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: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Brief Measure Information

NQF #: 0066

Corresponding Measures:

De.2. Measure Title: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Co.1.1. Measure Steward: American Heart Association

De.3. Brief Description of Measure: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior LVEF < 40% who were prescribed ACE inhibitor or ARB therapy

1b.1. Developer Rationale: In the absence of contraindications, ACE inhibitors or ARBs are recommended for all patients with a diagnosis of coronary artery disease and diabetes or reduced left ventricular systolic function. ACE inhibitors remain the first choice, but ARBs can be considered a reasonable alternative. Both pharmacologic agents have been shown to decrease the risk of death, myocardial infarction, and stroke. Additional benefits of ACE inhibitors include slowed disease progression and reduction of complications for patients with diabetes.

S.4. Numerator Statement: Patients who were prescribed ACE inhibitor or ARB therapy

S.6. Denominator Statement: All patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR current or prior LVEF <40%

S.8. Denominator Exclusions: Denominator Exceptions:

Documentation of medical reason(s) for not prescribing ACE inhibitor or ARB therapy (e.g., allergy, intolerance, pregnancy, renal failure due to ACE inhibitor, diseases of the aortic or mitral valve, other medical reasons)

Documentation of patient reason(s) for not prescribing ACE inhibitor or ARB therapy (e.g., patient declined, other patient reasons)

Documentation of system reason(s) for not prescribing ACE inhibitor or ARB therapy (e.g., lack of drug availability, other reasons attributable to the health care system)

De.1. Measure Type: Process

S.17. Data Source: Registry Data

S.20. Level of Analysis: Clinician : Individual

IF Endorsement Maintenance – Original Endorsement Date: Aug 10, 2009 **Most Recent Endorsement Date:** Dec 09, 2016

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? Not applicable. The measure is not paired or 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 2016

- In 2016, the developer included the 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease. The recommendation stated:
  - ACE inhibitors should be prescribed in all patients with stable ischemic heart disease (SIHD) who also have hypertension, diabetes mellitus, LVEF 40% or less, or chronic kidney disease (CKD), unless contraindicated. **Level of Evidence: Level A**
  - ARBs are recommended for patients with stable ischemic heart disease (SIHD) who have hypertension, diabetes mellitus, LV systolic dysfunction, or chronic kidney disease (CKD) and have indications for, but are intolerant of, ACE inhibitors." **Level of Evidence: Level A**
- The developer provided a systematic review of the body of evidence supporting the benefits of ACE inhibitor/ARB therapy for patients with ischemic heart disease and included a summary of the Quantity, Quality, and Consistency of the body of evidence.

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:**

Questions for the Committee:

- *The developer attests the underlying evidence for the measure has not changed since the last NQF endorsement review in 2016. Does the Committee agree the evidence basis for the measure has not changed and there is no need for repeat discussion on Evidence?*
- *Does the Committee agree to accept the rating from previous year's evaluation and not re-vote on Evidence?*

Guidance from the Evidence Algorithm

Process measure with systematic review and grading of the body of evidence (Box 3) →Summary of QQC (Box 4) →SR concludes QQC is High (Box 5a) → High

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 January 2018-December 2018 data from 774 providers who reported on this measure through the registry reporting for MIPS. The dataset reflects information at the provider level.
  - Of those 774 providers, all had at least one patient who qualified for the measure after accounting for exceptions for a total of 66,755 eligible patients.
  - The average number of eligible patients is 86 for the 774 providers.
  - The range of eligible patients for 774 providers is from 1 to 992.
- Based on the sample of 774 included providers, the developers reported:
  - The mean performance rate of 0.82
  - The median performance rate of 0.84
  - The mode of 1.0
  - The standard deviation of 0.18
  - The range of the performance rate of 1.00, with a minimum rate of 0.00 and a maximum rate of 1.00
  - The interquartile range of 0.14 (0.93–0.77)
- The developers also reported CMS published quality benchmarks for MIPS 2020, 2019 and 2018, which are created using historical performance rates:

Year	Submission Method	Average Performance Rate	Standard Deviation
2018	CQM	83.2	N/A
2017	Registry/QCDR	83.3	11.1
2016	Registry/QCDR	81.7	11.1

Disparities

- The developer did not provide any data on disparities from the measure as specified – this is encouraged for endorsement maintenance.
- The developer stated that while this measure is included in federal reporting programs, those programs have not yet made disparities data available to analyze and report.
- The developer provided data on disparities from Tran et al. (2017) using data from National Health and Nutrition Examination Survey. The data demonstrated that more men with coronary artery disease (CAD) took ACE-I/ARBs than women (55.1% (SE = 2.1%) vs 50.5% (SE = 2.3%)). However, there were

minimal disparities in use of ACE-I/ARBs between racial and ethnic minorities compared with non-Hispanic whites.

- The developer provided data on disparities from Arnold et al. (2017) using Diabetes Collaborative Registry from 2015 and 2016. The data showed that Cardiology practices were more likely to prescribe ACE-I/ARBs to patients with CAD and diabetes (median performance rate 67%) than endocrinology practices (median performance rate 59%) or primary care practices (median performance rate 58%) (P<0.001) (2017).
- A separate analysis of 2009 PINNACLE Registry data by Smolderen (2013) evaluated the impact of CAD patients' insurance status and the likelihood they would be prescribed an ACEI/ARB:

Insurance Coverage	Prescription rate
Privately-insured	75.5%
Publicly-insured	69.1%
Uninsured	66.7%

Questions for the Committee:

- Does the performance data provided continue to warrant a national performance measure?
- 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

- Strong evidence level (1A)
- Evidence applies directly to the structure, process and outcome
- no comments
- Evidence applies directly, appropriately outcome-related process.
- Existing measure. There is a systematic review of the evidence: 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease that provides information on the quantity, quality and consistency. Agree with preliminary rating as High
- Strong evidence. High rating.
- There is a 2014 focused update to the guidlines. No major changes, but would have been good to see in the review.
- Strong evidence that this process measure is associated with desired outcomes.
- high
- Evidence is high
- evidence is directly related

1b. Performance Gap

- Mean/median scores in low 80% suggesting room to improve. No data on racial/ethnic disparities given.
- Current performance data on the measure was provided with moderate opportunity improvement and usability
- no comments

- Performance gap still substantial enough to warrant national performance measure. Did not see population subgroup data.
- CMS data does not provide disparities information. Tran 2017 NHANES – more men than women but no racial or ethnic disparities. Performance range is 0 to 100% Mode being 1.0 (100%) but some opportunity to improve as mean is .82 Really need the federal government to start supplying information that measures disparities. Opportunity for improvement Moderate
- Performance gap exists, but not too bad.
- average performance ~82% shows a gap still exists. would like to see more of a breakdown for disparities. Disparities exist in some of the medical conditions for include (DM), so could infer disparities here.
- Still a performance gap, but improving year over year. No direct evidence of disparities in this measure, but good parallel studies that show it exists.
- moderate
- Performance gap is moderate. There is evidence of disparity by sex and public program/uninsure. Very little race data are available.
- it's beginning to top out, limited room for improvement

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.

Composite measures only:

2d. Empirical analysis to support composite construction. Empirical analysis should demonstrate that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct.

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

Evaluators: NQF Staff

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 staff 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 staff 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**

Staff Evaluation of Scientific Acceptability

Scientific Acceptability: Preliminary Analysis Form

Measure Number: 0066

Measure Title: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)

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_0066" 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.**
    - No concerns

RELIABILITY: TESTING

Submission document: "MIF_0066" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

3. **Reliability testing level** ☒ **Measure score** ☐ **Data element** ☐ **Neither**
4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure**
   ☒ **Yes** ☐ **No**
5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical <u>VALIDITY</u> testing** of <u>patient-level data</u> conducted?

   ☐ **Yes** ☐ **No**
6. **Assess the method(s) used for reliability testing**

   Submission document: Testing attachment, section 2a2.2
    - The data source included Registry data from the 2018 Merit-based Incentive Payment System (MIPS) Program for the time period of January 1st, 2018 through December 31st, 2018. 66,755 patients included in this reliability testing and analysis. These were the patients that were associated with providers who had at least one eligible patient in the year.
    - The developers used a beta-binomial model to assess the signal-to-noise ratio to conduct reliability testing. A reliability of zero implies that all the variability in a measure is attributable to measurement error. A reliability of one implies that all the variability is attributable to real differences in performance. The higher the reliability score, the greater is the confidence with which one can distinguish the performance of one physician from another. This is an appropriate test for measure score reliability. A reliability of 0.70 is generally considered a minimum threshold for reliability.
7. **Assess the results of reliability testing**

   Submission document: Testing attachment, section 2a2.3
    - The average reliability for providers with at least one eligible patient is 0.85. As the developer states, 0.80 – 0.90 is considered high reliability.
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 <u>all</u> 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.**
    - Precise, unambiguous and complete specification (Box 1) → reliability testing conducted with computed measure scores for each measured entity (Box 4) → based on reliability statistic and scope of testing, there is a high confidence that the performance measure scores are reliable (Box 6a) → High

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

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

    Submission document: Testing attachment, section 2b2.
    - No concerns; the developer analyzed the exceptions for frequency across providers and reported deciles of exceptions.

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

    Submission document: Testing attachment, section 2b4.
    - No concerns

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.
    - N/A

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

    Submission document: Testing attachment, section 2b6.
    - The developer stated that the MIPS dataset provided to us by CMS did not contain missing data, so this test was not performed. Nevertheless, missing data may have been rejected when submitted to CMS in which case those values would not be counted towards measure performance. There is no indication that this missing data was systematic, thus their omission would lead to unbiased performance results.

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

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

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

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

- N/A

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

- The developers used data from the 2018 MIPS Registry Program to perform the correlation analysis for this measure. Data came from the Registry version of Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (NQF 0066) and Coronary Artery Disease (CAD): Antiplatelet Therapy (NQF 0067)
- The developers chose Coronary Artery Disease (CAD): Antiplatelet Therapy (NQF 0067) to conduct correlation analysis due to the similarities in patient population and domain. They hypothesized that there exists a positive association of scores between providers who prescribe Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy on patients with diabetes or left ventricular systolic dysfunction (LVEF < 40%) and those who prescribe an antiplatelet therapy on patients with coronary artery disease within a 12 month period.
- Providers included in the analysis had at least one patient in the denominator after exceptions were removed. Results identify the multiple R value (the correlation coefficient) and P-value of the regression variables to assess the association between performance scores of these shared provider IDs.

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

Submission document: Testing attachment, section 2b2.3

- The results demonstrated that the Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (NQF 0066) has a moderate positive correlation with Coronary Artery Disease (CAD): Antiplatelet Therapy (NQF 0067).
- The correlation was highly statistically significant with a coefficient of correlation of 0.47, which showed moderate correlation, significant, and confirms the developer hypothesis. The moderate positive correlation with Coronary Artery Disease (CAD): Antiplatelet Therapy (NQF 0067) demonstrates the criterion validity of the measure.

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)

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.**

- All potential threats to validity are empirically assessed (Box 1) → Validity testing conducted with computed measure scores (Box 5) → Validity testing method was described and appropriate for assessing hypothesized relationships (Box 6) → moderate confidence that the performance measure scores are a valid indicator of quality (Box 6b) → Moderate

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.**

- N/A

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

2a. Reliability

- No issues
- no concerns
- no comments
- Data elements and analysis clearly defined. No concerns with consistent implementation.

- No issues regarding data elements, logic etc. Existing measure first endorsed 2009. Most recent endorsement 2016
- Specifications clear of previously endorsed measure.
- aligned with NQF assessment
- No issues
- high
- Reliability is high. The measure has been used for 11 years. No need to discuss.
- no concerns No issues
- no
- none
- No reliability concerns
- Signal to noise testing: Mean was .85 (good) No concerns
- No concerns. High for reliability.
- aligned with nqf assessment
- No
- high
- No concerns
- No

2b. Validity

- Moderate IMO. Not sure that correlation with performance on a CAD measure constitutes a robust validity test.
- no
- none
- No concerns with validity testing results.
- No concerns
- No concerns, score-level testing showed relatively low correlation (0.47), so moderate rating.
- I appreciate even though moderate positive correlation is it statistcally significant. i put more emphasis on significance, because measures may never be perfectly aligned.
- No
- moderate
- No particular concerns
- no N/A
- no
- no comments
- No serious threats to validity seen.
- MIPS data provided by CMS had no missing data. No evidence of systematic omissions
- None.
- no concerns and well documented by developer
- Missing data from QPP/MIPS unknown, so can't judge. Probably some bias since data comes from MIPS participants only.
- no

- No significant threats to validity
- no concerns No risk adjustment done, which can compromise validity of results.
- yes
- no comment
- Exclusions consistent with evidence. No risk adjustment noted.
- There is no risk adjustment. Exclusions are appropriate.
- No risk adjustment.
- would like to see some risk adjustment be considered for future evaluation
- SES not available in dataset, hope it is soon, but this is a CMS issue, not a measure issue.
- no
- This is not risk adjusted.
- no concerns N/A
- yes
- no comment

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.

- The developer noted that the data elements are generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition. Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims).
- ALL data elements are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS).
- All the data elements needed for this measure are collected through electronic data

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**

Committee Pre-evaluation Comments:
Criteria 3: Feasibility

- No concerns. Already part of MIPS
- don't now
- no comments
- No concerns with feasibility of data collection methods.
- Demonstrated feasibility - existing measure with years of performance data

- Fine. Moderate.
- No major concerns. Seems appropriate set of data for level of analysis
- No issues.
- high
- All of the data elements are collected during routine care.
- no concerns

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**

Accountability program details

- Performance results are used in the following programs:
    - Merit-based Incentive Payment System (MIPS) – sponsored by the Centers for Medicare and Medicaid Services (CMS) with the purpose to tie payments to clinicians, to provide quality and cost-efficient care, drive improvement in care processes, increase the use of healthcare data, and reduce the costs of care. The program began in 2017, nationally, and the clinicians are included in MIPS-Quality if they are an eligible clinician type and meet program requirements.
    - The PINNACLE Registry – sponsored by American College of Cardiology and its National Cardiovascular Data Registry. It began in 2008 and it was developed as an outpatient-based prospective quality improvement registry, for cardiology practices in the outpatient setting. Data is collected specifically for coronary artery disease, hypertension, heart failure and atrial fibrillation. Data collected includes patient demographics, medical history, vital signs, laboratory values, imaging results, medications, and contraindications to medications. It's implemented nationally.
    - The Diabetes Collaborative Registry (DCR) - It's a collaborative effort between the American College of Cardiology, American Diabetes Association, American College of Physicians, American Association of Clinical Endocrinologists, and Joslin Diabetes Center. It is part of the National Cardiovascular Data Registry. The DCR is a prospective, office-based, quality improvement registry for patients with diabetes mellitus and other metabolic needs globally.

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

- Performance results are provided to all participating clinicians across quality programs. Clinicians participating in the MIPS-Quality program receive performance results, i.e. their MIPS score and corresponding payment adjustment annually. The PINNACLE Registry provides user-friendly online benchmark reports to users via an interactive portal. Individual practice performance on measures is provided by quarter, alongside the national average by quarter. This allows clinicians to identify areas for improvement. The Diabetes Collaborative Registry provides user-friendly online benchmark reports.
- The feedback process includes providing user-friendly online benchmark reports to users via an interactive portal. Individual practice performance on measures is provided by quarter, alongside the national average by quarter.
- The developer mentioned that they have not received the feedback from those being measured; however, since their last submission to NQF, they have been asked about including angiotensin receptor neprilysin inhibitors (ARNIs) to the measure numerator.
    - To address the inclusion of ARNIs as one of the numerator compliant options, the developers worked with the technical expert panel to refine the measure and include a note on numerator in the measure specifications

Additional Feedback:

- None

***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**

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 noted that the MIPS quality benchmarks show a slight improvement in average performance rates between 2016 and 2018. The scores appear very similar.
- The developer also cited data from the literature: Makam et al. evaluated trends in the prescription of ACE-I/ARBs among eligible patients. Methods included analyzing over 5,000 patients discharged from various hospitals in central Massachusetts after acute myocardial infarction. The prescription of ACE-I/ARBs increased from 50% to 62% between 2001 and 2011, indicating improvement in prescribing patterns (2016). The developer highlighted that a gap in care persists.

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

- The developer provided data from a 2017 meta-analysis by Du, Cheng, Zhang, Li, & Mei that evaluated the relationship between medication adherence and clinical outcomes amongst ~100,000 patients with stable coronary artery disease.
- Study authors found that adherence to evidence-based medications, including ACE-I and ARB therapy, was related to a lower risk of all-cause mortality (risk ratio 0.56; 95% CI), lower risk of cardiovascular mortality (risk ratio 0.66; 95% CI), and lower risk of cardiovascular hospitalization/myocardial infarction(risk ratio 0.61; 95% CI)

Potential harms

- The developer stated that they are not aware of any unintended consequences.

Additional Feedback:

- N/A

***Questions for the Committee**:*

- Based on the improvement data provided, does the Standing Committee agree that there has been improvement in average performance rate?
- 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

4a. Use

- Already being reported publicly in various ways (including via PINNACLE)
- yes
- no comments
- No concerns with accountability and transparency or feedback provisions.
- Publicly reported & used in accountability programs - MIPS, PINNACLE, Diabetes Collaborative; Developer reports only feedback was a request to add ARNIs to measure. No mention of a specific mechanism for clinicians to provide feedback on measure and reporting to the developer
- Pass. MIPS and two registries.
- Leveraged in a variety of programs (MIPS, PINNACLE, and DCR). Seems like the measure has good, broad implementation.
- Being used and transparent. Corelates with parallel studies that look at social determinants of health.
- high

  The measure is publicly reported and used in accountability programs no concerns

4b. Usability

- None

- none
- no comments
- Usability appears good for improving care quality
- Based on the MIPS data provided there does not appear to be any meaningful improvement. Performance is linked to guideline adherence which would be an indicator of quality care. Benefits definitely outweigh the risks.
- No concerns. Moderate.
- There may be some conflicting data in the treatment of HTN with individuals with DM. The HTN guidelines do not have ACE/ARB as first line. Should not be a major issue, but wanted to raise.
- Usable, no harms
- high
- No harms have been identified
- no concerns

Criterion 5: Related and Competing Measures

Related or competing measures

- 0081 : Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
- 0081e : Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
- 0137 : ACEI or ARB for left ventricular systolic dysfunction- Acute Myocardial Infarction (AMI) Patients
- 1662 : Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

Harmonization

- The developer stated that the specifications are harmonized to the extent possible; Measure #0137 is specific to acute myocardial infarction patients. 1662 is specific to chronic kidney disease patients. And 0081/e are specific only to broader heart failure patients.
- Additionally, the developer highlighted that this measure addresses a distinct target population and/or quality action from other related measures, as described above. The measures are complementary to form a well-rounded view of the quality of care for patients with CAD.

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

- No
- yes
- no
- None noted
- There is considerable overlap of this measure with 0081/0081e It might be best for a new and separate measure for CAD patients with Diabetes regarding ACEI/ARB/ARNI prescription
- Yes, and harmonized as much as possible.

- seems to have a variety of measures in this area. would be good to hear how the developer would like to continue to mitigate burden.0081 and 0081e overlap. 0137 is a subset of this measure. Appear to be harmonized.
- No
- There are four related measures: 0081, 0081e, 0137 and 1662
- harmonized to the degree possible

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: June 12, 2020

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

2020_NQF_evidence_attachment_0066_Final.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.

No

1a. Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** 0066

Measure Title: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: Click here to enter composite measure #/ title

Date of Submission: 4/9/2020

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

Outcome

☐ Outcome: Click here to name the health outcome

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

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

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

☒ Process: Prescription of ACE inhibitor or ARB for patients with CAD and diabetes or LVSD

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

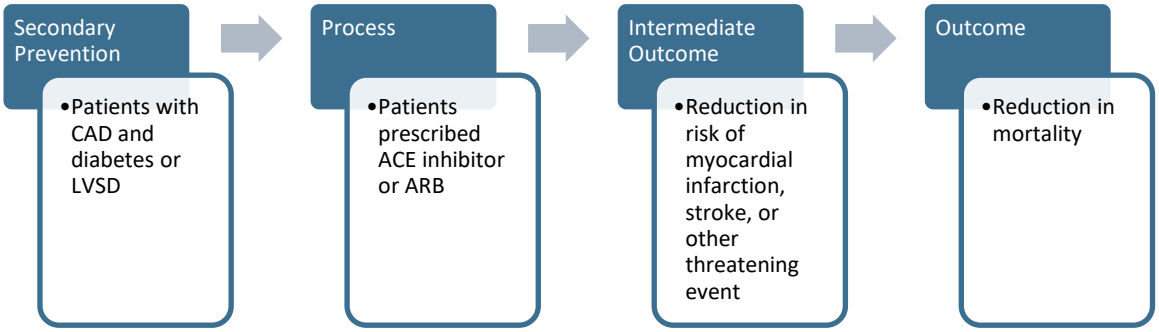
☐ Structure: Click here to name the structure

☐ Composite: Click here to name what is being measured

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

Nonadherence to cardioprotective medications is prevalent among outpatients with CAD and can be associated with a broad range of adverse outcomes, including all-cause and cardiovascular mortality, cardiovascular hospitalizations, and the need for revascularization procedures.

In the absence of contraindications, ACE inhibitors or ARBs are recommended for all patients with a diagnosis of CAD and diabetes or reduced left ventricular systolic function. ACE inhibitors remain the first choice, but ARBs can now be considered a reasonable alternative. Both pharmacologic agents have been shown to decrease the risk of death, myocardial infarction, and stroke. Additional benefits of ACE inhibitors include the reduction of diabetic symptoms and complications for patients with diabetes.



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

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

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

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

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

X 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**	**The guidelines supporting this measure remain unchanged. The American Heart Association (AHA) notes that evidence is reviewed at least twice a year, and updates are initiated on an as-needed basis.** • **Title: 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons.** • **Author: Fihn SD, Gardin JM, Abrams J, Berra K, Blankenship JC, Dallas P, Douglas PS, Foody JM, Gerber TC, Hinderliter AL, King SB III, Kligfield PD, Krumholz HM, Kwong RYK, Lim MJ, Linderbaum JA, Mack MJ, Munger MA, Prager RL, Sabik JF, Shaw LJ, Sikkema JD, Smith CR Jr, Smith SC Jr, Spertus JA, Williams SV.** • **Date: 2012** • **Citation: Fihn, S. D., Gardin, J. M., Abrams, J., Berra, K., Blankenship, J. C., Dallas, A. P., … Society of Thoracic Surgeons (2012). 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. Journal of the American College of Cardiology, 60(24), e405. doi:10.1016/j.jacc.2012.07.013** • **URL: https://www.ahajournals.org/lookup/doi/10.1161/CIR.0b013e318277d6a0**

<table>
<tr><td>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.</td><td>1. ACE inhibitors should be prescribed in all patients with SIHD who also have hypertension, diabetes mellitus, LVEF 40% or less, or CKD, unless contraindicated. (Class I Recommendation; Level A Evidence)
2. ARBs are recommended for patients with SIHD who have hypertension, diabetes mellitus, LV systolic dysfunction, or CKD and have indications for, but are intolerant of, ACE inhibitors. (Class I Recommendation, Level A Evidence)</td></tr>
<tr><td>Grade assigned to the evidence associated with the recommendation with the definition of the grade</td><td>The Level of Evidence is an estimate of the certainty of precision of the treatment effect. Both guideline recommendations received Level A Evidence.

<table><tr><td rowspan="2">Level A:</td><td>Multiple populations evaluated*</td></tr><tr><td>Data derived from multiple randomized clinical trials or meta-analyses</td></tr></table>
*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.</td></tr>
<tr><td>Provide all other grades and definitions from the evidence grading system</td><td><table><tr><td rowspan="2">Level A:</td><td>Multiple populations evaluated*</td></tr><tr><td>Data derived from multiple randomized clinical trials or meta-analyses</td></tr><tr><td rowspan="2">Level B:</td><td>Limited populations evaluated*</td></tr><tr><td>Data derived from a single randomized trial or non-randomized studies</td></tr><tr><td rowspan="2">Level C:</td><td>Very limited populations evaluated*</td></tr><tr><td>Only consensus opinion of experts, case studies, or standard of care</td></tr></table>
*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there</td></tr>
</table>

<table>
<tr><td></td><td>may be a very clear clinical consensus that a particular test or therapy is useful or effective.</td></tr>
<tr><td>Grade assigned to the recommendation with definition of the grade</td><td>The Class of Recommendation is an estimate of the size of the treatment effect, with consideration given to risks versus benefits as well as evidence and/or agreement that a given treatment or procedure is or is not useful/effective or in some situations may cause harm. Both recommendations received a Class I recommendation.

<table><tr><td rowspan="2">Class I</td><td>Benefit >>> Risk</td></tr><tr><td>Procedure/Treatment SHOULD be performed/administered</td></tr></table></td></tr>
<tr><td>Provide all other grades and definitions from the recommendation grading system</td><td><table><tr><td rowspan="2">Class I</td><td>Benefit >>> Risk</td></tr><tr><td>Procedure/Treatment SHOULD be performed/administered</td></tr><tr><td rowspan="2">Class IIa</td><td>Benefit >> Risk; Additional studies with focused objectives needed</td></tr><tr><td>IT IS REASONABLE to perform procedure / administer treatment</td></tr><tr><td rowspan="2">Class IIb</td><td>Benefit >= Risk; Additional studies with broad objectives needed; additional registry data would be helpful</td></tr><tr><td>Procedure / Treatment MAY BE CONSIDERED</td></tr><tr><td>Class III No Benefit</td><td>Procedure / Test = Not helpful
Treatment = No proven benefit</td></tr><tr><td>Class III Harm</td><td>Procedure / Test = Excess cost without benefit or harmful
Treatment = Harmful to patients</td></tr></table>
Recommendations with a Class I, Level A designation are characterized as:
-Recommendation that procedure or treatment is useful/effective
-Sufficient evidence from multiple randomized trials or meta-analyses</td></tr>
<tr><td>Body of evidence:
Quantity – how many studies?</td><td>The cited body of evidence includes 6 randomized controlled trials and 2 meta-analyses.</td></tr>
</table>

• Quality – what type of studies?	The quality of evidence and associated certainty are strong and this prompted the ACC/AHA Guideline 1A recommendation. The guideline states "clinical studies have demonstrated significant reductions in the incidence of acute myocardial infarction, unstable angina, and the need for coronary revascularization in patients after myocardial infarction with left ventricular dysfunction, independent of etiology" associated with the use of ACE inhibitors. The guideline further states that ARBs "significantly reduce LV mass and stroke incidences". Both drugs are associated with significant benefits for patients with ischemic heart disease.
Estimates of benefit and consistency across studies	ACE inhibitor-based regimens were associated with a 19% reduction in risk for stroke, a 16% reduction in risk for ischemic heart disease, and a 27% reduction in the risk for heart failure for each 5-mm Hg reduction in blood pressure. ARB-based regimens were associated with a 26% reduction in risk for stroke, 17% reduction in risk for ischemic heart disease, and a 12% reduction in risk for heart failure for each 5-mm Hg reduction in blood pressure.
What harms were identified?	The guideline does not mention any specific harms that were studied as part of the body of evidence. However, in their classification of the recommendations they assigned both as Class I recommendations with Level A evidence which indicates that anticipated benefits far outweigh potential harms. Additionally, there are no class III (harm) recommendations associated with the use of ACE inhibitors or ARBs in the guideline.
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	1. Rosendorff C, Lackland DT, Allison M, Aronow WS, Black HR, Blumenthal RS, Cannon CP, de Lemos JA, Elliott WJ, Findeiss L, Gersh BJ, Gore JM, Levy D, Long JB, O'Connor CM, O'Gara PT, Ogedegbe O, Oparil S, White WB; on behalf of the American Heart Association, American College of Cardiology, and American Society of Hypertension. Treatment of hypertension in patients with coronary artery disease: a scientific statement from the American Heart Association, American College of Cardiology, and American Society of Hypertension. Hypertension. 2015;65:1-36. 2. This is a scientific statement that provides recommendations regarding the treatment and secondary prevention of hypertension, specifically in the setting of coronary artery disease. 3. The recommendations in this statement are specific to patients who have coronary artery disease and hypertension, as well as diabetes or LVSD, which represent a subset of the

	patients included in the measure. The recommendations are consistent with those cited above in support of the measure. 4. The conclusions and recommendations put forth in this scientific statement are consistent with those in the 2012 stable ischemic heart disease guideline cited above. An updated literature search covering January 1, 2016 through January 31, 2020 was performed. A search using the MeSH search terms "Coronary Artery Disease," "Diabetes," and "Angiotensin-Converting Enzyme Inhibitors" resulted in 69 articles. A search using the MeSH search terms "Coronary Artery Disease," "Diabetes," and "Angiotensin Receptor Blocker Therapy" resulted in 17 articles. A search using the MeSH search terms "Coronary Artery Disease," "Left Ventricular Systolic Dysfunction," and "Angiotensin-Converting Enzyme Inhibitor" resulted in 9 articles. And a search using the MeSH search terms "Coronary Artery Disease," "Left Ventricular Systolic Dysfunction," and "Angiotensin Receptor Blocker Therapy" resulted in 2 articles. There were very few studies that were directly applicable to the target population of this measure, and none of the studies included new conclusions that would alter the recommendation to prescribe ACE Inhibitors or ARB Therapy to patients with coronary artery disease and diabetes or left ventricular systolic dysfunction.

1a.4 OTHER SOURCE OF EVIDENCE

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

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

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

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

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.

In the absence of contraindications, ACE inhibitors or ARBs are recommended for all patients with a diagnosis of coronary artery disease and diabetes or reduced left ventricular systolic function. ACE inhibitors remain the first choice, but ARBs can be considered a reasonable alternative. Both pharmacologic agents have been shown to decrease the risk of death, myocardial infarction, and stroke. Additional benefits of ACE inhibitors include slowed disease progression and reduction of complications for patients with diabetes.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. *(This is required for maintenance of endorsement. 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.*

A total of 774 providers reported on this measure through the registry reporting option for MIPS during the period between 1/1/2018-12/31/2018. This data set reflects information at the provider level and our analysis of the data as a whole is reflected throughout this submission. Of those 774 providers, all had at least one patient who qualified for the measure after accounting for exceptions for a total of 66,755 eligible patients. The average number of eligible patients is 86 for the 774 providers. The range of eligible patients for 774 providers is from 1 to 992.

Based on the sample of 774 included providers, the mean performance rate is 0.82, the median performance rate is 0.84 and the mode is 1.0. The standard deviation is 0.18. The range of the performance rate is 1.00, with a minimum rate of 0.00 and a maximum rate of 1.00. The interquartile range is 0.14 (0.93–0.77). Deciles are provided in the table below.

Decile	Performance
1	0.66
2	0.75
3	0.79
4	0.82
5	0.84
6	0.87
7	0.90
8	0.95
9	1.00
10	1.00

In addition, CMS published its quality benchmarks for MIPS 2020, 2019, and 2018. CMS describes that benchmarks are created using historical performance rates. For example, 2020 benchmarks are based on actual performance data submitted to the Quality Payment Program two years prior, 2018. Note that the performance scores listed in this section are not consistently derived from a nationally representative sample. The average performance rates and standard deviations for this measure from 2016 through 2018 are:

Year	Submission Method	Average Performance Rate	Standard Deviation
2018	CQM	83.2	N/A
2017	Registry/QCDR	83.3	11.1
2016	Registry/QCDR	81.7	11.1

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.

Figueroa et al. analyzed the utilization of evidence-based treatments among adults with coronary artery disease (CAD) enrolled in Medicare Advantage (MA) and Fee-for-Service (FFS) Medicare, using retrospective data from the PINNACLE (Practice Innovation and Clinical Excellence) Registry. Among the 35,563 patients with CAD enrolled in MA, 70.7% received angiotensin-converting enzyme inhibitors (ACE-I) or angiotensin II receptor blockers (ARBs) (P<.001) and among the 172,732 patients with CAD enrolled in FFS Medicare, 65.1% received ACE-I or ARBs (P<.001) (2019). Arnold et al. evaluated adherence to clinical guidelines using data from 574,972 patients between 2015 and 2016, in the Diabetes Collaborative Registry. Study investigators found that among 198,892 patients with CAD and diabetes, 67.2% received ACE-I or ARB therapy (2017). A similar study analyzed adherence to clinical guidelines using data from the PINNACLE Registry and found that among 175,223 patients with CAD and concurrent diabetes or left ventricular systolic dysfunction, 69% of patients received ACE-I or ARB therapy (Fleming et al., 2016). Lastly, Tran et al. evaluated trends in cardiac medication adherence amongst 1,789 American adults with a history of CAD. Using data from the National Health and Nutrition Examination Survey, authors found that between 2005 and 2014, 53.2% of American adults with CAD reported using ACE-I/ARBs (2017).

Citations:

1. Arnold, S. V., Goyal, A., Inzucchi, S. E., McGuire, D. K., Tang, F., Mehta, S. N., Sperling, L. S., Maddox, T. M., Einhorn, D., Wong, N. D., Hammar, N., Fenici, P., Khunti, K., Lam, C., & Kosiborod, M. (2017). Quality of Care of the Initial Patient Cohort of the Diabetes Collaborative Registry®. Journal of the American Heart Association, 6(8), e005999. https://doi.org/10.1161/JAHA.117.005999

2. Figueroa, J. F., Blumenthal, D. M., Feyman, Y., Frakt, A. B., Turchin, A., Doros, G., Gao, Q., Song, Y., & Joynt Maddox, K. E. (2019). Differences in Management of Coronary Artery Disease in Patients With Medicare Advantage vs Traditional Fee-for-Service Medicare Among Cardiology Practices. JAMA Cardiology, 4(3), 265–271. https://doi.org/10.1001/jamacardio.2019.0007

3. Fleming, L. M., Jones, P., Chan, P. S., Andrei, A. C., Maddox, T. M., & Farmer, S. A. (2016). Relationship of Provider and Practice Volume to Performance Measure Adherence for Coronary Artery Disease, Heart Failure, and Atrial Fibrillation: Results From the National Cardiovascular Data Registry. Circulation. Cardiovascular Quality and Outcomes, 9(1), 48–54. https://doi.org/10.1161/CIRCOUTCOMES.115.002159

4. Tran, H. V., Waring, M. E., McManus, D. D., Erskine, N., Do, V., Kiefe, C. I., & Goldberg, R. J. (2017). Underuse of Effective Cardiac Medications Among Women, Middle-Aged Adults, and Racial/Ethnic Minorities With Coronary Artery Disease (from the National Health and Nutrition Examination Survey 2005 to 2014). The American Journal of Cardiology, 120(8), 1223–1229. https://doi.org/10.1016/j.amjcard.2017.07.004

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.*

While this measure is included in a federal reporting program, that program has not yet made demographic data points available for us to calculate and report on disparities. See section 1b.5. for disparities data from the literature.

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

In addition to finding overall gaps in care, the Tran et al. study mentioned previously, which analyzed data from the National Health and Nutrition Examination Survey, found that more men with coronary artery disease (CAD) took ACE-I/ARBs than women (55.1% (SE = 2.1%) vs 50.5% (SE = 2.3%)). However, there were minimal disparities in use of ACE-I/ARBs between racial and ethnic minorities compared with non-Hispanic whites (2017). The Arnold et al. study referenced previously also found disparities in care amongst specialties, using data from the Diabetes Collaborative Registry from 2015 and 2016. Cardiology practices were more likely to prescribe ACE-I/ARBs to patients with CAD and diabetes (median performance rate 67%) than endocrinology practices (median performance rate 59%) or primary care practices (median performance rate 58%) (P<0.001) (2017). Another study found disparities by insurance status in patients' adherence to cardiac medications. Smolderen et al. analyzed 60,814 patients with CAD from the PINNACLE (Practice Innovation and Clinical Excellence) registry, and found that uninsured patients were less likely to be prescribed ACE-I/ARBs than privately-insured individuals (66.7% vs 75.5%, unadjusted RR=00.88; 95% CI, 0.84-0.93, P<0.001), and publicly-insured patients were less likely to be prescribed ACE-I/ARBs than privately-insured patients (69.1% vs 75.5%, unadjusted RR=0.91; 95% CI, 0.89-0.94; P<0.001) (2013). Lastly, a study that looked at adherence to cardiovascular performance measures within the PINNACLE Registry found gender disparities in prescribing patterns amongst clinicians. Specifically, the study cohort included 1493 individual practitioners who saw 769,139 patients; among patients with CAD and either diabetes mellitus or left ventricular systolic dysfunction, 70% treated by male practitioners and 66% treated by female practitioners received ACE-I/ARB therapy, respectively (P<0.001) (Gupta et al., 2018).

Citations:

1. Arnold, S. V., Goyal, A., Inzucchi, S. E., McGuire, D. K., Tang, F., Mehta, S. N., Sperling, L. S., Maddox, T. M., Einhorn, D., Wong, N. D., Hammar, N., Fenici, P., Khunti, K., Lam, C., & Kosiborod, M. (2017). Quality of Care of the Initial Patient Cohort of the Diabetes Collaborative Registry®. Journal of the American Heart Association, 6(8), e005999. https://doi.org/10.1161/JAHA.117.005999

2. Gupta, D., Tang, F., Masoudi, F. A., Jones, P. G., Chan, P. S., & Daugherty, S. L. (2018). Practitioner Gender and Quality of Care in Ambulatory Cardiology Practices: A Report From the National Cardiovascular Data Practice Innovation and Clinical Excellence (PINNACLE) Registry. The Journal of Cardiovascular Nursing, 33(3), 255–260. https://doi.org/10.1097/JCN.0000000000000443

3. Smolderen, K. G., Spertus, J. A., Tang, F., Oetgen, W., Borden, W. B., Ting, H. H., & Chan, P. S. (2013). Treatment differences by health insurance among outpatients with coronary artery disease: insights from the national cardiovascular data registry. Journal of the American College of Cardiology, 61(10), 1069–1075. https://doi.org/10.1016/j.jacc.2012.11.058

4. Tran, H. V., Waring, M. E., McManus, D. D., Erskine, N., Do, V., Kiefe, C. I., & Goldberg, R. J. (2017). Underuse of Effective Cardiac Medications Among Women, Middle-Aged Adults, and Racial/Ethnic Minorities With Coronary Artery Disease (from the National Health and Nutrition Examination Survey 2005 to 2014). The American journal of cardiology, 120(8), 1223–1229. https://doi.org/10.1016/j.amjcard.2017.07.004

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, Cardiovascular : Congestive Heart Failure, Cardiovascular : Coronary Artery Disease, Endocrine : Diabetes

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

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

Adults, Elderly, Populations at Risk

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.)*

The measure specifications are included with this submission. Additional measure details may be found at https://qpp.cms.gov/mips/explore-measures/quality-measures

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)*

No data dictionary **Attachment:**

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.

Supporting guidelines and coding included in the measure are reviewed on an annual basis. This annual review has resulted in minor changes to the coding.

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).

Patients who were prescribed ACE inhibitor or ARB therapy

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).

Time period for data collection: At least once during the measurement period

Note: For reporting, Submission Criteria 1 and 2, described below, are combined for a single reported performance score on the combined measure population. If a patient has both diabetes and LVSD, reporting Submission Criteria #2 (CAD with diabetes) will count as appropriate reporting for this patient.

Definition:

Prescribed – May include prescription given to the patient for ACE inhibitor or ARB therapy at one or more visits in the measurement period OR patient already taking ACE inhibitor or ARB therapy as documented in current medication list.

Numerator Note: Eligible clinicians who have given a prescription to the patient for or whose patient is currently taking a combination medication therapy, which contains either an ACE inhibitor or ARB (e.g., angiotensin receptor neprilysin inhibitor [ARNI, sacubitril/valsartan], ACEI+diuretic, ARB+diuretic, ACEI+calcium channel blocker) would meet performance for this measure.

FOR SUBMISSION CRITERIA 1: Patients who are 18 years and older with a diagnosis of CAD with current or prior LVEF < 40% (without a diagnosis of diabetes)

Report Quality Data Code G8935: Clinician prescribed angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy

FOR SUBMISSION CRITERIA 2: Patients who are 18 years and older with a diagnosis of CAD who have diabetes

Report Quality Data Code G8473: Angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy prescribed

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

All patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR current or prior LVEF <40%

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).

Time period for data collection: 12 consecutive months

Definition:

LVEF < 40% corresponds to qualitative documentation of moderate dysfunction or severe dysfunction.

FOR SUBMISSION CRITERIA 1: Patients who are 18 years and older with a diagnosis of CAD with current or prior LVEF < 40%

Patients aged >= 18 years on date of encounter

AND

Diagnosis for coronary artery disease (ICD-10-CM): I20.0, I20.1, I20.8, I20.9, I21.01, I21.02, I21.09, I21.11, I21.19, I21.21, I21.29, I21.3, I21.4, I21.9, I21.A9, I22.0, I22.1, I22.2, I22.8, I22.9, I24.0, I24.1, I24.8, I24.9, I25.10, I25.110, I25.111, I25.118, I25.119, I25.2, I25.5, I25.6, I25.700, I25.701, I25.708, I25.709, I25.710, I25.711, I25.718, I25.719, I25.720, I25.721, I25.728, I25.729, I25.730, I25.731, I25.738, I25.739, I25.750, I25.751, I25.758, I25.759, I25.760, I25.761, I25.768, I25.769, I25.790, I25.791, I25.798, I25.799, I25.810, I25.811, I25.812, I25.82, I25.83, I25.89, I25.9, Z95.1, Z95.5, Z98.61

AND

Patient encounter during the performance period (CPT): 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99324,

99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350

WITHOUT

Telehealth Modifier: GQ, GT, 95, POS 02

AND

Two Denominator Eligible Visits

AND

Left Ventricular Ejection Fraction (LVEF) < 40% or documentation of moderately or severely depressed left ventricular systolic function: G8934

FOR SUBMISSION CRITERIA 2: Patients who are 18 years and older with a diagnosis of CAD who have diabetes

Patients aged >= 18 years on date of encounter

AND

Diagnosis for coronary artery disease (ICD-10-CM): I20.0, I20.1, I20.8, I20.9, I21.01, I21.02, I21.09, I21.11, I21.19, I21.21, I21.29, I21.3, I21.4, I21.9, I21.A9, I22.0, I22.1, I22.2, I22.8, I22.9, I24.0, I24.1, I24.8, I24.9, I25.10, I25.110, I25.111, I25.118, I25.119, I25.2, I25.5, I25.6, I25.700, I25.701, I25.708, I25.709, I25.710, I25.711, I25.718, I25.719, I25.720, I25.721, I25.728, I25.729, I25.730, I25.731, I25.738, I25.739, I25.750, I25.751, I25.758, I25.759, I25.760, I25.761, I25.768, I25.769, I25.790, I25.791, I25.798, I25.799, I25.810, I25.811, I25.812, I25.82, I25.83, I25.89, I25.9, Z95.1, Z95.5, Z98.61

AND

Diagnosis for diabetes (ICD-10-CM): E10.10, E10.11, E10.21, E10.22, E10.29, E10.311, E10.319, E10.321, E10.329, E10.331, E10.339, E10.341, E10.349, E10.351, E10.359, E10.3211, E10.3212, E10.3213, E10.3219, E10.3291, E10.3292, E10.3293, E10.3299, E10.3311, E10.3312, E10.3313, E10.3319, E10.3391, E10.3392, E10.3393, E10.3399, E10.3411, E10.3412, E10.3413, E10.3419, E10.3491, E10.3492, E10.3493, E10.3499, E10.3511, E10.3512, E10.3513, E10.3519, E10.3521, E10.3522, E10.3523, E10.3529, E10.3531, E10.3532, E10.3533, E10.3539, E10.3541, E10.3542, E10.3543, E10.3549, E10.3551, E10.3552, E10.3553, E10.3559, E10.3591, E10.3592, E10.3593, E10.3599, E10.36, E10.37X1, E10.37X2, E10.37X3, E10.37X9, E10.39, E10.40, E10.41, E10.42, E10.43, E10.44, E10.49, E10.51, E10.52, E10.59, E10.610, E10.618, E10.620, E10.621, E10.622, E10.628, E10.630, E10.638, E10.641, E10.649, E10.65, E10.69, E10.8, E10.9, E11.00, E11.01, E11.10, E11.11, E11.21, E11.22, E11.29, E11.311, E11.319, , E11.3211, E11.3212, E11.3213, E11.3219, E11.3291, E11.3292, E11.3293, E11.3299, E11.3311, E11.3312, E11.3313, E11.3319, E11.3391, E11.3392, E11.3393, E11.3399, E11.3411, E11.3412, E11.3413, E11.3419, E11.3491, E11.3492, E11.3493, E11.3499, E11.3511, E11.3512, E11.3513, E11.3519, E11.3521, E11.3522, E11.3523, E11.3529, E11.3531, E11.3532, E11.3533, E11.3539, E11.3541, E11.3542, E11.3543, E11.3549, E11.3551, E11.3552, E11.3553, E11.3559, E11.3591, E11.3592, E11.3593, E11.3599, E11.36, E11.37X1, E11.37X2, E11.37X3, E11.37X9, E11.39, E11.40, E11.41, E11.42, E11.43, E11.44, E11.49, E11.51, E11.52, E11.59, E11.610, E11.618, E11.620, E11.621, E11.622, E11.628, E11.630, E11.638, E11.641, E11.649, E11.65, E11.69, E11.8, E11.9, E13.00, E13.01, E13.10, E13.11, E13.21, E13.22, E13.29, E13.311, E13.319, E13.3211, E13.3212, E13.3213, E13.3219, E13.3291, E13.3292, E13.3293, E13.3299, E13.3311, E13.3312, E13.3313, E13.3319, E13.3391, E13.3392, E13.3393, E13.3399, E13.3411, E13.3412, E13.3413, E13.3419, E13.3491, E13.3492, E13.3493, E13.3499, E13.3511, E13.3512, E13.3513, E13.3519, E13.3521, E13.3522, E13.3523, E13.3529, E13.3531, E13.3532, E13.3533, E13.3539, E13.3541, E13.3542, E13.3543, E13.3549, E13.3551, E13.3552, E13.3553, E13.3559, E13.3591, E13.3592, E13.3593, E13.3599, E13.36, E13.37X1,E13.37X2,E13.37X3,E13.37X9,E13.39, E13.40, E13.41, E13.42, E13.43, E13.44, E13.49, E13.51, E13.52, E13.59, E13.610, E13.618, E13.620, E13.621, E13.622, E13.628, E13.630, E13.638, E13.641, E13.649, E13.65, E13.69, E13.8, E13.9, O24.011, O24.012, O24.013, O24.019, O24.02, O24.03, O24.111, O24.112, O24.113, O24.119, O24.12, O24.13, O24.311, O24.312, O24.313, O24.319, O24.32, O24.33, O24.811, O24.812, O24.813, O24.819, O24.82, O24.83

AND

Patient encounter during the performance period (CPT): 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350

WITHOUT

Telehealth Modifier: GQ, GT, 95, POS 02

AND

Two Denominator Eligible Visits

Note: The eligible clinician should submit data on one of the submission criteria, depending on the clinical findings. If the patient has CAD and LVSD (without a diagnosis of Diabetes), use Denominator Submission Criteria 1. If the patient has CAD and Diabetes, use Denominator Submission Criteria 2. If the patient has both diabetes and LVSD, the eligible professional may submit quality data for Submission Criteria 2 and this will count as appropriate submission for this patient.

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

Denominator Exceptions:

Documentation of medical reason(s) for not prescribing ACE inhibitor or ARB therapy (e.g., allergy, intolerance, pregnancy, renal failure due to ACE inhibitor, diseases of the aortic or mitral valve, other medical reasons)

Documentation of patient reason(s) for not prescribing ACE inhibitor or ARB therapy (e.g., patient declined, other patient reasons)

Documentation of system reason(s) for not prescribing ACE inhibitor or ARB therapy (e.g., lack of drug availability, other reasons attributable to the health care system)

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.)*

Time period for data collection: During the encounter within the 12-month period

Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. The patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences. The AHA and ACC exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For measure 0066, exceptions may include medical reason(s) (e.g., allergy, intolerance, pregnancy, renal failure due to ACE Inhibitor, diseases of the aortic or mitral valve, other medical reasons), patient reason(s) (e.g., patient declined, other patient reasons), or system reason(s) (e.g., lack of drug availability, other reasons attributable to the health care system) for not prescribing ACE inhibitor or ARB therapy. Although this methodology does not require the external reporting of more detailed exception data, the AHA and ACC recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The AHA and ACC also advocates for the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement.

Additional details:

FOR SUBMISSION CRITERIA 1: Patients who are 18 years and older with a diagnosis of CAD with current or prior LVEF<40% Report Quality Data Code G8936: Clinician documented that patient was not an eligible candidate for angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy (e.g., allergy, intolerance, pregnancy, renal failure due to ACE inhibitor, diseases of the aortic or mitral valve, other medical reasons) or (e.g., patient declined, other patient reasons) or (e.g., lack of drug availability, other reasons attributable to the health care system)

FOR SUBMISSION CRITERIA 2: Patients who are 18 years and older with a diagnosis of CAD who have diabetes

Report Quality Data Code G8474: Angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy not prescribed for reasons documented by the clinician (e.g., allergy, intolerance, pregnancy, renal failure due to ACE inhibitor, diseases of the aortic or mitral valve, other medical reasons) or (e.g., patient declined, other patient reasons) or (e.g., lack of drug availability, other reasons attributable to the health care system)

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.)*

Consistent with CMS' Measures Management System Blueprint and national recommendations put forth by the IOM (now NASEM) and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer.

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

No risk adjustment or risk stratification

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.)*

THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE:

1) Patients who are 18 years and older with a diagnosis of CAD with LVEF < 40%

OR

2) Patients who are 18 years and older with a diagnosis of CAD who have diabetes

Note: For reporting, Submission Criteria 1 and Submission Criteria 2 are combined for a single reported performance score on the combined measure population. If a patient has both diabetes and LVSD, reporting Submission Criteria #2 (CAD with diabetes) will count as appropriate reporting for this patient. For the purposes of this measure, the single performance rate can be calculated as follows:

Performance Rate = (Numerator 1 + Numerator 2)/ [(Denominator 1 - Denominator Exceptions 1) + (Denominator 2 - Denominator Exceptions 2)]

Calculation algorithm for Submission Criteria 1: Patients who are 18 years and older with a diagnosis of CAD with current or prior LVEF<40%

1. Find the patients who meet the initial population (i.e., the general group of patients that a set of performance measures is designed to address).

2. From the patients within the initial population criteria, find the patients who qualify for the denominator (i.e., the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases, the initial population and denominator are identical.

3. From the patients within the denominator, find the patients who meet the numerator criteria (i.e., the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator.

4. From the patients who did not meet the numerator criteria, determine if the provider has documented that the patient meets any criteria for exception when denominator exceptions have been specified [for this measure: medical reason(s) (e.g., allergy, intolerance, pregnancy, renal failure due to ACE Inhibitor, diseases of the aortic or mitral valve, other medical reasons), patient reason(s) (e.g., patient declined, other patient reasons), or system reason(s) (e.g., lack of drug availability, other reasons attributable to the health care system) for not prescribing ACE inhibitor or ARB therapy)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation.

Although the exception cases are removed from the denominator population for the performance calculation, the exception rate (i.e., percentage with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure.

Calculation algorithm for Submission Criteria 2: Patients who are 18 years and older with a diagnosis of CAD who have diabetes

1. Find the patients who meet the initial population (i.e., the general group of patients that a set of performance measures is designed to address).

2. From the patients within the initial population criteria, find the patients who qualify for the denominator (i.e., the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial population and denominator are identical.

3. From the patients within the denominator, find the patients who meet the numerator criteria (i.e., the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator.

4. From the patients who did not meet the numerator criteria, determine if the provider has documented that the patient meets any criteria for exception when denominator exceptions have been specified [for this measure: medical reason(s) (e.g., allergy, intolerance, pregnancy, renal failure due to ACE Inhibitor, diseases of the aortic or mitral valve, other medical reasons), patient reason(s) (e.g., patient declined, other patient reasons), or system reason(s) (e.g., lack of drug availability, other reasons attributable to the health care system) for not prescribing ACE inhibitor or ARB therapy)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation.

Although the exception cases are removed from the denominator population for the performance calculation, the exception rate (i.e., percentage with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure.

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.

Not applicable. The measure is not based on a sample.

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.

Not applicable. The measure is not based on a survey.

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

If other, please describe in S.18.

Registry 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.

This measure is currently being used in the ACCF PINNACLE registry for the outpatient office settingQuality Payment Program – MIPS Quality Program.

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)*

Clinician : Individual

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

Home Care, Outpatient Services, Post-Acute Care

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.)*

Not applicable. The measure is not a composite.

2. Validity – See attached Measure Testing Submission Form

CAD_0066_Testing_Attachment_2020_Final_revisions.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.

No - This measure is not risk-adjusted

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.

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

Measure Number (*if previously endorsed*)**:** 0066
Measure Title: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)
Date of Submission: 1/6/2020
Type of Measure:

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

1.1. 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: Click here to describe	☐ other: Click here to describe

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).

Previous testing

The data source is EHR data from the PQRS program, provided by the Center for Medicare & Medicaid Services (CMS).

Current testing

The data source is Registry data from the 2018 Merit-based Incentive Payment System (MIPS) Program. This data source was the most comprehensive source available at the time of analysis. Our analysis was limited to include only data that was reported at the unique NPI level.

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

Previous testing

The data are for the time period January 2014 through December 2014 and cover the entire United States.

Current testing

The data are for the time period January 1st, 2018 through December 31st, 2018.

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: Click here to describe	☐ other: Click here to describe

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*)

Previous testing

The total number of physicians reporting on this measure is 2296. Of those, 1128 physicians had all the required data elements and met the minimum number of quality reporting events (10) for inclusion in the reliability analysis. For this measure, 49.1 percent of physicians are included in the analysis, and the average

number of quality reporting events is 49.0 for a total of 55,272 events. The range of quality reporting events for 1128 physicians included is from 507 to 10. The average number of quality reporting events for the remaining 50.9 percent of physicians that aren't included is 0.07.

Current testing

A total of 774 providers are reporting on this measure through the registry reporting option for MIPS during the period between 1/1/2018-12/31/2018. This data set reflects information at the provider level and our analysis of the data as a whole is reflected throughout this submission. Of those 774 providers, all had at least one patient who qualified for the measure after accounting for exceptions for a total of 66,755 eligible patients. The average number of eligible patients is 86 for the 774 providers. The range of eligible patients for 774 providers is from 1 to 992.

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*)

Previous testing

There were 55,272 patients included in this testing and analysis. These were the patients that were associated with physicians who had 10 or more patients eligible for this measure.

Current testing

There were 66,755 patients included in this reliability testing and analysis. These were the patients that were associated with providers who had at least one eligible patient in the year.

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.

Previous testing

The same data sample was used for reliability testing and exceptions analysis.

Current testing

The same data samples were used for reliability testing and exceptions analysis.

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.

Previous testing

Patient-level socio-demographic (SDS) variables were not captured as part of the testing.

Current testing

Patient-level socio-demographic (SDS) variables were not captured as part of the testing.

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*)

Previous testing

Reliability of the computed measure score was measured as the ratio of signal to noise. The signal in this case is the proportion of the variability in measured performance that can be explained by real differences in physician performance. Reliability at the level of the specific physician is given by:

Reliability = Variance (physician-to-physician) / [Variance (physician-to-physician) + Variance (physician-specific-error]

Reliability is the ratio of the physician-to-physician variance divided by the sum of the physician-to-physician variance plus the error variance specific to a physician. A reliability of zero implies that all the variability in a measure is attributable to measurement error. A reliability of one implies that all the variability is attributable to real differences in physician performance.

Reliability testing was performed by using a beta-binomial model. The beta-binomial model assumes the physician performance score is a binomial random variable conditional on the physician's true value that comes from the beta distribution. The beta distribution is usually defined by two parameters, alpha and beta. Alpha and beta can be thought of as intermediate calculations to get to the needed variance estimates.

Reliability is estimated at two different points, at the minimum number of quality reporting events for the measure and at the mean number of quality reporting events per physician.

Current testing

Reliability of the computed measure score was measured as the ratio of signal to noise. The signal in this case is the proportion of the variability in measured performance that can be explained by real differences in provider performance and the noise is the total variability in measured performance. Reliability at the level of the specific provider is given by:

Reliability = Variance (provider-to-provider) / [Variance (provider-to-provider) + Variance (provider-specific-error]

Reliability is the ratio of the provider-to-provider variance divided by the sum of the provider-to-provider variance plus the error variance specific to a provider. A reliability of zero implies that all the variability in a measure is attributable to measurement error. A reliability of one implies that all the variability is attributable to real differences in provider performance.

Variance (provider-to-provider) = alpha*beta/ ((alpha + beta + 1) * (alpha + beta) ^2)

Variance (provider-specific-error) = p(1-p)/n

Where p is the passing rate for a provider and n is the number of patients for that provider

Reliability testing was performed by using a beta-binomial model. The beta-binomial model assumes the provider performance score is a binomial random variable conditional on the provider's true value that comes

from the beta distribution. The beta distribution is usually defined by two parameters, alpha and beta. Alpha and beta can be thought of as intermediate calculations to get to the needed variance estimates.

For this analysis Alpha = 5.7133 and Beta = 1.3209. These parameters are used to calculate the variance (provider-specific-error) which is approximately equal to 0.006. Reliability is then calculated for each provider using this value and the variance (provider-to-provider). Average reliability is reported by averaging reliability for each provider with at least 1 patient for the measure.

A reliability of 0.70 – 0.80 is generally considered the acceptable threshold for reliability, 0.80 – 0.90 is considered high reliability, and 0.90 – 1.0 is considered very high. [1]

1. Adams JL, Mehrotra A, McGlynn EA, Estimating Reliability and Misclassification in Physician Profiling, Santa Monica, CA: RAND Corporation, 2010. www.rand.org/pubs/technical_reports/TR863. (Accessed on February 24, 2012.)

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*)

Previous testing

This measure has 0.58 reliability when evaluated at the minimum level of quality reporting events and 0.87 reliability at the average number of quality events.

Current testing

The average reliability for providers with at least one eligible patient is 0.85. We also report the average reliability at each decile of the sample shown in the table below.

Reliability Statistics														
Denominator (Patients)	**Mean**	**SD**	**Min**	**Max**	**Decile**									
					1	2	3	4	5	6	7	8	9	10
1+	0.85	0.19	0.13	1.00	0.38	0.68	0.82	0.87	0.91	0.94	0.96	0.98	0.99	1.00

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?*)

Previous testing

Reliability at the minimum level of quality reporting events is moderate. Reliability at the average number of quality events is high.

Current testing

The average reliability for this measure is high with reliability increasing as the denominator size increases for both years.

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).*

Previous testing

Face validity of the measure score as an indicator of quality was systematically assessed as follows.

After the measure was fully specified, the expert panel was asked to rate their agreement with the following statement:

The scores obtained from the measure as specified will provide an accurate reflection of quality and can be used to distinguish good and poor quality.

Scale 1-5, where 1= Strongly Disagree; 2= Disagree; 3= Neither Agree nor Disagree; 4= Agree; 5= Strongly Agree

The expert panel included 18 members. Panel members were comprised of experts from the AHA Council on Clinical Cardiology. The list of expert panel members is as follows:

Jonathan Dukes, MD

Win Shen, MD

Michelle Albert, MD, MPH

Randal Thomas, MD

Deborah L. Crabbe, MD

Paul Wang, MD

Robert L Page II, PharmD

Vera Bittner, MD

Lori Blauwet, MD

Jennifer Cook, MD

Sana Al-Khatib, MD

Jeff Washam, PharmD

Benjamin D. Levine, MD

Jose Joglar, MD

Kiran Musunuru, MD, PhD, MPH

Michael W Rich, MD

Mauricio G. Cohen, MD

Gregory Barsness, MD

To satisfy NQF's ICD-10 Conversion Requirements, we are providing the information below:

- NQF ICD-10-CM Requirement 1: Statement of intent related to ICD-10 CM

  Goal was to convert this measure to a new code set, fully consistent with the original intent of the measure.

- NQF ICD-10-CM Requirement 2: Coding Table

  See attachment in S.2b

- NQF ICD-10-CM Requirement 3: Description of the process used to identify ICD-10 codes

  The PCPI's ICD-10 conversion approach was used to identify ICD-10 codes for this measure. The PCPI uses the General Equivalence Mappings (GEMs) as a first step in the identification of ICD-10 codes. We then review the ICD-10 codes to confirm their inclusion in the measure is consistent with the measure intent, making additions or deletions as needed. We have two RHIA-credentialed professionals on our staff who review all ICD-10 coding. For measures included in PQRS, the ICD-10 codes have also been reviewed and vetted by the CMS contractor. Comments received from stakeholders related to ICD-10 coding are first reviewed internally. Depending on the nature of the comment received, we also engage clinical experts to advise us as to whether a change to the specifications is warranted.

Current testing

Validity testing method

Coronary Artery Disease (CAD): Antiplatelet Therapy (NQF 0067) was chosen as a suitable candidate for correlation analysis due to the similarities in patient population and domain. We hypothesize that there exists a positive association of scores between providers who prescribe Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy on patients with diabetes or left ventricular systolic dysfunction (LVEF < 40%) and those who prescribe an antiplatelet therapy on patients with coronary artery disease within a 12 month period.

Providers included in the analysis had at least one patient in the denominator after exceptions were removed. Datasets were reviewed to identify providers based on the provider identifier. Comparing performance scores of those shared provider IDs, the empirical analysis uses regression with Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (NQF 0066) as the outcome and Coronary Artery Disease (CAD): Antiplatelet Therapy (NQF 0067) as the predictor. Results identify the multiple R value (the correlation coefficient) and P-value of the regression variables to assess the association between performance scores of these shared provider IDs.

We use the following guidance to describe correlation[1]:

Correlation	Interpretation
0.80 – 1.00	Very Strong
0.60 – 0.79	Strong
0.40 – 0.59	Moderate
0.20 - 0.39	Weak
0 – 0.19	Very Weak

1. "11. Correlation and Regression." *The BMJ*, 21 March 2019, https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/11-correlation-and-regression/ .

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

Previous testing

Frequency Distribution of Ratings

1 – 1 response (Strongly Disagree)

2 – 0 responses (Disagree)

3 – 0 responses (Neither Agree nor Disagree)

4 – 7 responses (Agree)

5 – 10 responses (Strongly Agree)

The results of the expert panel rating of the validity statement were as follows: N = 17; Mean rating = 4.39 and 94.4% of respondents either agree or strongly agree that this measure can accurately distinguish good and poor quality.

Current Testing

Data from the 2018 MIPS Registry Program were used to perform the correlation analysis for this measure. Data comes from the Registry version of Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (NQF 0066) and Coronary Artery Disease (CAD): Antiplatelet Therapy (NQF 0067)

Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (NQF 0066) was positively correlated with Coronary Artery Disease (CAD): Antiplatelet Therapy (NQF 0067).

NQF #0066

Coefficient of correlation = 0.47
Alpha level = 0.05
P-value = < 0.001
Number of shared Providers based on Provider identifier = 520

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?*)

Previous testing

Based on the mean rating by the expert panel, this measure is valid as specified.

Current Testing

Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (NQF 0066) has a moderate positive correlation with Coronary Artery Disease (CAD): Antiplatelet Therapy (NQF 0067). The correlation is highly statistically significant. With a coefficient of correlation of 0.47, the correlation is moderate, significant, and confirms our hypothesis. The moderate positive correlation with Coronary Artery Disease (CAD): Antiplatelet Therapy (NQF 0067) demonstrates the criterion validity of the measure. The strength of the correlation is within our expectations.

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*)

Previous testing

Since not all patients with CAD will meet the guideline recommendations for antiplatelet therapy, exclusions in this

Exceptions include:

- Documentation of medical reason(s) for not prescribing angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy.
- Documentation of patient reason(s) for not prescribing angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy.

Exceptions were analyzed for frequency across providers.

Current Testing

This measure does not include exclusions and does specify exceptions that we analyzed.

Exceptions include:

- Clinician documented that patient was not an eligible candidate for angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy (e.g., allergy, intolerance, pregnancy, renal failure due to ACE inhibitor, diseases of the aortic or mitral valve, other medical reasons) or (e.g., patient declined, other patient reasons) or (e.g., lack of drug availability, other reasons attributable to the health care system)

Exceptions were analyzed for frequency across providers and deciles of exceptions were reported.

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*)

Previous testing

Exceptions Analysis:

Amongst the 1,128 physicians with the minimum (10) number of quality reporting events, there were a total of 2,222 exceptions reported. The average number of exceptions per physician in this sample is 2.0. The overall exception rate is 3.9%.

Current Testing

Amongst the 980 included providers, there were a total of 774 exceptions reported. The average number of exceptions per provider in this sample is 2.3. The proportion of exceptions to patients is 0.02. Exception deciles illustrate the spread of exceptions amongst providers. According to the results, 80% of providers had 2 or fewer exceptions across eligible patients for the year under study.

Decile	Exceptions
1	0
2	0
3	0
4	0
5	0
6	0
7	1
8	2
9	5
10	179

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*)

Previous testing

Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons.

Without these being removed, the performance rate would not accurately reflect the true performance of each physician, which would result in an increase in performance failures and false negatives.

AHA recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. AHA also advocates for the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement.

Current Testing

The AHA follows the PCPI methodology in distinguishing between denominator exceptions and denominator exclusions.

Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. The patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences. The PCPI exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For measure Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or

Left Ventricular Systolic Dysfunction (LVEF < 40%), exceptions may include medical reason(s) (e.g., allergy, intolerance, pregnancy, renal failure due to ACE Inhibitor, diseases of the aortic or mitral valve, other medical reasons), patient reason(s) (e.g., patient declined, other patient reasons), or system reason(s) (e.g., lack of drug availability, other reasons attributable to the health care system) for not prescribing ACE inhibitor or ARB therapy. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement.

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** Click here to enter number of factors **risk factors**

☐ **Stratification by** Click here to enter number of categories **risk categories**

☐ **Other,** Click here to enter description

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.

Previous testing

Not applicable

Current Testing

Not applicable

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.

Previous testing

Not applicable

Current Testing

Not applicable

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?

Previous testing

Not applicable

Current Testing

Not applicable

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)**

Current Testing

Not applicable

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

Previous testing

Not applicable

Current Testing

Not applicable

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.**

Previous testing

Not applicable

Current Testing

Not applicable

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*)

Previous testing

Not applicable

Current Testing

Not applicable

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*)**:**

Previous testing

Not applicable

Current Testing

Not applicable

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

Previous testing

Not applicable

Current Testing

Not applicable

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

Previous testing

Not applicable

Current Testing

Not applicable

2b3.9. Results of Risk Stratification Analysis:

Previous testing

Not applicable

Current Testing

Not applicable

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*)

Previous testing

Not applicable

Current Testing

Not applicable

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*)

Previous testing

Not applicable

Current Testing

Not applicable

_____

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)*

Previous testing

Measures of central tendency, variability, and dispersion were calculated.

Current Testing

Measures of central tendency, variability, and dispersion were calculated.

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*)

Previous testing

Based on the sample of 1,128 included physicians, the mean performance rate is 0.71 the median performance rate is 0.74 and the mode is 0.67. The standard deviation is 0.19. The range of the performance rate is 1.00, with a minimum rate of 0.00 and a maximum rate of 1.00. The interquartile range is 0.18 (0.64-0.83).

Current Testing

Based on the sample of 774 included providers, the mean performance rate is 0.82, the median performance rate is 0.84 and the mode is 1.0. The standard deviation is 0.18. The range of the performance rate is 1.00, with a minimum rate of 0.00 and a maximum rate of 1.00. The interquartile range is 0.14 (0.93–0.77). Deciles are provided in the table below:

Decile	Performance
1	0.66
2	0.75
3	0.79
4	0.82
5	0.84
6	0.87
7	0.90
8	0.95
9	1.00

10	1.00

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?*)

Previous testing

The range of performance from 0.64 to 0.83 suggests there's clinically meaningful variation across physicians' performance.

Current Testing

The range of performance from 0.00 to 1.00 suggests there's clinically meaningful variation across providers' performance. Outliers are considered to be values less than quartile 1 (0.77) or greater than quartile 3 (0.93) by more than 1.5 the IQR (0.15). Quartiles are provided in the table below:

Quartile	Performance
1	0.77
2	0.84
3	0.93
4	1.00

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*)

Previous testing

This test was not performed for this measure.

Current Testing

Not applicable

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*)

Previous testing
This test was not performed for this measure.

Current Testing
Not applicable

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*)

Previous testing
This test was not performed for this measure.

Current Testing
Not applicable

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*)

Previous testing

Data are not available to complete this testing.

Current Testing

The MIPS dataset provided to us by CMS did not contain missing data, so this test was not performed. Nevertheless, missing data may have been rejected when submitted to CMS in which case those values would not be counted towards measure performance. There is no indication that this missing data was systematic, thus their omission would lead to unbiased performance results.

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*)

Previous testing

Data are not available to complete this testing.

Current Testing

This test was not performed for this measure. There was no missing data.

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*)

Previous testing

Data are not available to complete this testing.

Current Testing

The MIPS dataset provided to us by CMS did not contain missing data, so this test was not performed. Nevertheless, missing data may have been rejected when submitted to CMS in which case those values would not be counted towards measure performance. There is no indication that this missing data was systematic, thus their omission would lead to unbiased performance results.

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.

generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition, Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims)

If other:

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 clinical data (e.g., clinical registry, nursing home MDS, home health OASIS)

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).

All the data elements needed for this measure are collected through electronic data

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.

We have not identified any areas of concern or made any modifications as a result of testing and operational use of the measure in relation to data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, and other feasibility issues unless otherwise noted.

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)*.

The Measures, while owned and copyrighted by the AHA, ACC, and PCPI Foundation, can be reproduced and distributed, without modification, for noncommercial purposes, eg, use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measures into a product or service that is sold, licensed or distributed for commercial gain. Commercial uses of the Measures require a license agreement between the user and AHA. The AHA nor its members shall be responsible for any use 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)

	Public Reporting Merit-based Incentive Payment System (MIPS) https://qpp.cms.gov/mips/quality-measures Merit-based Incentive Payment System (MIPS) https://qpp.cms.gov/mips/quality-measures Payment Program Merit-based Incentive Payment System (MIPS) https://qpp.cms.gov/mips/quality-measures Quality Improvement (external benchmarking to organizations) PINNACLE Registry® https://cvquality.acc.org/NCDR-Home/registries/outpatient-registries/pinnacle-registry The Diabetes Collaborative Registry® https://cvquality.acc.org/NCDR-Home/registries/outpatient-registries/the-diabetes-collaborative-registry

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

1. NAME: Merit-based Incentive Payment System (MIPS)-Sponsored by the Centers for Medicare and Medicaid Services (CMS).
PURPOSE: MIPS-Quality. The purpose of the program is to tie payments to clinicians, to provide quality and cost-efficient care, drive improvement in care processes, increase the use of healthcare data, and reduce the costs of care. The program began in 2017.
GEOGRAPHIC AREA: National. Clinicians are included in MIPS-Quality if they are an eligible clinician type and meet program requirements.
LEVEL OF MEASUREMENT: Clinician-level. Professional services rendered under Medicare Part B.
2. NAME: The PINNACLE (Practice Innovation and Clinical Excellence) Registry sponsored by American College of Cardiology and its National Cardiovascular Data Registry.
PURPOSE: The PINNACLE Registry was developed as an outpatient-based prospective quality improvement registry, for cardiology practices in the outpatient setting. Data is collected specifically for coronary artery disease, hypertension, heart failure and atrial fibrillation. Data collected includes patient demographics, medical history, vital signs, laboratory values, imaging results, medications, and contraindications to medications. Registry began in 2008.
GEOGRAPHIC AREA: National. Includes cardiac outpatients. In 2013, the PINNACLE Registry contained information on 2,898,505 patients, cared for by 4,859 providers in 431 practices. By 2017, the registry contained information on 6,040,996 patients, cared for by 8,853 providers in 724 practices.
LEVEL OF MEASUREMENT: Clinician and outpatient care.
3. NAME: The Diabetes Collaborative Registry (DCR) is a collaborative effort between the American College of Cardiology, American Diabetes Association, American College of Physicians, American Association of Clinical Endocrinologists, and Joslin Diabetes Center. It is part of the National Cardiovascular Data Registry.
PURPOSE: The DCR is a prospective, office-based, quality improvement registry for patients with diabetes mellitus and other metabolic needs.
GEOGRAPHIC AREA: Global.
LEVEL OF MEASUREMENT: Clinician and outpatient care.

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?*)
Not applicable.

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.*)

Not applicable.

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.

Performance results are provided to all participating clinicians across quality programs. Clinicians participating in the MIPS-Quality program receive performance results, i.e. their MIPS score and corresponding payment adjustment annually. The PINNACLE Registry provides user-friendly online benchmark reports to users via an interactive portal. Individual practice performance on measures is provided by quarter, alongside the national average by quarter. This allows clinicians to identify areas for improvement. The Diabetes Collaborative Registry provides user-friendly online benchmark reports.

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.

The feedback process is described in Section 4a2.1.1 and includes providing user-friendly online benchmark reports to users via an interactive portal. Individual practice performance on measures is provided by quarter, alongside the national average by quarter.

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.

Throughout the year, the American Heart Association receives feedback on its measures from a variety of sources:

1. Ad-hoc tickets/emails sent to the QPP help desk from measure implementers
2. Feedback during public comment periods of regulatory cycles
3. 3. Feedback from the ACC/AHA Task Force on Performance Measures Committee

4a2.2.2. Summarize the feedback obtained from those being measured.

Since our last submission to NQF, we have been asked by implementers to specifically name angiotensin receptor neprilysin inhibitors (ARNIs) as one of the numerator compliant options. We have not received feedback from those being measured.

4a2.2.3. Summarize the feedback obtained from other users

Since our last submission to NQF, we have been asked about including angiotensin receptor neprilysin inhibitors (ARNIs) to the measure numerator. We have not received feedback from those being measured.

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.

To address the inclusion of ARNIs as one of the numerator compliant options, we worked with our technical expert panel to refine the measure and included the following note within the measure specifications:

NUMERATOR NOTE: Eligible clinicians who have given a prescription to the patient for or whose patient is currently taking a combination medication therapy, which contains either an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) (e.g., angiotensin receptor neprilysin inhibitor [ARNI, sacubitril/valsartan], ACEI+diruretc, ARB+diruretic, ACEI+calcium channel blocker) would meet performance for this measure.

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.

The intent of this measure is to improve care amongst individuals with coronary artery disease. The MIPS quality benchmarks cited in 1b2 of this form show a slight improvement in average performance rates between 2016 and 2018. However, reporting rates represent but one facet of the quality improvement process. While we create measures with the goal of improving quality of care, measurement is a mechanism to drive improvement but does not equate improvement. Measurement can help identify opportunities for improvement with actual improvement requiring making changes to health care processes. In order to promote improvement, quality measurement systems need to provide feedback to front-line clinical staff in as close to real time as possible and at the point of care whenever possible (Conway, Mostashari, & Clancy, 2013).

Within the literature we found that Makam et al. evaluated trends in the prescription of ACE-I/ARBs amongst eligible patients. Methods included analyzing over 5,000 patients discharged from various hospitals in central Massachusetts after acute myocardial infarction. The prescription of ACE-I/ARBs increased from 50% to 62% between 2001 and 2011, indicating improvement in prescribing patterns (2016). However, a gap in care persists.

Citations:

1. Conway, P. H., Mostashari, F., & Clancy, C. (2013). The future of quality measurement for improvement and accountability. JAMA, 309(21), 2215–2216. https://doi.org/10.1001/jama.2013.4929

2. Makam, R. C., Erskine, N., McManus, D. D., Lessard, D., Gore, J. M., Yarzebski, J., & Goldberg, R. J. (2016). Decade-Long Trends (2001 to 2011) in the Use of Evidence-Based Medical Therapies at the Time of Hospital Discharge for Patients Surviving Acute Myocardial Infarction. The American journal of cardiology, 118(12), 1792–1797. https://doi.org/10.1016/j.amjcard.2016.08.065

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 are not aware of any unintended consequences at this time, but we take unintended consequences very seriously and therefore continuously monitor to identify actions that can be taken to mitigate them.

4b2.2. Please explain any unexpected benefits from implementation of this measure.

A recent meta-analysis evaluated the relationship between medication adherence and clinical outcomes amongst ~100,000 patients with stable coronary artery disease. Study authors found that adherence to evidence-based medications, including ACE-I and ARB therapy, was related to a lower risk of all-cause mortality (risk ratio 0.56; 95% CI), lower risk of cardiovascular mortality (risk ratio 0.66; 95% CI), and lower risk of cardiovascular hospitalization/myocardial infarction(risk ratio 0.61; 95% CI) (Du, Cheng, Zhang, Li, & Mei, 2017).

Citation:

Du, L., Cheng, Z., Zhang, Y., Li, Y., & Mei, D. (2017). The impact of medication adherence on clinical outcomes of coronary artery disease: A meta-analysis. European journal of preventive cardiology, 24(9), 962–970. https://doi.org/10.1177/2047487317695628

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)

0081 : Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

0081e : Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

0137 : ACEI or ARB for left ventricular systolic dysfunction- Acute Myocardial Infarction (AMI) Patients

1662 : Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

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.

0137 is specific to acute myocardial infarction patients. 1662 is specific to chronic kidney disease patients. And 0081/e are specific only to broader heart failure patients.

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.)

This measure addresses a distinct target population and/or quality action from other related measures, as described above. The measures are complementary to form a well-rounded view of the quality of care for patients with CAD.

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): American Heart Association

Co.2 Point of Contact: Melanie, Shahriary, melanie.shahriary@heart.org, 301-651-7548-

Co.3 Measure Developer if different from Measure Steward: American Heart Association

Co.4 Point of Contact: Melanie, Shahriary, melanie.shahriary@heart.org, 301-651-7548-

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.

Work Group members:

Joseph Drozda, MD, FACC (Co-Chair) (cardiology; methodology)

Joseph V. Messer, MD, MACC, FAHA (Co-Chair) (cardiology)

John Spertus, MD, FACC, FAHA (Co-Chair) (cardiology)

Bruce Abramowitz, MD, FACC (interventional cardiology; measure implementation)

Karen Alexander, MD, FACC (cardiology; geriatrics)

Craig T. Beam, CRE (patient representative)

Robert O. Bonow, MD, MACC, FAHA, FACP (cardiology)

Jill S. Burkiewicz, PharmD, BCPS (pharmacy)

Michael Crouch, MD, MSPH (family medicine)

David C. Goff, Jr., MD, PhD, FAHA, FACP (internal medicine)

Richard Hellman, MD, FACP, FACE (endocrinology)

Thomas James, III, FACP, FAAP (health plan representative)

Marjorie L. King, MD, FACC, MAACVPR (cardiology; cardiac rehabilitation)

Edison A. Machado, Jr., MD, MBA (measure implementation)

Eduardo Ortiz, MD, MPH (internal medicine; guideline development)

Michael O'Toole, MD, FACC (cardiology; electrophysiology; measure implementation)

Stephen D. Persell, MD, MPH (internal medicine; measure implementation)

Jesse M. Pines, MD, MBA, MSCE, FAAEM (emergency medicine)

Frank J. Rybicki, MD, PhD (radiology)

Lawrence B. Sadwin (patient representative)

Joanna D. Sikkema, MSN, ANP-BC, FAHA (cardiology)

Peter K. Smith, MD (thoracic surgery)

Patrick J. Torcson, MD, FACP, MMM (hospital medicine)

John B. Wong MD, FACP (internal medicine)

ACCF, AHA, and PCPI measures are developed through cross-specialty, multi-disciplinary work groups. All medical specialties and other health care professional disciplines participating in patient care for the clinical condition or topic under study are invited to participate as equal contributors to the measure development process. In addition, the ACCF, AHA and PCPI strive to include on their work groups individuals representing the perspectives of patients, consumers, private health plans, and employers. This broad-based approach to measure development ensures buy-in on the measures from all stakeholders and minimizes bias toward any individual specialty or stakeholder group. All work groups have at least two co-chairs who have relevant clinical and/or measure development expertise and who are responsible for ensuring that consensus is achieved and that all perspectives are voiced.

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2003

Ad.3 Month and Year of most recent revision: 09, 2019

Ad.4 What is your frequency for review/update of this measure? Supporting guidelines, specifications, and coding for this measure are reviewed annually

Ad.5 When is the next scheduled review/update for this measure? 09, 2020

Ad.6 Copyright statement: Physician performance measures and related data specifications were developed by the PCPI Foundation, the American College of Cardiology (ACC), and the American Heart Association (AHA) to facilitate quality improvement activities by physicians. These performance measures are not clinical guidelines and do not establish a standard of medical care, and have not been tested for all potential applications. While copyrighted, they can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the performance measures for commercial gain, or incorporation of the performance measures into a product or service that is sold, licensed or distributed for commercial gain. Commercial uses of the measures require a license agreement between the user and the PCPI Foundation or the ACC or the AHA. Neither the AMA, ACC, AHA, the PCPI nor its members shall be responsible for any use of these measures.

THE MEASURES AND SPECIFICATIONS ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND.

Ad.7 Disclaimers: Physician performance measures and related data specifications were developed by the PCPI Foundation, the American College of Cardiology (ACC), and the American Heart Association (AHA) to facilitate quality improvement activities by physicians. These performance measures are not clinical guidelines and do not establish a standard of medical care, and have not been tested for all potential applications. While copyrighted, they can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the performance measures for commercial gain, or incorporation of the performance measures into a product or service that is sold, licensed or distributed for commercial gain. Commercial uses of the measures require a license agreement between the user and the PCPI Foundation or the ACC or the AHA. Neither the AMA, ACC, AHA, the PCPI nor its members shall be responsible for any use of these measures.

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Ad.8 Additional Information/Comments: None.