618,035	79.7	710,176	81.4
Black	35,529	13.2	87,017	11.2	83,130	9.5
Asian	9,885	3.7	18,425	2.4	23,072	2.6
Hispanic	11,157	4.2	23,601	3.0	23,930	2.7
North American Native	1,072	0.4	2,798	0.4	2,661	0.3
Other	7,203	2.7	15,145	2.0	17,565	2.0
Unknown	3,637	1.4	10,205	1.3	12,202	1.4
LIS and/or Dual	81,294	30.3	200,902	25.9	219,056	25.1
Disability as reason for Medicare entitlement	35,606	13.3	88,690	11.4	93,876	10.8
RASA: renin-angiotensin system antagonist; LIS: low-income subsidy						

For the Medicaid testing, the initial population ages 18 years and older included 5,358,811 individuals. After applying all inclusion/exclusion criteria, the Diabetes population included 234,185 individuals, the RASA population included 572,736 individuals, and the Statins population included 478,586 individuals. For all therapeutic classes, over 90% of beneficiaries were between 18 and 64 years old. For all therapeutic classes, a majority of the population was female, ranging between 59% (RASA & Statins) and 64% (Diabetes), and the proportion of the population that identified as white race was between 35% (Diabetes) and 42% (Statins). For the Medicaid population, about 14% of the population was classified as having an “other/unknown” race. (see Table 3).

Table 3. Population Characteristics for Medicaid – By Therapeutic Category

	Diabetes (n = 234,185)		RASA (n = 572,736)		Statins (n = 478,586)	
Characteristic	**n**	**%**	**n**	**%**	**n**	**%**
Age Group						
18-54	140,882	60.2	339,519	59.3	259,195	54.2
55-64	79,185	33.8	201,415	35.2	189,561	39.6
65-69	4,820	2.1	10,081	1.8	9,953	2.1
70-74	4,156	1.8	9,007	1.6	8,688	1.8
75-79	2,935	1.3	6,790	1.2	6,298	1.3
80+	2,207	0.9	5,924	1.0	4,891	1.0
Gender						
Male	85,145	36.4	237,688	41.5	195,843	40.9
Race						
White	82,416	35.2	222,499	38.9	200,878	42.0
Black	44,398	19.0	138,581	24.2	86,970	18.2
Asian	14,347	6.1	24,851	4.3	30,052	6.3
Hispanic	56,617	24.2	103,417	18.1	84,094	17.6
North American Native	1,560	0.7	3,583	0.6	2,574	0.5
Other	11,137	4.8	22,515	3.9	22,155	4.6
Unknown	23,710	10.1	57,290	10.0	51,863	10.8

RASA: renin-angiotensin system antagonist

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

All testing was conducted using the same datasets for each line of business except the following:

- empirical validity testing: conducted using publicly available national-level Centers for Medicare and Medicaid Services (CMS) Medicare data from 2016 as these measures are used in the Medicare Part D Star Ratings program,
- missing data and unadjusted reliability testing for Medicare: used the 100% CMS Medicare PDE data from 2014, and
- **additional testing:** additional unadjusted and risk-adjusted reliability testing conducted using 100% CMS Medicare PDE data from 2017.

1.8 What were the social risk factors that were available and analyzed? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

Variables selected for analyses for the Medicare population included beneficiary-, community- (9-digit zip code) and county-level variables. (see Table 4).

Table 4. SDS Variables Considered for Risk Adjustment for the Medicare Population

Variable Level	Variable
Beneficiary-level	Age
	Gender
	LIS status or Dual eligibility status
	Disability as original reason for Medicare entitlement
	Race
Community-level (9-digit zip code)	Median income
	Percent of households where residents are married
	Percent of households where residents completed college
	Percent of households where residents own their home
County-level	Federally designated primary care professional shortage area
	Federally designated mental healthcare professional shortage area

LIS: low-income subsidy; SDS: sociodemographic status

No social risk factors were analyzed for the Medicaid population.

2a2. RELIABILITY TESTING

***Note**: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.*

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)

☐ **Critical data elements used in the measure** (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)

☒ **Performance measure score** (e.g., *signal-to-noise analysis*)

2a2.2. For each level checked above, describe the method of reliability testing and what it tests (*describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used*)

Reliability testing was conducted for the unadjusted measure scores for Medicare and Medicaid, and the risk-adjusted measure scores for Medicare.

The reliability of a measurement refers to the degree to which repeated measurements of the same entity agree with each other. For the health plan/contract-level performance measures, reliability characterizes the extent to which repeated measurements of the same plans/contracts produce similar results.

For the Medicare and Medicaid unadjusted measure rates, the reliability of the computed measure scores was measured as the ratio of signal-to-noise. The signal is the proportion of the variability in measured performance that can be explained by true differences in plan (or contract) performance. Reliability scores range from 0 to 1, with a score of 0 signifying that all variation is due to measurement error. A value of 1 signifies that the variation represents true differences in performance scores between plans. A reliability score of 0.7 is the minimum threshold for reliability.

A beta-binomial model was used to calculate plan-specific reliability scores based on the method outlined by Adams.[1] The reliability score is defined as the ratio of the plan-to-plan variance to the sum of the plan-to-plan variance and the plan-specific error. The plan-to-plan variance is an estimate of the variance of the true rates. The plan-specific error variance is the sampling or measurement error.

$$reliability = \frac{\sigma^2_{plan-to-plan}}{\sigma^2_{plan-to-plan} + \sigma^2_{plan-specific-error}}$$

Risk adjustment was applied at the measure score level. As such, the Adams beta binomial methodology described above could not be used to assess reliability of the risk-adjusted measure scores. To assess reliability of the risk-adjusted measure scores for Medicare, we employed a split-half approach where plan-contract performance was measured using a random sample of beneficiaries, and then measured again using a second random sample. The two groups are independent samples, with each sample including half of the population within each plan-contract. This means that each plan-contract is measured twice, but each measurement is made using an entirely distinct set of beneficiaries. As a metric of agreement, we calculated the intra-class correlation coefficient (ICC)[2] and assessed the values according to conventional standards.[3]

References:

1. Adams JL. The reliability of provider profiling: a tutorial. Santa Monica, CA: RAND Corporation. 2009. Retrieved from http://www.rand.org/pubs/technical_reports/TR653.
2. Shrout P, Fleiss J. Intraclass correlations: uses in assessing rater reliability. Psychological Bulletin 1979; 86:420-428. PMID: 27330520.
3. Koo TK, Li MY. A guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. Journal of Chiropractic Medicine. 2016; 15(2):155-63. PMID: 27330520.

2a2.3. For each level of testing checked above, what were the statistical results from reliability testing? (e.*g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis*)

Unadjusted Measure Scores

Using the parameter estimates from the beta-binomial model, we computed individual plan/contract reliability scores. Table 5a shows the distribution of the plan/contract level scores for Medicare and Medicaid.

Table 5a. Unadjusted Plan/Contract Reliability Scores – By Therapeutic Category

Statistic	Medicare			Medicaid		
	Diabetes	RASA	Statins	Diabetes	RASA	Statins
Mean	0.8492	0.8953	0.9171	0.9174	0.9340	0.9305
Standard Deviation	0.1785	0.1579	0.1319	0.1008	0.0990	0.1005
Minimum	0.2161	0.2664	0.3321	0.6207	0.5587	0.5763
25th Percentile	0.7747	0.8768	0.9025	0.8903	0.9262	0.9260
50th Percentile	0.9316	0.9724	0.9793	0.9655	0.9798	0.9781
75th Percentile	0.9792	0.9941	0.9951	0.9879	0.9938	0.9933
Maximum	0.9998	1.0000	1.0000	0.9992	0.9996	0.9995
Interquartile Range	0.2045	0.1172	0.0926	0.0976	0.0676	0.0674

RASA: renin-angiotensin system antagonist

Note: Reliability testing for Medicare conducted using the 2014 100% CMS PDE data.

The mean reliability score for the Medicare plan-contract (with median) was 0.8492 (0.9316) for Diabetes, 0.8953 (0.9724) for RASA, and 0.9171 (0.9793) for Statins.

The mean reliability score for the Medicaid plans (with median) was 0.9174 (0.9655) for Diabetes, 0.9340 (0.9798) for RASA, and 0.9305 (0.9781) for Statins.

Additional Testing: Using 2017 100% CMS PDE Data for Medicare

Table 5b. Unadjusted Plan-Contract Reliability Scores for Medicare – By Therapeutic Category

Statistic	Medicare		
	Diabetes	RASA	Statins
Mean	0.8553	0.8774	0.9211
Standard Deviation	0.1811	0.1815	0.1284
Minimum	0.2346	0.2257	0.3710
25th Percentile	0.7912	0.8393	0.9109
50th Percentile	0.9377	0.9706	0.9834
75th Percentile	0.9853	0.9945	0.9967
Maximum	0.9999	1.0000	1.0000
Interquartile Range	0.1941	0.1552	0.0858

RASA: renin-angiotensin system antagonist

Note: Additional reliability testing for Medicare conducted using the 2017 100% CMS PDE data.

The mean reliability score for the Medicare plan-contract (with median) was 0.8553 (0.9377) for Diabetes, 0.8774 (0.9706) for RASA, and 0.9211 (0.9834) for Statins. (see Table 5b). These results were similar to the 2014 100% CMS PDE analysis in Table 5a.

Risk-Adjusted Measure Scores for Medicare

Using the 2016 5% Medicare sample

The intra-class correlation between the two risk standardized scores among the two samples was 0.3548 for Diabetes, 0.3513 for RASA and 0.5022 for Statins.

Additional Testing: Using the 2017 100% CMS PDE data

The intra-class correlation between the two risk standardized scores among the two samples was 0.7756 for Diabetes, 0.7260 for RASA and 0.8806 for Statins.

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.*e., what do the results mean and what are the norms for the test conducted?*)

Unadjusted Measure Scores

A reliability score of 0.7 is considered the minimum threshold for reliability. Based on the mean reliability scores between 0.85 (Diabetes) and 0.92 (Statins) for Medicare and 0.92 (Diabetes) and 0.93 (RASA and Statins) for Medicaid, the measure scores for the three therapeutic categories are considered reliable.

Risk-Adjusted Measure Scores for Medicare (2016 5% sample)

The ICC scores for Diabetes and RASA are considered low, while the ICC score for Statins is considered moderate according to conventional interpretation.[1] However, it is important to note that the analysis was conducted using the 5% sample of the Medicare population, and sample size is one of the drivers of reliability.

Smaller plan-contracts may negatively impact the ICC as the random split is more likely to introduce noise, since the two halves may not be equally balanced, unlike large plan-contracts where we expect both samples to be normally distributed due to the law of large numbers. Thus, we anticipate the reliability would improve when applied to the total Medicare population. This is evident in the high reliability for the unadjusted measure scores for Medicare, which was conducted using the 100% CMS PDE data.

Additional Testing (2017 100% CMS PDE Data):

As expected, reliability of the risk-adjusted measure scores improved significantly when applied to the 100% CMS PDE Medicare dataset, ranging from 0.73 (RASA) to 0.88 (Statins). Based on conventional interpretation,[1] reliability for all three measures were good.

References:

1. Koo TK, Li MY. A guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. Journal of Chiropractic Medicine. 2016; 15(2):155-63. PMID: 27330520.

2b1. VALIDITY TESTING

2b1.1. What level of validity testing was conducted? (*may be one or both levels*)

☐ **Critical data elements** (*data element validity must address ALL critical data elements*)

☒ **Performance measure score**

☒ **Empirical validity testing**

☒ **Systematic assessment of face validity of performance measure score as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

2b1.2. For each level of testing checked above, describe the method of validity testing and what it tests (*describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)*

We assessed convergent validity of the measure score at the plan-contract level (correlation with related measure in the same performance year) for Medicare and face validity for all lines of business.

Convergent Validity

Convergent validity was tested for each therapeutic category for the Medicare population using the publicly available CMS Medicare Part C & D Star Ratings data.[1] Correlation was examined using the Pearson correlation statistics between each of the therapeutic categories and other performance measures used in the Star Ratings program.

For Diabetes, we examined whether the measure rate is correlated with the *Diabetes Care – Blood Sugar Controlled* measure used in the CMS Part C Star Ratings program. We hypothesized that organizations that perform well on the PDC Diabetes measure should perform well on the *Diabetes Care – Blood Sugar Controlled* measure as both focus on diabetes care, and adherence to anti-hyperglycemic agents can lower blood sugar and decrease complications such as visual loss and renal failure.[2,3]

For RASA, convergent validity was tested by exploring whether the measure rate is correlated with the *Controlling Blood Pressure* measure used in the CMS Part C Star Ratings program. We hypothesized that organizations that perform well on the PDC RASA measure should perform well on the *Controlling Blood Pressure measure*. According to the 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA hypertension guidelines and the 2018 American Diabetes Association guidelines, medication nonadherence is a major contributor to poor control of hypertension and a key barrier to reducing mortality.[4,5] Moreover, studies have shown improved clinical outcomes for individuals who are adherent to their medications.[6]

For Statins, convergent validity was tested by exploring whether the measure rate is correlated with the *Statin Use in Persons with Diabetes* measure used in the CMS Part D Display measures. We hypothesized that organizations that perform well on the PDC Statins measure should perform well on the *Statin Use in Persons with Diabetes* measure. Atherosclerotic cardiovascular disease (ASCVD) is the leading cause of morbidity and mortality for individuals with diabetes in addition to being the largest contributor to costs of diabetes care.[4] Individuals with diabetes who are 40-75 years old are at a markedly increased lifetime risk for the development of ASCVD, experience greater morbidity, and are at a decreased likelihood of survival following the onset of ASCVD. HMG-CoA reductase inhibitors, also known as statins, are recommended for management of dyslipidemia and/or primary prevention of cardiovascular disease (CVD) in several treatment guidelines.[7-11] By lowering LDL cholesterol, statins decrease the risk of CVD morbidity and mortality.[12]

References:

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12. Cholesterol Treatment Trialists' (CTT) Collaborators, Mihaylova B, Emberson J, Blackwell L, et al. The effects of lowering LDL cholesterol with statin therapy in people at low risk of vascular disease: meta-analysis of individual data from 27 randomised trials. Lancet. 2012; 380(9841):581-90. PMID: 22607822.

Face Validity

PQA uses a systematic, transparent, consensus-based measure development, testing, and endorsement process. That process was used in 2008 to develop this measure. The measure was assessed for face validity (i.e., whether it appears to measure what it intends to measure) through review by workgroup participants that developed the measure (PQA Adherence Workgroup), the PQA Quality Metrics Expert Panel (QMEP), and PQA's full membership.

The 2018 PQA Measure Update Panel and QMEP most recently reviewed this measure. These panels include individuals with expertise and experience in pharmacy, medicine, research, and clinical or other technical expertise related to quality improvement and measure development.

2b1.3. What were the statistical results from validity testing? (*e.g., correlation; t-test*)

Results for convergent validity testing for the Medicare population is shown in Table 6. For all three therapeutic categories, there was a positive relationship with the comparator, and all three were statistically significant at alpha <0.0001.

Table 6. Convergent Validity Testing for Medicare – By Therapeutic Category

Therapeutic Category	Comparison	Correlation Coefficient	*p*-Value
Diabetes	C15: Diabetes Care - Blood Sugar Controlled	0.465	<0.0001
RASA	C16: Controlling Blood Pressure	0.517	<0.0001
Statins	DMD15: Statin Use in Persons with Diabetes	0.346	<0.0001

RASA: renin-angiotensin system antagonists

Note: Correlation analyses conducted using the CMS Medicare Part C & D Star Ratings Data from January – December 2016.

2b1.4. What is your interpretation of the results in terms of demonstrating validity? (i.*e., what do the results mean and what are the norms for the test conducted?*)

All three therapeutic categories showed statistically significant positive correlation, which indicates that the measure demonstrates convergent validity.

Based upon the systematic, consensus-based PQA measure development process designed to assure face validity, the measure has been determined to have face validity.

2b2. EXCLUSIONS ANALYSIS

NA ☐ no exclusions — *skip to section* 2b3

2b2.1. Describe the method of testing exclusions and what it tests (*describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)

We examined the overall proportion of Medicare and Medicaid beneficiaries impacted as well as the proportion of individuals who would be impacted by the exclusions at the plan/contract-level.

Hospice

Individuals in hospice care are excluded from the measure because adherence to most chronic therapies does not necessarily align with the therapeutic goals and balance of risk and benefits for individuals in hospice care. In 2015, the PQA Patient & Caregiver Advisory Panel recommended that hospice should generally be an exclusion for PQA measures unless the measures are directly relevant to, and align with, the therapeutic goals for individuals in hospice care.

End-Stage Renal Disease

Individuals with end-stage renal disease (ESRD) are excluded from the measure because adherence to diabetes, hypertension, and statin medications may not be accurately reflected in pharmacy claims data due to frequent dosage and medication adjustments.

Individuals with diabetes and ESRD are at higher risk for hypoglycemia than the general population. Reasons for fluctuation in blood glucose can range from drug accumulation to more complex reasons like increased glucose utilization following the correction of anemia by erythropoietin.[1] Peritoneal dialysis patients may also have glucose-containing dialysate that influences glycemic control, with alternating hyperglycemia and hypoglycemia and resultant adjustments to diabetes medications.[2] Additionally, individuals with ESRD often have spontaneous hypoglycemia due to reduced renal gluconeogenesis or concurrent hepatic disease, but also experience fluctuations in insulin resistance due to the process of dialysis.[1]

Individuals with ESRD may require RASA medication dosage adjustments due to severe fluid imbalances resulting in high blood pressure, followed by sudden hypotension when fluids are removed with dialysis.[3] A confounding factor is variable adherence to dietary regimens (e.g., fluid restrictions). Therefore, assessing adherence to oral antihypertensive medications using pharmacy claims data in individuals with ESRD is

imprecise due to frequent fluctuations in blood pressure and resulting medication adjustments (e.g., they are often held, changed, discontinued, or restarted).

Individuals with ESRD may also feel generalized weakness and adherence to statins may be a lower clinical priority than interventions to manage mineral bone disease and fluid management (e.g., medication and dietary modifications).[4] Although individuals with ESRD are at increased risk for cardiovascular events related to sudden cardiac arrest, left ventricular hypertrophy, vascular calcifications from hyperphosphatemia and hyperparathyroidism, and large fluid shifts[5-7] there is a lack of direct evidence that statin treatment is beneficial in dialysis patients in the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines.[8]

Insulin for Diabetes

Currently, there is not a standardized method to assess adherence to insulin using prescription claims data.[9] Individuals on insulin are excluded from the Diabetes rate because insulin requires titration and frequent dosage adjustments, which in turn can result in frequent dosage adjustments of other diabetes medications.

Sacubitril/Valsartan for RASA

The RASA rate is intended to evaluate adherence to medications used for treating hypertension. Individuals receiving sacubitril/valsartan are excluded from the measure because this product, although it includes a RASA (i.e., valsartan), is only indicated for treating heart failure.

References:

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2b2.2. What were the statistical results from testing exclusions? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)

For the Medicare population, overall, the percentage of individuals excluded were <1% (except for insulin for Diabetes). However, at the plan-contract level, some plan-contracts were disproportionately impacted, with the percentage of individuals in hospice who were excluded from the measure ranging from 0.0% to 3.8% for Diabetes, 0.0% - 4.8% for RASA and 0.0% - 5.6% for Statins. The ESRD exclusions among plan-contracts ranged from 0.0% to 9.6% for Diabetes, 0.0% to 16.4% for RASA and 0.0% - 21.9% for Statins.

In addition, for Diabetes, individuals on insulin are excluded from the measure. This exclusion ranged from 0.0% - 26.2% of individuals impacted within plan-contracts. For RASA, individuals are excluded if they were on sacubitril/valsartan at any time during the measurement year. This exclusion ranged from 0.0% - 3.3% of individuals impacted within plan-contracts. (see Table 7).

Table 7. Means Distribution of Proportion of Individuals Impacted Across Plan-Contracts for Medicare

Exclusion by therapeutic class (n = 2,203,754)	N	%	Distribution across plan-contracts; min, 25th, 50th, 75th, max
Diabetes			
ESRD	5,353	0.24	(0.00, 0.00, 0.00, 0.12, 9.59)
Hospice	5,013	0.23	(0.00, 0.00, 0.15, 0.28, 3.77)
Insulin	80,274	3.64	(0.00, 2.71, 3.64, 4.74, 26.19)
RASA			
ESRD	11,787	0.53	(0.00, 0.00, 0.12, 0.33, 16.44)
Hospice	11,253	0.51	(0.00, 0.00, 0.38, 0.60, 4.82)
Sacubitril/Valsartan	9,013	0.41	(0.00, 0.00, 0.30, 0.52, 3.33)
Statins			
ESRD	16,333	0.74	(0.00, 0.00, 0.21, 0.45, 21.92)
Hospice	12,115	0.55	(0.00, 0.00, 0.42, 0.67, 5.63)

ESRD: end-stage renal disease; RASA: renin-angiotensin system antagonist

As with Medicare, the overall percentage of individuals impacted by the exclusions in the Medicaid population was <1% (except insulin for Diabetes). At the plan-level however, this impact was disproportionate, with the percentage of individuals in hospice who were excluded from the measure ranged from 0.0% to 8.0% for all three therapeutic areas. The ESRD exclusions among plans ranged from 0.0% to 1.3% for Diabetes, 0.0% to 2.3% for RASA and 0.0% - 0.6% for Statins. (see Table 8).

In addition, for Diabetes, individuals on insulin are excluded from the measure. This exclusion ranged from 0.0% - 7.1% of individuals impacted within plans. For RASA, individuals are excluded if they were on sacubitril/valsartan at any time during the measurement year. This exclusion ranged from 0.0% - 2.2% of individuals impacted within plans. (see Table 8).

Table 8. Means Distribution of Proportion of Individuals Impacted Across Plans for Medicaid

Exclusion by therapeutic class (n = 5,358,811)	N	%	Distribution across plan-contracts; min, 25th, 50th, 75th, max
Diabetes			
ESRD	1,655	0.03	(0.00, 0.00, 0.01, 0.03, 1.28)
Hospice	6,874	0.13	(0.00, 0.00, 0.05, 0.12, 8.00)
Insulin	93,797	1.75	(0.00, 1.00, 1.46, 1.99, 7.14)
RASA			
ESRD	5,500	0.10	(0.00, 0.00, 0.05, 0.11, 2.27)
Hospice	6,874	0.13	(0.00, 0.00, 0.05, 0.12, 8.00)
Sacubitril/Valsartan	4,485	0.08	(0.00, 0.00, 0.02, 0.06, 2.17)
Statins			
ESRD	5,052	0.09	(0.00, 0.00, 0.05, 0.10, 0.58)
Hospice	6,874	0.13	(0.00, 0.00, 0.05, 0.12, 8.00)

ESRD: end-stage renal disease; RASA: renin-angiotensin system antagonist

2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., the value outweighs the burden of increased data collection and analysis. Note: **If patient preference is an exclusion**, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion*)

Although the overall impact of these exclusions was low, the impact varied substantially at the plan/contract level. Within the Medicare population, there was significant impact of the ESRD exclusion, with up to 22% of beneficiaries in some plan-contracts impacted by this exclusion (Statins). The impact of hospice was lower, with up to 5% of beneficiaries impacted in some plan-contracts. There was also significant impact of applying the insulin requirement to the diabetes population (up to 26%) and a lesser impact of the sacubitril/valsartan exclusion to the RASA population (up to 3%). Without applying these exclusions, these beneficiaries would be included in the measure. These are significant proportions of the population that could potentially impact the measure rate at the plan-contract level.

Similar to the Medicare population, although the overall impact of the exclusions was low, the impact varied by plan with the ESRD exclusion showing the most impact. The results show that in some plans, up to 8% of the population had ESRD and would be included in the measure if ESRD was not excluded. In addition, up to 7% of the populations were impacted by the insulin exclusions. These are significant proportions of the population that could potentially impact the measure rate.

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES

If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section 2b4.

2b3.1. What method of controlling for differences in case mix is used?

☐ **No risk adjustment or stratification**

☒ **Statistical risk model with 5 sociodemographic risk factors**

☐ **Stratification by risk categories**

☐ **Other,**

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

Within-Contract Outcome Comparisons

To ensure that beneficiary comparisons were made within plan-contracts, we employed a multivariable, random-effects logistic regression model controlling for the Medicare Part D contract for each therapeutic category rate. This approach acknowledges the variability in an outcome that is attributable to the plan-contract and only allows comparisons among beneficiaries that are in the same plan-contract.

The regression models produce odds ratios (ORs) that assess the increased or decreased odds that beneficiaries with the SDS risk factors will have an outcome, as compared to beneficiaries without those risk factors. Univariate regression models were used to explore the association between the measure outcomes and single covariates. A multivariable regression model was used to explore the association between the measure outcomes adjusted for all covariates that were statically significant based on the univariate models.

SDS Risk Factors

Using variables identified through literature review and subject matter experts, initial univariate and multivariable analyses included beneficiary-, community- (9-digit zip code), and county-level variables. Because prescription drug data have little information regarding beneficiaries' socioeconomic status, each beneficiary's 9-digit zip code of residence was linked to zip code-specific socioeconomic data contained in the Acxiom InfoBase Geo data procured by PQA. County-level variables from the publicly available 2015-2016 Health Resources & Services Administration Area Health Resource Files data were also linked to the dataset via beneficiary 5-digit zip code. All variables were classified as categorical variables. (see Tables 11-13).

In addition to the full model using all the variables of interest (Table 4), the same methods were used to assess the impact of a more parsimonious model, which only included the beneficiary-level risk factors that are available in CMS PDE data (i.e., age, gender, LIS/dual status, disability and race). The reduced model was used to assess whether these commonly available beneficiary-level SDS variables would yield similar or different results than the full model.

Finally, to address concerns raised by the PQA Risk Adjustment Advisory Panel (RAAP) members around the accuracy and completeness of the race variable, as well as the NQF Disparities Standing Committee concern around the use of race as a proxy for socioeconomic status, PQA also looked at the reduced model described above without race, i.e. limiting to age, gender, LIS/dual eligibility status and disability. These models were compared to the full model to determine the impact of the 9-digit zip code level characteristics and race on the outcomes.

Predictive Ability of Model and Multicollinearity

C-statistics and risk decile plots were used to assess the predictive validity and discrimination of the models. The Variance Inflation Factor (VIF) was calculated to determine if any variables were multicollinear and which variables to ultimately include in the models. A threshold of VIF greater than 10 was used to determine if variables were multicollinear, and therefore needed to be excluded from the model.

Risk-Adjusted Score Calculation

Using the variables from the most parsimonious model (i.e., age, gender, LIS/dual, and disability status), a risk-adjusted score was calculated for each Medicare Part D contract, for each of the three therapeutic categories, to determine the extent of score change after risk adjustment. For each Part D contract, the expected measure rate was calculated as the average of the patient predicted probabilities of adherence for each plan-contract based on the multivariable logistic regression model. The risk-adjusted measure score for each plan-contract was then calculated as the ratio of observed (or unadjusted) measure score to the expected score, multiplied by the aggregate unadjusted score for all Part D contracts.

Equations

Adherence to medication was modeled as:

$$ln\left(\frac{p_{ij}}{1-p_{ij}}\right) = \alpha_j + \beta_1 x_{1ij} + \beta_2 x_{2ij} \ldots\ldots + \beta_k x_{kij}$$

where P_{ij} is the probability of being adherent for beneficiary i in the plan-contract j, β_k are model parameters; x_{kij} are values of variables being adjusted for including the categorical variables for age, gender, LIS/dual and disability status, α_j is an intercept term. The intercept term is taken to be random and different for each plan-contract.[1]

Coefficients

See Section 2b3.4a for coefficient estimates, odds ratios and 95% confidence intervals for the risk factors included in the final model.

Definitions for SDS Risk Factors Available and Analyzed

The beneficiary-level variables were obtained from the CMS RIF data, and defined as follows:

- Age: This is the member's age calculated at the beginning of the measurement year using the member's date of birth.
- Gender: Refers to the member's gender as identified in the RIF data.
- Low-Income Subsidy (LIS) status: Refers to Medicare beneficiaries with income below 150% of the federal poverty level and limited resources who receive additional premium and cost-share assistance for prescription drugs under Medicare Part D. The LIS status is indicated in the RIF data if a beneficiary received a low-income subsidy at least one month during the measurement year.
- Dual eligibility status: Denotes beneficiaries enrolled in both Medicare and Medicaid. The dual eligible status is indicated if the beneficiary was dual eligible at least one month in the measurement year.

- Disability as reason for Medicare entitlement: Indicates whether a beneficiary was eligible for Medicare because of a disability, at the end of the measurement year.
- Race: Denotes the race of the beneficiary, as identified in the RIF data.

The community-level variables were obtained from the Acxiom InfoBase Geo data linked to the CMS RIF data at the 9-digit zip code level. The variables are as follows:

- Median household income: Refers to the median income range of the households in the geographic area.
- Percent of households where residents are married: Denotes the number of households containing married individuals.
- Percent of households where residents completed college: Refers to the number of households where the first individual has a college degree.
- Percent of households where residents own their home: Denotes the number of households that own their home.

The county-level variables were obtained from the HRSA area resource file and linked to the PDE data at the 5-digit zip code level.[2] The variables are as follows:

- Federally designated primary care professional shortage areas: Refers to beneficiaries living in areas designated by HRSA as having a shortage in primary care practitioners as reported in 2015-2016. The following criteria are used to determine primary care shortage areas:
    A. The area is a rational area for the delivery of primary medical services.
    B. One of the following conditions prevails within the area:
        i. The area has a population to full-time-equivalent primary care physician ratio of at least 3,500:1.
        ii. The area has a population to full-time-equivalent primary care physician ratio of less than 3,500:1 but greater than 3,000:1 and has unusually high needs for primary care services or insufficient capacity of existing primary care providers.
    C. Primary medical care professionals in contiguous areas are overutilized, excessively distant or inaccessible to the population of the area under consideration.
- Federally designated mental healthcare professional shortage areas: Denotes beneficiaries living in areas designated by HRSA as having a shortage in mental health practitioners as reported in 2015-2016. The following criteria are used to determine mental health shortage areas:
    A. The area is a rational area for the delivery of mental health services.
    B. One of the following conditions prevails within the area:
        a. The area has:
            i. population-to-core-mental-health-professional ratio greater than or equal to 6,000:1 and a population-to-psychiatrist ratio greater than or equal to 20,000:1 or
            ii. a population-to-core-professional ratio greater than or equal to 9,000:1 or
            iii. a population-to-psychiatrist ratio greater than or equal to 30,000:1;
        b. The area has unusually high needs for mental services, and has:
            i. population-to-core-mental-health-professional ratio greater than or equal to 4,500:1 and a population-to-psychiatrist ratio greater than or equal to 15,000:1 or
            ii. a population-to-core-professional ratio greater than or equal to 6,000:1, or
            iii. a population-to-psychiatrist ratio greater than or equal to 20,000:1.
    C. Mental health professionals in contiguous areas are overutilized, excessively distant or inaccessible to residents of the area under consideration.

References:

1. Dharmarajan S, Bentley JP, Banahan BF, West-Strum DS. Measuring pharmacy performance in the area of medication adherence: addressing the issue of risk adjustment. J Manag Care Spec Pharm. 2014;20(10):1057-68. PMID: 25278328.
2. Health Resources and Services Administration. Health Professional Shortage Area (HPSA) Application and Scoring. Available at: http://bhpr.hrsa.gov/shortage/hpsas/designationcriteria/designationcriteria.html.

2b3.2. If an outcome or resource use component measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

After careful review and consideration of all existing PQA measures, the RAAP recommended the PQA PDC 3-rates by therapeutic category measure for risk adjustment considerations as these are currently used for performance evaluation in a national payment program – the Medicare Part D Star Ratings program. To that end, PQA decided to focus on Medicare, and will evaluate SDS risk adjustment for Medicaid as these measures are incorporated into Medicaid programs (such as the Medicaid adult core set). As a result, all the risk adjustment work was focused on the Medicare population, with Medicaid risk adjustment to be considered in the future.

2b3.3a. Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*) **Also discuss any "ordering" of risk factor inclusion**; for example, are social risk factors added after all clinical factors?

The PQA Risk Adjustment Advisory Panel (RAAP)

To address the issue of whether to adjust performance measures for SDS, the National Quality Forum (NQF) convened an expert panel in 2014. The NQF panel recommended that performance-based measures should be risk-adjusted for sociodemographic factors if these criteria are met: (1) there is a conceptual relationship between SDS and the outcome(s), and (2) there is empirical evidence that SDS affects the outcome(s) of interest.[1]

In light of the NQF trial period that began in April 2015, PQA convened a Risk Adjustment Advisory Panel (RAAP), comprised of representatives with experience in healthcare disparities, risk adjustment methods, and medication adherence research (see Table 9 for list of RAAP members). The goals of the group included: 1) identifying which PQA measures may be appropriate for SDS risk adjustment; and 2) recommending a valid risk adjustment methodology for those measures, which included determining which SDS variables to use for adjustment and how to report the measure rates by plan/contract. The panel decided to focus on the PQA PDC 3-rates by therapeutic category measure (Diabetes, RASA, and Statins).

The RAAP met monthly over the course of 18 months. Through a systematic review of literature, discussion, and voting, the RAAP selected variables for risk adjustment and developed a valid risk adjustment model for the three therapeutic categories.

Table 9. PQA Risk Adjustment Advisory Panel Members

Name	Organization
John Bentley	The University of Mississippi
Greg Berger	America's Health Insurance Plans (AHIP)
Anton Berisha	Lexis Nexis
Heather Black	Merck
Joyce Chan	Health First
Rebecca Chater	Ateb, Inc.
Kelly Conn	St. John Fisher College
Jeff Cooley	Humana

Name	Organization
Joseph Couto	Cigna
Patrick Gleason	Prime Therapeutics
Kelly Hollenack	ZA Pharma
Rita Hui	Kaiser Permanente
Taline Jaghasspanian	Health Net
Tom Kornfield	America's Health Insurance Plans (AHIP)
Patrick Meek	Albany College of Pharmacy and Health Sciences
Brian Meissner	Bristol Myers Squibb
David Nau	College of Pharmacy Nova Southeastern University
Kyle Null	Takeda
Jennifer Polinski	CVS Health
Nathaniel Rickles (Chair)	Northeastern University
Rene Saucedo	University of Florida
Xi Tan	West Virginia University
Christie Teigland	Inovalon

Variable Selection

The RAAP recommended a list of potential risk factors to examine, based on a conceptual framework related to medication adherence[2] as well as a review of published literature. The underlying conceptual framework that was selected focused on older adults, given that the Medicare population is primarily 65 years and older. This framework recognizes inherent challenges attributed to age-related factors (such as declining cognitive and physical functions), but also the importance of social factors, environmental and financial constraints that may impact medication adherence.

Variables selected based on a review of published literature included risk factors that are not directly under the control of providers, as these would be most appropriate for risk adjustment. Table 10 below lists the SDS variables that negatively correlate with adherence that were identified from a meta-analysis[3] and other supporting literature.[4-18]

Table 10. SDS Variables and Literature on Negative Effect on Medication Adherence

SDS Variable		Negative Effect on Adherence[3]
Beneficiary-level	Age	• Age - older and younger age groups (vs. adults)[4] • Very old age (older than 85 years)[5]
	Gender	• Male[4,5]
	Low-income subsidy status or dual eligibility status	• Low income[4,6] • Poverty[7,8] • Lower socioeconomic status[9,10] • Financial constraints[11,12]
	Disability as original reason for Medicare entitlement	• Disability[13,14]
	Race	• Latinos (vs. Euro-Americans)[10] • Hispanic patients (in the US, in TB)[4] • Monolingual Spanish speakers[10] • Non-white women[5]
Community-level	Median income	• Financial constraints[11,12] • Poverty[7,8] • Lower socioeconomic status[4,10]
	Percent of households where residents are married	• Single or divorced (vs. married)[6,15]
	Percent of households where residents completed college	• Illiteracy[4] • (inverse) education[9, 11]
	Percent of households where residents own their home	• Unstable housing[16,17]
County-level	Federal designated healthcare provider shortage area	• Barriers to high-quality care[10] • Lack of providers /caregiver availability[8] • Rural settings[8] • Poor access to a healthcare facility (e.g., long waiting times, inconvenient opening hours)[6] • Poor follow-up by providers[17,18]

SDS: sociodemographic status

Statistical Methods

Univariate regression models were used to explore the association between the measure outcomes and single covariates. Variables that were statistically significant at alpha = 0.05 for any of the therapeutic categories were subsequently included in the multivariable regression model. The multivariable regression model was used to explore the association between the measure outcomes adjusted for all covariates that were statically significant based on the univariate models. Multicollinearity was not observed (VIF <10 for all variables), and no interaction terms were included in any of the models.

References:

1. National Quality Forum. Risk adjustment for socioeconomic status or other sociodemographic factors. 2014. Available at: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=77474.
2. Murray MD, Morrow DG, Weiner M, et al. A conceptual framework to study medication adherence in older adults. Am J Geriatr Pharmacother. 2004;2(1):36-43. PMID: 15555477.
3. Kardas P, Lewek P, Matyjaszczyk M. Determinants of patient adherence: a review of systematic reviews. Front Pharmacol. 2013;25;4:91. PubMed PMID: 23898295.

4. Munro SA, Lewin SA, Smith HJ, Engel ME, Fretheim A, Volmink J. Patient adherence to tuberculosis treatment: a systematic review of qualitative research. PLoS Med. 2007; 24;4(7):e238. PMID: 17676945.
5. Ruddy K, Mayer E, Partridge A. Patient adherence and persistence with oral anticancer treatment. CA Cancer J Clin. 2009; 59(1):56-66. PMID: 19147869.
6. Jindal RM, Joseph JT, Morris MC, Santella RN, Baines LS. Noncompliance after kidney transplantation: a systematic review. Transplant Proc. 2003; 35(8):2868-72. PMID: 14697924.
7. Costello K, Kennedy P, Scanzillo J. Recognizing nonadherence in patients with multiple sclerosis and maintaining treatment adherence in the long term. Medscape J Med. 2008; 10(9):225. PMID: 19008986.
8. Vreeman RC, Wiehe SE, Pearce EC, Nyandiko WM. A systematic review of pediatric adherence to antiretroviral therapy in low- and middle-income countries. Pediatr Infect Dis J. 2008 ;27(8):686-91. PMID: 18574439.
9. Young GJ, Rickles NM, Chou CH, Raver E. Socioeconomic characteristics of enrollees appear to influence performance scores for Medicare part D contractors. Health Aff. 2014; 33(1):140-6. PMID: 24395946.
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13. Inovalon. An investigation of Medicare Advantage dual-eligible member level performance on CMS Five Star quality measures. Available at: http://resources.inovalon.com/papers/an-investigation-of-medicare-advantage-dual-eligible-member-level-performance-on-cms-five-star-quality-measures. Accessed April 2017.
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15. Julius RJ, Novitsky MA Jr, Dubin WR. Medication adherence: a review of the literature and implications for clinical practice. J Psychiatr Pract. 2009; 15(1):34-44. PMID: 19182563.
16. Hirsch-Moverman Y, Daftary A, Franks J, Colson PW. Adherence to treatment for latent tuberculosis infection: systematic review of studies in the US and Canada. Int J Tuberc Lung Dis. 2008; 12(11):1235-54. PMID: 18926033.
17. Reisner SL, Mimiaga MJ, Skeer M, Perkovich B, Johnson CV, Safren SA. A review of HIV antiretroviral adherence and intervention studies among HIV-infected youth. Top HIV Med. 2009; 17(1):14-25. PMID: 19270345.
18. Gold DT, Alexander IM, Ettinger MP. How can osteoporosis patients benefit more from their therapy? Adherence issues with bisphosphonate therapy. Ann Pharmacother. 2006; 40(6):1143-50. PMID: 16735667.

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

☒ **Published literature**

☐ **Internal data analysis**

☒ **Other (please describe)** – subject matter experts consensus

2b3.4a. What were the statistical results of the analyses used to select risk factors?

Univariate random effects logistic regression models were used to explore the association between the measure outcomes and single covariates to determine which risk factors were associated with adherence. Variables that were statistically significant at alpha = 0.05 for any of the therapeutic categories were included in the multivariable random effects logistic regression models. Tables 11-13 show the coefficients, odds ratios (ORs), and 95% confidence interval (CI) for the final univariate and multivariable regression models.

Note: The univariate models were run with one variable at a time but reported together in one table. The multivariable models were run with all variables at the same time in the model. p ≤0.001 for all variables in univariate analysis unless otherwise specified. All analyses were conducted using SAS Foundation 9.4.

Table 11. Univariate (Unadjusted) and Multivariable (Adjusted) Logistic Regression Results – Diabetes

	Unadjusted			Adjusted			
Characteristic	**Coeff Estimate**	**OR**	**95% CI**	**Coeff Estimate**	**OR**	**95% CI**	**p-Value**
Age Group (Ref = 80+)							
18-54	-0.6429	0.53	0.50, 0.53	-0.1491	0.86	0.79, 0.94	0.0004
55-64	-0.2558	0.77	0.75, 0.80	0.0936	1.10	1.03, 1.17	0.0054
65-69	-0.0100	0.99	0.96, 1.02	-0.0290	0.97	0.94, 1.00	0.0768
70-74	0.0357	1.04	1.00, 1.07	0.0145	1.02	0.98, 1.08	0.3940
75-79	0.0447	1.05	1.01, 1.08	0.0287	1.03	0.99, 1.07	0.1180
Gender (Ref = Female)							
Male	-0.1403	0.87	0.85, 0.89	-0.1329	0.88	0.86, 0.89	<.0001
LIS or Dual (Ref = Non-LIS/Non-Dual)	-0.3054	0.74	0.72, 0.75	-0.1666	0.85	0.83, 0.87	<.0001
Disability (Ref = No Disability)	-0.5041	0.60	0.59, 0.62	-0.4408	0.64	0.60, 0.69	<.0001

Coeff: Coefficient; CI: confidence interval; OR: odds ratio; Ref: reference group; LIS: low-income subsidy

Note: For age group 65-69, the p-value in the univariate analysis was > 0.05.

Table 12. Univariate (Unadjusted) and Multivariable (Adjusted) Logistic Regression Results – RASA

	Unadjusted			Adjusted			
Characteristic	**Coeff Estimate**	**OR**	**95% CI**	**Coeff Estimate**	**OR**	**95% CI**	**p-value**
Age Group (Ref = 80+)							
18-54	-0.7257	0.48	0.47, 0.50	-0.0942	0.91	0.86, 0.96	0.0008
55-64	-0.2357	0.79	0.77, 0.81	0.1978	1.22	1.17, 1.27	<.0001
65-69	0.0889	1.09	1.07, 1.12	0.0683	1.07	1.05, 1.09	<.0001
70-74	0.1289	1.14	1.11, 1.16	0.1076	1.11	1.09, 1.14	<.0001
75-79	0.0844	1.09	1.06, 1.11	0.0693	1.07	1.05, 1.10	<.0001
Gender (Ref = Female)							
Male	-0.0096	0.990	0.98, 1.00	-0.0030	1.00	0.98, 1.01	0.6583
LIS or Dual (Ref = Non-LIS/Non-Dual)	-0.5205	0.59	0.58, 0.60	-0.3902	0.68	0.67, 0.69	<.0001
Disability (Ref = No Disability)	-0.5990	0.55	0.54, 0.56	-0.4648	0.63	0.60, 0.66	<.0001

Coeff: Coefficient; CI: confidence interval; OR: odds ratio; Ref: reference group; LIS: low-income subsidy

Note: For gender, the p-value for males in the univariate analysis was >0.05.

Table 13. Univariate (Unadjusted) and Multivariable (Adjusted) Logistic Regression Results – Statins

	Unadjusted			Adjusted			
Characteristic	**Coeff Estimate**	**OR**	**95% CI**	**Coeff Estimate**	**OR**	**95% CI**	**p-Value**
Age Group (Ref = 80+)							
18-54	-0.5927	0.55	0.54, 0.57	-0.0631	0.94	0.90, 0.99	0.0105
55-64	-0.2826	0.75	0.74, 0.77	0.0857	1.09	1.05, 1.13	<.0001
65-69	-0.1156	0.89	0.88, 0.91	-0.1408	0.87	0.85, 0.88	<.0001
70-74	-0.0566	0.95	0.93, 0.96	-0.0826	0.92	0.91, 0.94	<.0001
75-79	-0.0543	0.95	0.93, 0.97	-0.0734	0.93	0.91, 0.95	<.0001
Gender (Ref = Female)							
Male	-0.1490	0.86	0.85, 0.87	-0.1473	0.86	0.85, 0.87	<.0001
LIS or Dual (Ref = Non-LIS/Non-Dual)	-0.3569	0.70	0.69, 0.71	-0.2581	0.77	0.76, 0.78	<.0001
Disability (Ref = No Disability)	-0.4255	0.65	0.64, 0.66	-0.4393	0.64	0.62, 0.67	<.0001

Coeff: Coefficient; CI: confidence interval; OR: odds ratio; Ref: reference group; LIS: low-income subsidy

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors *(e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.)* **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**

Empirical Association with Outcome (Univariate Analysis)

For all three therapeutic categories, younger beneficiaries were less likely to be adherent compared to the older population (e.g., OR = 0.53, 0.48 and 0.55 for age group 18-54 years, for Diabetes, RASA, and Statins, respectively; OR = 0.99, 1.09, and 0.89 for age group 65-69 years for Diabetes, RASA, and Statins, respectively). For Diabetes and Statins, males were less likely to be adherent than females (OR = 0.87 and 0.86, respectively) while for RASA, there was no statistical difference in adherence between males and females. The LIS/Dual population was less likely to be adherent to medications for all three therapeutic categories (OR = 0.74. for Diabetes, OR = 0.59 for RASA, and OR = 0.70 for Statins). For all therapeutic categories, those persons with disability as the reason for Medicare entitlement were less likely to be adherent to their medications (OR = 0.60 for Diabetes, OR = 0.55 for RASA, and OR = 0.65 for Statins).

Low vs. High Performing Plan-Contracts (Multivariable Analysis)

Several members of the RAAP expressed concerns that SDS risk adjustment may mask real disparities and create lower standards of performance for beneficiaries in disadvantaged populations. To assess the impact of risk adjustment on the highest and lowest performing plan-contracts, plan-contracts were ranked based on unadjusted and risk-adjusted scores. (see Figures 1-3). For all three therapeutic categories, the lowest performing plan-contracts prior to SDS risk adjustment continued to perform poorly after risk adjustment. This trend also held true for the highest performing plan-contracts.

This showed that very poor performers and top performers stay the same after risk adjustment, with most of the movement occurring in the middle performing plan-contracts. Thus, risk adjustment provided a more accurate reflection of the relative risk of the population of the plan-contract, but still showed which plan-contracts were performing worse compared to plan-contracts serving similar beneficiaries.

Note: The higher the ranking, the better the plan-contract performance

Figure 1. Unadjusted vs. Risk-Adjusted Rankings – Diabetes

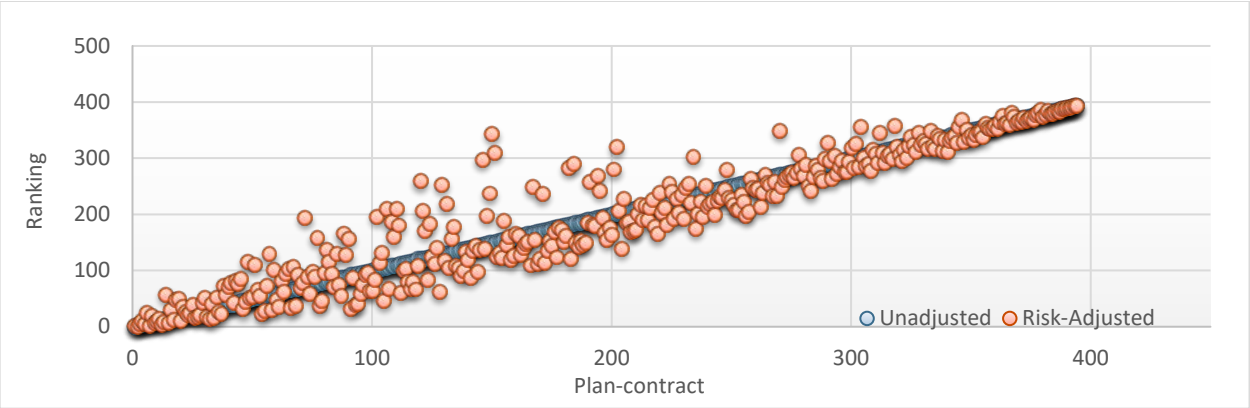


Figure 2. Unadjusted vs. Risk-Adjusted Rankings – RASA

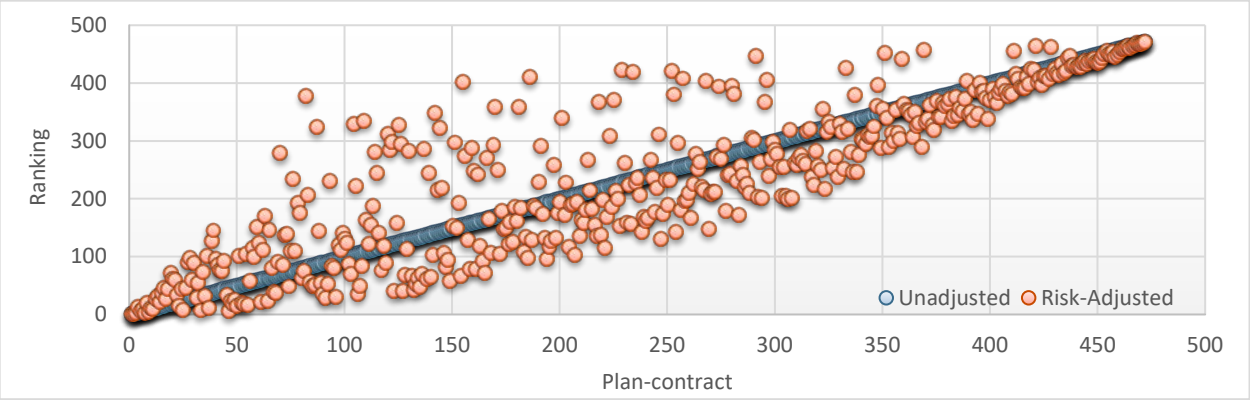
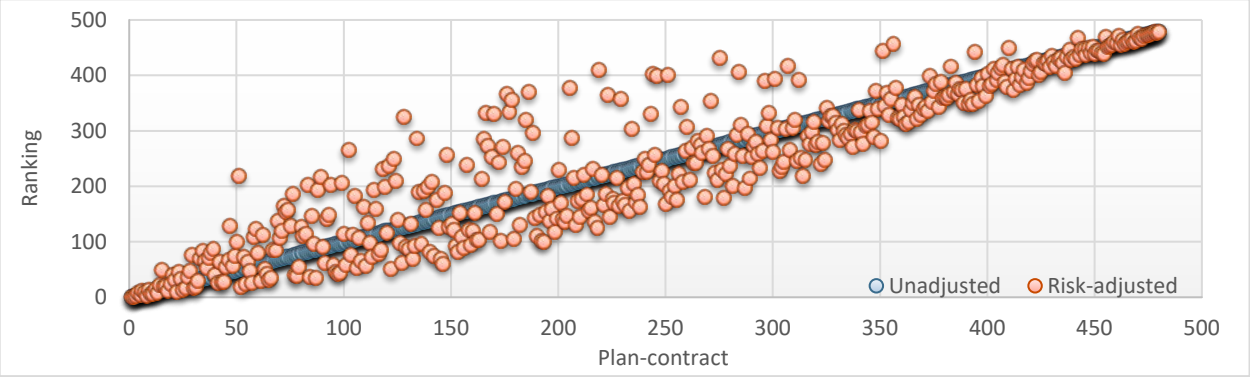


Figure 3. Unadjusted vs. Risk-Adjusted Rankings – Statins



2b3.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (*describe the steps—do not just name a method; what statistical analysis was used*)

Risk adjustment is important in making fair comparisons among plan-contracts. However, it may introduce an uncertainty when alternative statistical methodologies do not agree on which plan-contracts are identified as high- and low-quality.[1-3] Based on literature review[4-6] and discussions with subject matter experts, the RAAP identified the multivariable, random effects logistic regression model as the suitable method for SDS risk adjustment. To validate this statistical methodology, we considered an alternative approach, using the classical logistic regression model, which assumes that individuals are independent observations in the dataset, and does not account for the nesting of contracts within plans.

We hypothesized that risk-adjusted measure scores would show better overall agreement with each other than with the unadjusted compared to each risk-adjusted score. We compared the two methods and looked at the weighted kappa as the measure of agreement.

References:

1. Iezzoni LI. The risks of risk adjustment. JAMA. 1997;278(19):1600-7. PMID: 9370507.
2. DeLong ER, Peterson ED, DeLong DM, Muhlbaier LH, Hackett S, Mark DB. Comparing risk-adjustment methods for provider profiling. Stat Med. 1997;16(23):2645-64. PMID: 9421867.
3. Li Y, Dick AW, Glance LG, et al. Misspecification Issues in Risk Adjustment and Construction of Outcome-Based Quality Indicators.' Health Services and Outcomes Research Methodology 2007;7: 39–56.
4. Dharmarajan S, Bentley JP, Banahan Iii BF, West-Strum DS. Measuring pharmacy performance in the area of medication adherence: addressing the issue of risk adjustment. J Manag Care Spec Pharm. 2014;20(10):1057-68. PMID: 25278328.
5. Young GJ, Rickles NM, Chou CH, Raver E. Socioeconomic characteristics of enrollees appear to influence performance scores for Medicare part D contractors. Health Aff. 2014;33(1):140-6. PMID: 24395946.
6. Li Y, Cai X, Glance LG, Spector WD, Mukamel DB. National release of the nursing home quality report cards: implications of statistical methodology for risk adjustment. Health Serv Res. 2009;44(1):79-102. PMID: 19146565.

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.

If stratified, skip to 2b3.9

2b3.6. Statistical Risk Model Discrimination Statistics (*e.g., c-statistic, R-squared*)**:**

Table 14 shows the area under the receiver operating characteristic (ROC) curve (the c-statistic) for the primary method used for risk adjustment (random effects logistic regression models) for each therapeutic category.

Table 14. C-statistic for Random Effects Logistic Regression Models – By Therapeutic Category

Therapeutic Category	c-statistic
Diabetes	0.583
RASA	0.597
Statins	0.591

We also show the agreement between the unadjusted and the primary method (random effects), as well as the primary method and the alternative method (classical logistic regression). (see Table 15).

Table 15. Agreement (Weighted Kappa) Between Measure Scores – By Therapeutic Category

Comparison	Diabetes	RASA	Statins
Unadjusted vs. Random effects model	0.803 (0.775, 0.831)	0.693 (0.658, 0.729)	0.748 (0.718, 0.777)
Random effects vs. Classical logistic regression	0.989 (0.984, 0.995)	0.977 (0.969, 0.984)	0.975 (0.967, 0.983)

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):

The generalized linear mixed (GLIMMIX) procedure with random intercept in SAS was used for risk adjustment. While this method is well suited for binary measures, there is no formal statistic to assess the goodness of fit (GOF) for these models. We used an extension of the Hosmer-Lemeshow (H-L) GOF test developed and validated by Li et al[1] to determine the model calibration.

In large datasets, small/unimportant deviations from good calibration can still lead to large H-L test statistic or small p-value, and therefore may not be useful. As such we provide risk decile plots to measure predictive ability.

References:

1. Li R, Su Z, Mendelsohn A, Gemmen E. Extension of the Hosmer-Lemeshow Goodness of Fit statistic to linear models with repeated measurements. Value in Health 16(2013) A1-A298.

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:

The risk decile plot provides a graphical representation of the deciles calculated to measure predictive ability as calculated above in 2b3.7. Figures 4-6 show the distribution of the observed and expected PDC deciles for each of the therapeutic categories.

Figure 4. Risk Decile Plot for Diabetes

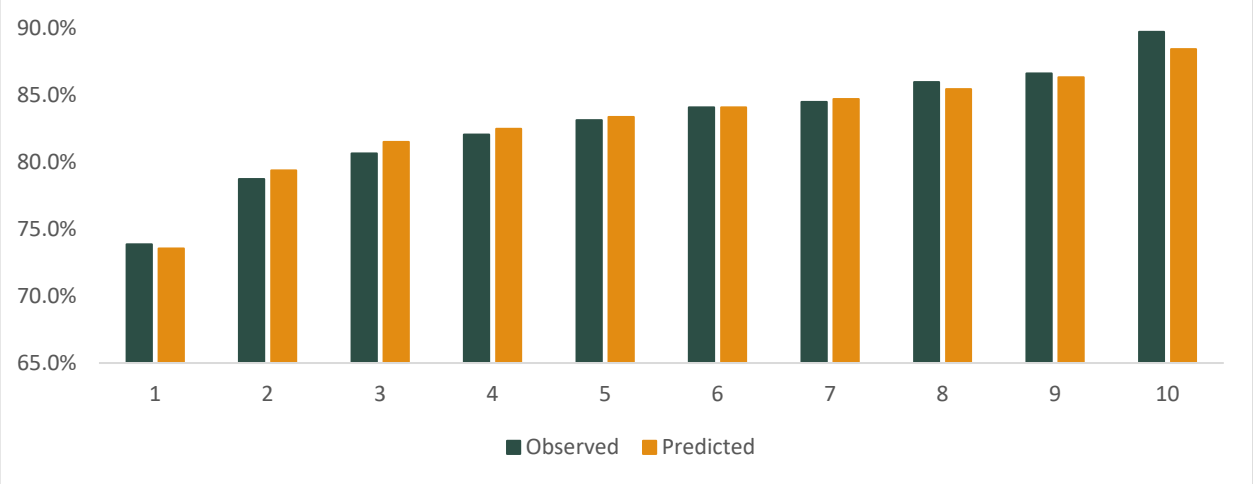


Figure 5. Risk Decile Plot for RASA

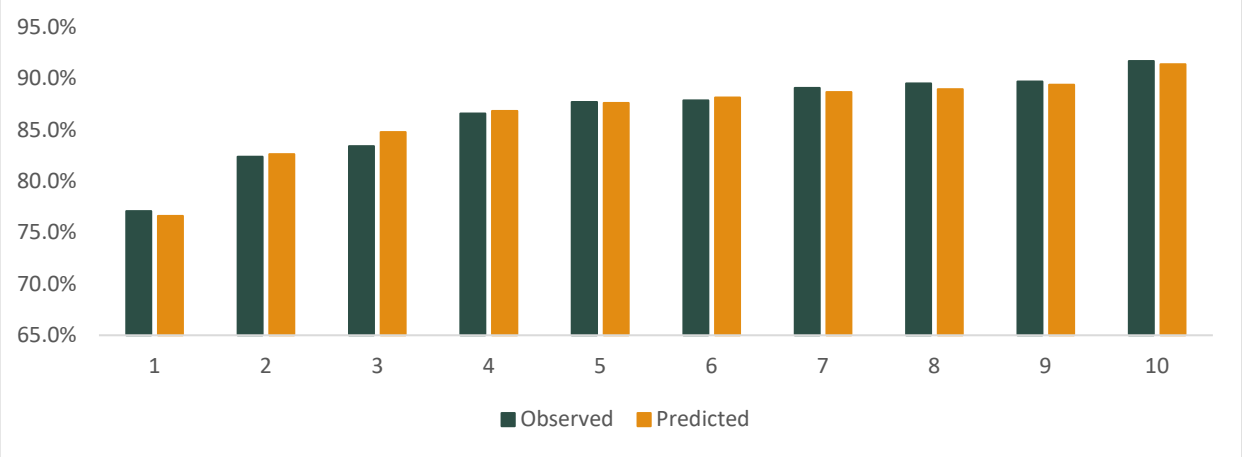
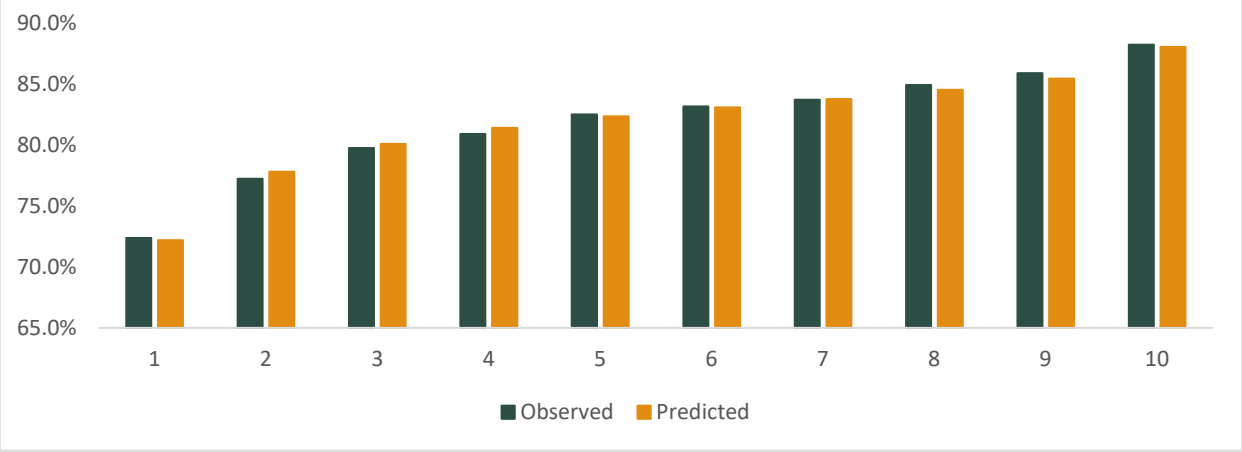


Figure 6. Risk Decile Plot for Statins



2b3.9. Results of Risk Stratification Analysis:

N/A

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.*e., what do the results mean and what are the norms for the test conducted*)

A comparison of agreement between the two risk adjustment methodologies showed almost perfect agreement, with kappa = 0.99 for Diabetes, 0.98 for RASA and 0.97 for Statins. This was much higher than the unadjusted vs. random effects models (0.69-0.80). This showed that SDS risk adjustment was more appropriate for evaluating performance scores compared to the unadjusted measure scores. In addition, as shown in Tables 19-21, we observed significant shifts in deciles post risk-adjustment, with over 50% of plan-contracts changing deciles.

The c-statistic is used to assess model discrimination, and ranges from 0.5 to 1.0 with 0.5 indicating the model is no better than random prediction and 1.0 showing perfect prediction. In research, a c-statistic of 0.7 or greater indicate acceptable discrimination. However, with performance measurement, the purpose of risk adjustment is to reduce bias due to patient characteristics present at the start of care, not to completely explain variations in outcomes, and therefore does not include variables related to quality of care.

It is important to note that the variables included in this analysis have been found to have an impact on outcome measures in other studies. This suggests that although the covariates used for risk adjustment in this study are important, there may be other covariates that could improve the model, such as clinical variables for diagnoses, disease severity, etc. As with any risk adjustment modeling, the model can only account for measurable and available covariates. Therefore, if any unmeasured factors are not randomly distributed within contracts, the risk adjustment methodology may not adequately mitigate the impact of these unmeasured factors.

Finally, the risk decile plots show that the higher deciles of the predicted outcomes were associated with higher observed outcomes. In addition, within each decile, there is no meaningful discrepancy between the observed PDC score in a decile and that predicted by the model, which shows good discrimination and predictive ability of the models.

2b3.11. Optional Additional Testing for Risk Adjustment (*not required, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed*)

In 2016, PQA contracted with CMS to examine the PDC 3-rates measure (Diabetes, RASA, and Statins) to determine if SDS risk adjustment was needed. As part of this work, PQA received the 2014 CMS PDE data containing information (including age, gender, LIS/dual eligibility status, race, disability as reason for Medicare entitlement, flag for numerator inclusion, etc.) about individuals eligible for inclusion in the measure calculations for each of the three therapeutic categories. PQA, working with the RAAP conducted the study to examine SDS risk adjustment for the Medicare population, and based on the results of the study, recommended that all three therapeutic categories should be risk-adjusted for age, gender, LIS/dual eligibility status and disability status.

Part of the study included examining not just the beneficiary-level risk factors available in the CMS PDE data, but community- and county-level variables. A review of the three models (full – with all beneficiary, community and county; reduced with race, which included all beneficiary-level variables; and reduced without race, which included all beneficiary-level variables except race) showed similar results in terms of magnitude and direction of the odds ratios, with one exception in the PDC Diabetes model, where the odds ratio for the 65-69 years age group changed from 1.02 in the reduced model with race to 0.97 in the reduced model without race. In addition, the movement of plan-contracts post risk adjustment was similar for all three models. (see Tables 16-18).

Table 16. Risk-Adjusted Decile Rankings for Full vs. Reduced Models – Diabetes

	Full Model	Reduced (w/ race)	Reduced (w/o race)
Contracts adjusted to a higher decile	25.8%	25.0%	20.2%
contracts adjusted to a lower decile	44.6%	43.4%	40.3%
contracts adjusted to the same decile	29.6%	31.5%	39.5%
Average (absolute) change in decile	1.6	1.4	0.9
Average decile change for contracts adjusted to a higher decile	2.5	2.3	2.2
Average decile change for contracts adjusted to a lower decile	-2.0	-1.6	-1.1

Table 17. Risk-Adjusted Decile Rankings for Full vs. Reduced Models – RASA

	Full Model	Reduced (w/ race)	Reduced (w/o race)
Contracts adjusted to a higher decile	26.7%	25.7%	24.4%
contracts adjusted to a lower decile	46.4%	47.6%	46.8%
contracts adjusted to the same decile	26.9%	26.7%	28.8%
Average (absolute) change in decile	1.3	1.3	1.1
Average decile change for contracts adjusted to a higher decile	2.5	2.5	2.3
Average decile change for contracts adjusted to a lower decile	-1.4	-1.4	-1.2

Table 18. Risk-Adjusted Decile Rankings for Full vs. Reduced Models – Statins

	Full Model	Reduced (w/ race)	Reduced (w/o race)
Contracts adjusted to a higher decile	25.2%	24.5%	20.6%
contracts adjusted to a lower decile	43.6%	42.8%	36.9%
contracts adjusted to the same decile	31.2%	32.7%	42.5%
Average (absolute) change in decile	1.1	1.1	0.8
Average decile change for contracts adjusted to a higher decile	2.2	2.2	1.9
Average decile change for contracts adjusted to a lower decile	-1.3	-1.2	-1.1

The results of the study using the 100% CMS PDE data provide additional validation of the risk adjustment models and results reported in section 2b3 above using the 5% Medicare sample. A comparison of the plan-contract movement at the decile-level post risk adjustment using the final list of recommended SDS risk factors (age, gender, LIS/dual eligibility, and disability status) was similar using the 2014 100% PDE data and the 2016 5% sample. (see Tables 19-21).

Table 19. Risk-Adjusted Decile Rankings for 100% vs.5% Sample PDE Datasets – Diabetes

	2016 5% Sample	2014 100% Data
Contracts adjusted to a higher decile	20.6%	20.2%
contracts adjusted to a lower decile	29.7%	40.3%
contracts adjusted to the same decile	49.8%	39.5%
Average (absolute) change in decile	0.6	0.9
Average decile change for contracts adjusted to a higher decile	1.6	2.2
Average decile change for contracts adjusted to a lower decile	-1.1	-1.1

Table 20. Risk-Adjusted Decile Rankings for 100% vs.5% Sample PDE Datasets – RASA

	2016 5% Sample	2014 100% Data
Contracts adjusted to a higher decile	22.7%	24.4%
contracts adjusted to a lower decile	39.4%	46.8%
contracts adjusted to the same decile	37.9%	28.8%
Average (absolute) change in decile	1.0	1.1
Average decile change for contracts adjusted to a higher decile	2.2	2.3
Average decile change for contracts adjusted to a lower decile	-1.3	-1.2

Table 21. Risk-Adjusted Decile Rankings for 100% vs.5% Sample PDE Datasets – Statins

	2016 5% Sample	2014 100% Data
Contracts adjusted to a higher decile	22.9%	20.6%
contracts adjusted to a lower decile	35.4%	36.9%
contracts adjusted to the same decile	41.7%	42.5%
Average (absolute) change in decile	0.8	0.8
Average decile change for contracts adjusted to a higher decile	1.8	1.9
Average decile change for contracts adjusted to a lower decile	-1.2	-1.1

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

2b4.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified (*describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided related to performance gap in 1b)*

To assess significant differences in measure rates, unadjusted measure rates for Medicare and Medicaid, as well as risk-adjusted rates for Medicare were used to calculate the mean, median, standard deviation, and interquartile range. In addition, the rates were divided into quartiles, and a Student's t-test was used to compare the rates of the plans/contracts in the 25th percentile to the rates of the plans/contracts in the 75th percentile. Finally, to assess impact of risk adjustment on measure rates, plan-contracts were placed into deciles using the unadjusted as well as the risk adjusted rates and assessed to determine the rate of decile shifts post risk adjustment.

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., *number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined*)

For the Medicare population, for Diabetes, the mean rate (with standard deviation [SD]) was 82.1% (5.5%), for RASA the mean rate (SD) was 85.7% (5.0%) and for Statins the mean rate (SD) was 80.6% (5.9%). (see Table 22).

Table 22. Means Distribution of Unadjusted Measure Rates for Medicare – By Therapeutic Category

Statistic	Diabetes	RASA	Statins
Mean	82.1%	85.7%	80.6%
Std. Deviation (Mean)	5.5%	5.0%	5.9%
Minimum	62.5%	63.9%	59.3%
25th Percentile	78.8%	83.0%	77.3%
50th Percentile	82.5%	86.7%	81.7%
75th Percentile	85.8%	88.9%	84.2%
Maximum	96.8%	97.2%	97.1%
Interquartile Range	7.0%	5.9%	7.0%
Student's t-test p-value	<.0001	<.0001	<.0001

RASA: renin-angiotensin system antagonist

For the Medicaid population, for Diabetes, the mean rate (SD) was 59.6% (11.4%), for RASA the mean rate (SD) was 62.2% (10.7%) and for Statins the mean rate (SD) was 58.7% (11.0%). (see Table 23).

Table 23. Means Distribution of Measure Rates for Medicaid – By Therapeutic Category

Statistic	Diabetes	RASA	Statins
Mean	59.6%	62.2%	58.7%
Std. Deviation (Mean)	11.4%	10.7%	11.0%
Minimum	32.1%	34.1%	31.9%
25th Percentile	53.0%	55.6%	52.2%
50th Percentile	60.9%	63.0%	59.6%
75th Percentile	67.1%	68.7%	65.6%
Maximum	85.0%	85.4%	86.6%
Interquartile Range	14.1%	13.1%	13.4%
Student's t-test p-value	<.0001	<.0001	<.0001

RASA: renin-angiotensin system antagonist

Table 24 shows the means distribution of the risk-adjusted measure rates for Medicare, with Tables 19-21 above highlighting the impact of risk adjustment on decile rankings for Medicare plan-contracts.

Table 24. Means Distribution of Risk-Adjusted Measure Rates for Medicare – By Therapeutic Category

Statistic	Diabetes	RASA	Statins
Mean	81.8%	85.5%	80.1%
Std. Deviation (Mean)	5.1%	4.3%	5.4%
Minimum	61.1%	61.0%	55.9%
25th Percentile	79.0%	83.8%	77.9%
50th Percentile	81.9%	85.9%	80.6%
75th Percentile	84.7%	88.0%	83.4%
Maximum	96.3%	96.4%	97.3%
Interquartile Range	5.6%	4.1%	5.5%
Student's t-test p-value	<.0001	<.0001	<.0001

RASA: renin-angiotensin system antagonist

2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities? (i.*e., what do the results mean in terms of statistical and meaningful differences?*)

As expected, given the importance of these three PDC measure rates in the CMS Part D Star Ratings program (each is triple weighted), the variations were lower in the unadjusted measure rates for Medicare than in the Medicaid population, as health plans work to improve their measure scores to maximize overall Star Ratings and payment. However, there was some variation in Medicare, with a standard deviation ranging from 5.0% (RASA) to 5.9% (Statins) and an interquartile range from 5.9% (RASA) to 7.0% (Diabetes & Statins). There is also a statistically significant difference in measure rates between the top and bottom quartile of the plan-contracts included in the testing (P< .0001 at alpha = 0.05) for all three therapeutic categories in both adjusted and unadjusted measure scores. This variation shows that there are statistically significant and meaningful differences in rates across plan-contracts.

Within Medicaid, the variation was even more pronounced, with a standard deviation ranging from 10.7% (RASA) to 11.4% (Diabetes) and an interquartile range from 13.1% (RASA) to 14.1% (Diabetes). There is a statistically significant difference in measure rates between the top and bottom quartile of the plan-contracts included in the testing (P< .0001 at alpha = 0.05) for all three therapeutic categories. This variation shows that there are statistically significant and meaningful differences in rates across plans.

In addition, a review of the unadjusted and risk-adjusted rates showed that between 21% (Diabetes) and 23% (RASA & Statins) of plan-contracts were adjusted to a higher decile while 30% (Diabetes), 35% (RASA) and 39% (Statins) were adjusted to a lower decile after risk adjustment, showing that risk adjustment had an impact on measure rates at the decile-level. (see Tables 19-21). However, it is unclear what impact SDS risk adjustment will have on the Star Ratings of plan-contracts in the Medicare program.

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS

If only one set of specifications, this section can be skipped.

Note: *This item is directed to measures that are risk-adjusted (with or without social risk factors)* ***OR*** *to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eMeasures). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator).* ***Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.***

2b5.1. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications (*describe the steps—do not just name a method; what statistical analysis was used*)

N/A

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)

N/A

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i.*e., what do the results mean and what are the norms for the test conducted*)

N/A

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

With the use of prescription claims data as the data source for this measure, the dispensing information (including medication, days' supply, quantity dispensed, and dosage) is available for each beneficiary. Since each of these data elements are available via prescription claims data, it is not expected—nor was it found—that missing data would result.

The final risk adjustment model included only variables available in the CMS PDE data, and were considered to be reliable as many of these variables, including age, LIS status, disability as reason for Medicare entitlement are all important for determining eligibility for enrollment and payment of services.

In addition, race was excluded from the SDS risk adjustment in part because of RAAP concerns about the lack of completeness of the race variable, where about 20% of individuals' race in the 2014 100% CMS PDE was classified as "unknown".

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each*)

Race was found to be "unknown" for about 20% of the population in the 2014 100% CMS PDE and was therefore not included in the final model. As discussed in section 2b3.11, the models were run with and without race to determine impact of race on the models.

2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias**?** (i.*e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis, provide rationale for the selected approach for missing data*)

As discussed in 2b3.11, a comparison of the models with and without race show that the models were similar for all three rates with respect to the coefficient estimate direction and odds ratios of the included covariates with one exception in the Diabetes model, where the odds ratio for the 65-69 years age group changed from 1.02 in the reduced model with race to 0.97 in the reduced model without race.

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Other

If other: Prescription claims and enrollment data

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*) Update this field for **maintenance of endorsement**.

ALL data elements are in defined fields in electronic claims

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

N/A

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

Prescription claims data is required for payment to health plans, so there is no extra burden or cost in the collection of the data. There have been no feasibility issues with the use of this measure.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified *(e.g., value/code set, risk model, programming code, algorithm)*.

PQA develops and maintains numerous performance measures related to the medication use system. The measures are the proprietary property of PQA, and it is in the interest of PQA to protect and promote the appropriate use of the measures. PQA may approve an organization's use of the measures; however, no organization may use the measures without first obtaining permission from PQA prior to using the measures. Certain uses of the measures are only approved with a licensing agreement from PQA that specifies the terms of use and the licensing fee. PQA reserves the right to determine the conditions under which it will approve and/or license the measures.

Licenses are granted on a year-to-year basis. Licensees using PQA measures for commercial purposes are required to pay a fee. The licensing fee may be structured as a fixed annual amount or as a variable amount that is dependent on the volume of utilization of the measures.

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
Regulatory and Accreditation Programs Quality Improvement (Internal to the specific organization)	Public Reporting Centers for Medicare & Medicaid Services (CMS) Part C and Part D quality and performance measurement system (Star Ratings) http://www.medicare.gov/find-a-plan/results/planresults/planratings/compare-plan-ratings.aspx?PlanType=MAPD Integrated Healthcare Association http://www.iha.org/ Payment Program Centers for Medicare & Medicaid Services (CMS) Part C and Part D quality and performance measurement system (Star Ratings) http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html Centers for Medicare & Medicaid Services (CMS) Part C and Part D quality and performance measurement system (Star Ratings) http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html

4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

Public Reporting

1. Name and sponsor: Centers for Medicare & Medicaid Services (CMS) Part C and Part D quality and performance measurement system (Star Ratings)

- Purpose: The Centers for Medicare & Medicaid Services (CMS) publishes the Star Ratings each year to assist beneficiaries in finding the best plan for them. The PDC measure (3 rates) is included in the Star Ratings. A plan can get a rating between 1 and 5 stars. A plan can get a rating between 1 and 5 stars, with 5 being the highest and 1 being the lowest rating. The purpose of this program is that the ratings will help consumers compare plans based on quality and performance.
- Geographic area, etc.: The Star Ratings program is national in scope. For the 2019 Stars Ratings, reflecting the 2017 measurement year, 471 plan contracts—including 417 MA-PDs and 54 PDPs—representing nearly 40 million beneficiaries were scored on the PDC 3 Rates measure.

Payment

1. Name and sponsor: Centers for Medicare & Medicaid Services (CMS) Part C and Part D quality and performance measurement system (Star Ratings)
- Purpose: The Centers for Medicare & Medicaid Services (CMS) publishes the Star Ratings each year to determine Medicare Advantage Quality Bonus Payments. The purpose of the Medicare Star Ratings program is to tie federal reimbursement to performance of Medicare Advantage plans. Bonus payments are made to Medicare Advantage plans based on ratings from performance and quality measures. Prescription Drug Plans (PDPs) have marketing advantages based on their Star Ratings.
- Geographic area, etc.: The Star Ratings program is national in scope. For the 2019 Star Ratings, reflecting the 2017 measurement year, 471 plan contracts—including 417 MA-PDs and 54 PDPs—representing nearly 40 million beneficiaries were scored on the PDC 3 Rates measure.
Quality Improvement (external benchmarking):
1. CMS Part C and Part D quality and performance measurement system (Star Ratings) (as above)
2. Name and sponsor: Integrated Healthcare Association (IHA)
- Purpose: The IHA is a California multi-stakeholder, non-profit association that promotes quality improvement, accountability and affordability of health care in California. IHA operates the Align. Measure. Perform. program.
- Geographic area, etc.: This program collects data and reports results on behalf of 12 health plans covering approximately 11.8 million members in California.

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)

N/A

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)

N/A

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

PQA´s measure development and maintenance is a transparent, consensus-driven process to draft, test, refine, endorse and maintain measures.

During the development phase, PQA selects partners to test its draft measures. For plan-level measures, testing partners often are PQA member health plans (i.e., those that would be measured) with expertise in performance measurement that also have access to the data sources needed to calculate the measure rates. Testing partners implement the technical specifications within their existing data sets and conduct analyses included in the testing plan. During this phase, PQA provides technical assistance to testers, and may refine specifications based on questions received, to further clarify specifications to support ease of future implementation.

Once implemented, PQA provides technical assistance to CMS, CMS contractors, and measure users directly, which may include the following:

- Providing timely responses to questions received;

- Reviewing de-identified data to verify measure rate calculations, as needed; and

- Webinars or other educational offerings as requested.

Additionally, the PDC 3 Rates measure scores are publicly reported through the Medicare Part D Star Ratings program. Through the data provided by CMS, Part D plans (Medicare Advantage [MA-PD] and stand-alone

Prescription Drug Plans [PDP]) have visibility to their own performance on the measure as well as how their performance compares to other plans. The reporting is inclusive of all MA-PDs and PDPs, provided they meet the reporting requirements (e.g., meet the minimum denominator size of 30).

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

As stated in 4a2.1.1., CMS provides the measure scores and ratings on the PDC 3 Rates measure through the Medicare Part D Star Ratings program. Plans receive their scores and ratings twice annually:

- End of August/early September: Plan preview period for Part C & D Star Ratings; and

- October: Part C & D Star Ratings go live on medicare.gov.

PQA does not provide data or measure scores; however, as the measure steward, PQA provides technical assistance to support accurate implementation of the measure specifications.

As PQA receives feedback from measure users via a web form or email (measureuse@PQAalliance.org). PQA staff then provide timely (i.e., 24-48 hours) responses to all inquiries by email, telephone or webinar. Frequently asked questions and other recommendations are reviewed by PQA staff and brought to the Measure Update Panel (MUP), which then determines whether refinements or clarifications to the specifications are needed.

Furthermore, CMS shares all comments related to PQA measures included in their quality programs -- including those specific to the PDC 3 Rates measure -- that they receive in response to proposed rules and the Part D draft Call Letter, which are released on an annual basis. Comments then are reviewed by PQA staff and brought to the Measure Update Panel (MUP), which then determines whether refinements or clarifications to the specifications are needed.

Additionally, high performing plans are invited to present during PQA´s Annual Meeting and during PQA´s Quality Forum webinars, to highlight their quality improvement interventions that have been effective in showing improvement in PQA measures used in the Part D Star Ratings, including the PDC 3 Rates measure.

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

As PQA receives feedback from measure users via a web form or email (measureuse@PQAalliance.org), and also from CMS.

Feedback from measured entities:

Health plans recommended the following changes to the PDC 3 Rates measure:

- Exclude individuals in hospice care from all three measure rates;

- Exclude individuals with end-stage renal disease from all three measure rates;

- Exclude individuals with 1 or more prescription claims for sacubitril/valsartan for the PDC-RASA rate;

- Revise the enrollment criteria to not allow any gaps in enrollment for all three measure rates; and

- Consider sociodemographic (SDS) risk adjustment for all three measure rates.

Feedback from others:

- PQA's Patient and Caregiver Advisory Panel (PCAP) recommended that individuals in hospice care be excluded from all three measure rates.

4a2.2.2. Summarize the feedback obtained from those being measured.

Health plans recommended the following changes to the PDC 3 Rates measure:

- Exclude individuals in hospice care from all three measure rates;

- Exclude individuals with end-stage renal disease from all three measure rates;

- Exclude individuals with 1 or more prescription claims for sacubitril/valsartan for the PDC-RASA rate; and

- Revise the enrollment criteria to not allow any gaps in enrollment for all three measure rates; and

- Consider sociodemographic (SDS) risk adjustment for all three measure rates.

4a2.2.3. Summarize the feedback obtained from other users

PQA's Patient and Caregiver Advisory Panel (PCAP) recommended individuals with end-stage renal disease and those in hospice care be excluded from all three measure rates.

Based on recommendations from NQF to consider performance measures for SDS risk adjustment, as well as recommendations from health plans, PQA convened the risk adjustment advisory panel (RAAP) to determine which PQA measures should be considered for risk adjustment, as well as the risk factors and valid risk adjustment methodology. The RAAP decided, based on literature review and empirical evidence, that the PDC 3-rates measure was most appropriate for SDS risk adjustment, and as a first step to apply it to the Medicare program, as this is used in a national quality payment program.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

During measure development:

- Performance measures that are recommended by the QMEP for endorsement consideration by PQA membership are posted on the PQA web site for member review, written comments are requested, and a webinar for member organizations is held to address comments and questions. This process allows stakeholders to discuss their views on the measures in advance of the voting period. PQA member organizations vote on endorsement of performance measures.

For revisions:

- After endorsement, PQA leverages a multi-stakeholder panel, the Measure Update Panel (MUP), to consider feedback for potential measure revisions. As stated in 4a2.1.2, feedback received from measure users is shared with the MUP. Material changes – those that affects the measure result – are also evaluated and approved by PQA´s Quality Metrics Expert Panel (QMEP). This process, which engages diverse stakeholders -- including measured entities, ensures feedback is reviewed and applied based on consensus and evidence.

Based on feedback received on the PDC-3 Rates measure, PQA´s MUP and QMEP considered the following recommendations:

1. Revise specifications to exclude individuals in hospice care from the PDC-3 Rates measure

- Both the MUP and QMEP voted in favor of making this change, because adherence to most chronic therapies does not necessarily align with the therapeutic goals and balance of risk and benefits for individuals in hospice care.

- Additionally, in 2015, the PQA Patient & Caregiver Advisory Panel recommended that hospice should generally be an exclusion for PQA measures unless the measures are directly relevant to, and align with, the therapeutic goals for individuals in hospice care.

2. Revise specifications to exclude individuals with end-stage renal disease (ESRD) from the PDC 3 Rates measure

- Both the MUP and QMEP voted in favor of making this change because adherence to diabetes, hypertension, and statin medications may not be accurately reflected in pharmacy claims data due to frequent dosage and medication adjustments. Furthermore, there is a lack of direct evidence that statin treatment is beneficial in dialysis patients.

3. Revise specifications to exclude individuals with 1 or more prescription claims for sacubitril/valsartan from the PDC-RASA rate only

- Both the MUP and QMEP voted in favor of making this change to the PDC-RASA rate because this product, although it includes a RASA (i.e., valsartan), is only indicated for treating heart failure (and the RASA rate is intended to evaluate adherence to medications used for treating hypertension).

4. Revise the enrollment criteria to not allow any gaps in enrollment for the PDC 3 Rates measure

- PQA convened a Technical Expert Panel (TEP) to review the continuous enrollment criteria. The TEP recommended not allowing any gap in enrollment for the PDC measure because allowing gaps could contribute to false negatives being included in the numerator.

- The QMEP voted in favor of making this change to the continuous enrollment criteria for the PDC 3 Rates measure.

5. Consider sociodemographic (SDS) risk adjustment for the PDC 3 Rates measure

- Based on recommendations from NQF to consider performance measures for SDS risk adjustment, as well as comments received from health plans, PQA convened its risk adjustment advisory panel (RAAP) to determine which PQA measures should be considered for risk adjustment. The RAAP decided, based on literature review and empirical evidence, that the PDC 3 Rates measure was most appropriate for SDS risk adjustment in the Medicare Part D Star Ratings, a national quality payment program.

- Based on the work of the RAAP, as well as a study conducted in collaboration with CMS, PQA has recommended that the PDC 3-rates measure be SDS risk adjusted.

The five changes listed above, now are reflected in the PDC 3 Rates measure specifications.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

As stated above, the PDC-3 Rates measure is used by CMS in the Medicare Part D Star Ratings Program to evaluate Medicare prescription drug plans. CMS has reported considerable variation across plans during the last 5 reporting years (2013-2017). This variation demonstrates the performance gap and opportunity for health plans to improve adherence rates for all three rates.

PDC-Diabetes Rate:

The mean rate has increased steadily over the last 5 reporting years (2013-2017), indicating overall improvement across plans.

- For MA-PDs, the mean rate improved from 76.8% in 2013 to 81.5% in 2017.

- For PDPs, the mean rate improved from 79.3% in 2013 to 83.4% in 2017.

The standard deviation has decreased modestly over the last 5 reporting years (2013-2017), indicating that the difference in rates between high and low performing plans has narrowed slightly.

- For MA-PDs, the standard deviation decreased from 5.9% in 2013 to 4.6% in 2017.

- For PDPs, the standard deviation decreased from 4.8% in 2013 to 3.6% in 2017.

PDC-RASA Rate:

The mean rate has increased steadily over the last 5 reporting years (2013-2017), indicating overall improvement across plans.

- For MA-PDs, the mean rate improved from 78.3% in 2013 to 83.4% in 2017.

- For PDPs, the mean rate improved from 81.1% in 2013 to 85.8% in 2017.

The standard deviation has decreased modestly over the last 5 reporting years (2013-2017), indicating that the difference in rates between high and low performing plans has narrowed slightly.

- For MA-PDs, the standard deviation decreased from 5.5% in 2013 to 4.3% in 2017.

- For PDPs, the standard deviation decreased from 4.5% in 2013 to 3.5% in 2017.

PDC-Statins Rate:

The mean rate has increased steadily over the last 5 reporting years (2013-2017), indicating overall improvement across plans.

- For MA-PDs, the mean rate improved from 74.0% in 2013 to 80.2% in 2017.

- For PDPs, the mean rate improved from 76.6% in 2013 to 82.7% in 2017.

The standard deviation has decreased modestly over the last 5 reporting years (2013-2017), indicating that the difference in rates between high and low performing plans has narrowed slightly.

- For MA-PDs, the standard deviation decreased from 7.1% in 2013 to 5.8% in 2017.

- For PDPs, the standard deviation decreased from 5.1% in 2013 to 4.3% in 2017.

The Medicare Part D Star Ratings program is national in scope. For the 2019 Stars Ratings, reflecting the 2017 measurement year, 471 plan contracts—including 417 MA-PDs and 54 PDPs—representing nearly 40 million beneficiaries were scored on the PDC-3 Rates measure.

4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

We have not identified any unexpected findings.

4b2.2. Please explain any unexpected benefits from implementation of this measure.

As stated in the CMS 2018 Impact Assessment Report, patient impact analyses and cost estimates were conducted for the PDC-3 Rates measure for PDPs and MA-PDs (2011–2015). Health care costs avoided based on patient impacts were estimated at $4.2 billion-$26.9 billion.

Patient Impact (Increased # of patients adherent to the medication from baseline)

- Statins: 2.8 million

- RASA: 2.5 million

- Diabetes: 520,000

Costs Avoided (Health care costs avoided based on patient impacts)

- Statins: $1.5 billion–$3.3 billion

- RASA:$2.1 billion–$19.8 billion

- Diabetes: $659.5 million–$3.8 billion

- Total: $4.2 billion–$26.9 billion

1. 2018 National Impact Assessment of the Centers for Medicare & Medicaid Services (CMS) Quality Measures Report. Baltimore, MD: US Department of Health and Human Services, Centers for Medicare & Medicaid Services; February 28, 2018. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/National-Impact-Assessment-of-the-Centers-for-Medicare-and-Medicaid-Services-CMS-Quality-Measures-Reports.html

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

1879 : Adherence to Antipsychotic Medications for Individuals with Schizophrenia

1880 : Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

N/A

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;
OR
The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):
Are the measure specifications harmonized to the extent possible?

Yes

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

Although the measures address adherence using the same methodology (i.e., proportion of days covered [PDC]), they have different areas of focus and different target populations.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);
OR
Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):
Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

N/A

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

No appendix **Attachment:**

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): Pharmacy Quality Alliance

Co.2 Point of Contact: Lynn, Pezzullo, lpezzullo@pqaalliance.org, 703-347-7963-

Co.3 Measure Developer if different from Measure Steward: Pharmacy Quality Alliance

Co.4 Point of Contact: Lynn, Pezzullo, lpezzullo@pqaalliance.org, 703-347-7963-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

PQA is a consensus-based membership organization. PQA members represent a diverse group of stakeholders with expertise in clinical, quality improvement, measure development, administrative claims and other types of data. This performance measure was developed by the PQA membership in 2008.

PQA´s Measure Update Panel (MUP) reviews PQA-endorsed measures regularly. The MUP´s charge is to:

- evaluate PQA-endorsed measures to identify the need for updates to reflect current evidence, guidelines and standards;
- identify new medications that have entered the marketplace and medications that have been discontinued, which impact NDC lists and therefore a change to the measure specifications; and
- update and revise PQA endorsed measures to improve clarity, consistency, and harmonization, when appropriate, with other measures.

Members of the MUP that completed the most recent review of this measure, along with the organization each represents, include:

Amber Baybayan, OutcomesMTM

Chris Beets, Cigna-Healthspring

Kristen Borowski, Bristol Myers Squibb

Holly Budlong, Fairview

Vanessa Campbell, UPMC

Pauline Chan, California Department of Health Care Services

Chris Chan, Inland Empire Health Plan

Rebecca Chater, Omnicell

Sheena Cherian, PerformRx

Mark Conklin, Pharmacy Quality Solutions

Laurin Dixon, Humana

Jeff Durthaler, Centers for Disease Control

Elizabeth Gozdziak, Aetna

Anna Hall, Enhanced Medication Services

Bethany Holderread, University of Oklahoma

Anna Legreid Dopp American Society of Health-System Pharmacists

Kevin Leung, Anthem

Robert Lipsy, MMC University of AZ

Marsha Moore, CVS Health

Madeline Ritchie, Academy of Managed Care Pharmacy

Victoria Romo-LeTourneau, Sanofi

Maria Scarlatos, Merck

Kathleen Shoemaker, Premier

Nancy Tan, Astellas

Eleni Theodoropoulos, URAC

Tony Trahan, New York State Office of Mental Health

Iris Young, Kaiser Permanente

The MUP´s recommendations then are reviewed by PQA´s Quality Metrics Expert Panel (QMEP). The QMEP members that considered and approved revisions to this measure, along with the organization each represents, include:

Ben Banahan, University of MS

Amanda Brummel, Fairview

Steven Burch, Sunovion

Lynn Deguzman, Kaiser Permanente

Jessica Frank, OutcomesMTM

Shellie Keast, University of OK

Alice Lee Martin, CMS

Jenny Lo Ciganic, University of Florida

Tripp Logan, MedHere Today

Jeff Pohler, Enhanced Medication Services

Christopher Powers, Healthspring

Dan Rehrauer, HealthPartners

Steve Riddle, Wolters Kluwer Health

Craig Schilling, AstraZeneca

David Stauffer, Walgreens

Stephanie Taylor, Anthem

Christi Teigland, Inovalon

Jennifer Van Meter, Novartis

Jenny Weber, Humana

Keith Widmer, Express ScriptsPQA is a consensus-based membership organization. PQA members represent a diverse group of stakeholders with different expertise in clinical, quality improvement and prescription drug data. This performance measure was developed by PQA membership and tested in 2008.

The Measure Update Committee reviews PQA endorsed measures annually. The Committee's role is to evaluate the measure in light of any new evidence or medications and to address any questions posed to PQA regarding the measure within the past year.

The Measure Update Committee reviewed this measure in 2013. Members of that Committee and the organization that they represent include:

Alice Lee-Martin	CMS
Amber Baybayan	OutcomesMTM
Annet Arakelian	Am. Society of Health-System Pharmacists (ASHP)
Brandy Stiles	United American Insurance Company
Cameron James	HealthSpring
Crystal Chang	SCAN Health Plan
David Mostellar	Wellcare
Deb Devereaux	Gorman Health Group
Deirdre Smith	Catalina Health Resource
Greg Moore	Express Scripts, Inc.
Hany Abdelaal	VNSNY CHOICE Plan
Iris Morant	PharmPix
Jeff Bubp	First DataBank
Jeff Pohler	UnitedHealth Group
Jenny Weber	Humana
Joel Montavon	Catamaran
Joseph Gruber	ActualMeds Corporation
Karen Stockl	UnitedHealth Group
Kevin Leung	Amerigroup
Kevin Masci	Target
Kinya Ono	Applied Research Works
Kristian Marquez	Inovalon, Inc.
Kristin Garnett	CVS/Caremark
Lorraine Fletcher	Catamaran
Maria Osborne	American Pharmacists Association (APhA)
Meghan Kelly	Medication Management Systems
Michelle Juhanson	PerformRx
Mike Gaisbauer	United American Insurance Company
Mitzi Wasik	Coventry Health Care
Pat daCosta	RelayHealth
Patrick Gleason	Prime Therapeutics
Paul Miner	Gilead Sciences
Peter Mikhail	Academy of Managed Care Pharmacy
Rick Mohall	Rite Aid
Rose Mulligan	PerformRx

Shannon Harrison Highmark

Shekar Mehta Am Society of Health-System Pharmacists

Steven Friedman PDX, Inc.

Sue Vansomphone Kaiser Permanente

Tim Weippert National Association of Chain Drug Stores

Tori Erxleben PharmMD

Trina Clark GlaxoSmithKline

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2009

Ad.3 Month and Year of most recent revision: 09, 2018

Ad.4 What is your frequency for review/update of this measure? Annually

Ad.5 When is the next scheduled review/update for this measure? 08, 2019

Ad.7 Disclaimers:

Ad.8 Additional Information/Comments: