

MIPS Peer-Reviewed Journal Article Requirement Template

Section 101(c)(1) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires submission of new measures for publication in applicable specialty-appropriate, peer-reviewed journals prior to implementing in the Merit-based Incentive Payment System (MIPS). Such measures will be submitted by the Centers for Medicare & Medicaid Services (CMS), to a journal(s), before including any new measure on the MIPS Quality Measures List. The measure submitter shall provide the required information for article submission under the MACRA per the MIPS Annual Call for Quality Measures submission process.

Interested parties submitting measures for consideration through the MIPS Annual Call for Quality Measures must complete the required information by the CMS Annual Call for Measures deadline (8 p.m. ET on May 1, 2025). Some of the information requested below may be listed in specific fields in the CMS Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT); however, to ensure that CMS has all of the necessary information and avoid delays in the evaluation of your submission, please fully complete this form as an attached Word document. The information in MERIT must be consistent with the information below, including the following, but not limited to:

- **Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management**
- **Closing the Gaps in Care**

Measure Steward: American Heart Association

Measure Developer: American Heart Association

Description: Percentage of patients aged 18 years and older with clinical atherosclerotic cardiovascular disease (ASCVD) who received a low-density lipoprotein cholesterol (LDL-C) test via lipid panel and achieved an LDL-C of <70mg/dL on the most recent test during the measurement period

1. Statement

- Background (Why is this measure important?).

Elevated low density lipoprotein cholesterol (LDL-C) levels contribute to clinical atherosclerotic cardiovascular disease (ASCVD) and once identified can be addressed via lipid management.[Grundy] Studies support that LDL-C lowering produces marked reduction in clinical ASCVD and that lower is better for LDL-C. [Grundy] The 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA CCD guideline recommends high-intensity statin therapy to achieve an LDL lowering of $\geq 50\%$ from baseline.[Virani] Virani, et al. further stated, "The expected percent reduction in LDL-C levels with high-intensity statin therapy is $\geq 50\%$ and should be used to assess clinical efficacy. However, baseline LDL-C levels in patients before statin initiation are not always available in clinical practice. The threshold of LDL-C ≥ 70 mg/dL is then useful to determine whether to intensify lipid management."

- Environmental scan (Are there existing measures in this area?).

There are currently no similar existing measures in use in CMS programs, as previous lipid monitoring measures were identified as topped-out with recent quality measurement focusing on statin therapy and management. In 2011, a joint ACCF/AHA/AMA-PCPI TEP identified the need for measurement and approved the LDL-C monitoring measure. [Drozda] In 2025, Williams, et al. reaffirmed the need for measurement in the chronic coronary disease (CCD) population and included a LDL-C management measure. [Williams]

2. Gap Analysis

- Provide evidence for the measure (What are the gaps and opportunities to improve care?).
Following the retirement of national lipid monitoring measures a gap in care was identified using both AHA registry data and US Veterans data. [Ward] In 2022, the AHA implemented two measures addressing lipid monitoring and management in their Get With The Guidelines – Outpace™ registry (Outpace) which supports a continued gap for

both lipid monitoring and management. Validity and reliability testing revealed the monitoring measure had a mean performance rate of 46.8% (range 30% - 100%) and the management measure performance data indicated a mean performance rate of 64.9% (range 18.2%-85.7%). Ward, et al. identified that monitoring occurred in approximately 24% of individuals with ASCVD while 44% had a LDL-C of <70 mg/dl at the start of their quality

- Expected outcome (patient care/patient health improvements, cost savings).

It is anticipated that earlier intervention will result in improved health care outcomes for patients and improved cost savings for the US.

The AHA has found and estimated, "One in 3 US adults received care for a cardiovascular risk factor or condition in 2020." [Kazi] Cholesterol-lowering therapy leading to LDL-C lowering has consistently been shown to reduce the risk of ASCVD. [Grundy, Baigent] By monitoring LDL-C rates over time, it is anticipated that earlier intervention with cholesterol-lowering therapy will occur and lead to improved patient outcomes over time when paired with healthy lifestyle choices.

Annual inflation-adjusted (2022 US dollars) health care costs of cardiovascular risk factors are projected to triple between 2020 and 2050, from \$400 billion to \$1344 billion. For cardiovascular conditions, annual health care costs are projected to almost quadruple, from \$393 billion to \$1490 billion, and productivity losses are projected to increase by 54%, from \$234 billion to \$361 billion." [Kazi]

- Recommendation for the measure (Is it based on a study, consensus opinion, USPSTF recommendation etc.?).

The measure is based on Level A and Class 1 guideline recommendation statements:

- In adults who are 20 years of age or older and not on lipid-lowering therapy, measurement of either a fasting or nonfasting plasma lipid profile is effective in estimating ASCVD risk and documenting baseline LDL-C. (Class 1, Level of Evidence: B-NR) [Grundy]
- In patients who are 75 years of age or younger with clinical ASCVD, high-intensity statin therapy should be initiated or continued with the aim of achieving a 50% or greater reduction in LDL-C Levels. (Class 1, Level of Evidence: A) [Grundy]
- In patients with clinical ASCVD in who high-intensity statin therapy is contraindicated or who experience statin-associated side effects, moderate- intensity statin therapy should be initiated or continued with the aim of achieving a 30% to 49% reduction in LDL-C levels. (Class 1, Level of Evidence: A) [Grundy]
- In patients with CCD, high-intensity statin therapy is recommended with the aim of achieving a ≥50% reduction in LDL-C levels to reduce the risk of MACE. (Class 1, Level of Evidence: A) [Virani]
- The expected percent reduction in LDL-C levels with high-intensity statin therapy is ≥50% and should be used to assess clinical efficacy. However, baseline LDL-C levels in patients before statin initiation are not always available in clinical practice. The threshold of LDL-C ≥70 mg/dL is then useful to determine whether to intensify lipid management. [Virani]

REFERENCES

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Kazi DS, Elkind MSV, Deutsch A, et al. Forecasting the Economic Burden of Cardiovascular Disease and Stroke in the United States Through 2050: A presentidal Advisory From the American Heart Association. *Circulation*. 2024; 150(4): e65–e88.

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Tunncliffe DJ, Palmer SC, Cashmore BA, et al. HMG CoA reductase inhibitors (statins) for people with chronic kidney disease not requiring dialysis. *Cochrane Database of Systematic Reviews* 2023, Issue 11. Art. No.: CD007784. DOI: 10.1002/14651858.CD007784.pub3. Accessed 10 April 2025.

Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA guideline for the management of patients with chronic coronary disease: a report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2023;82:833-955.

Ward R, Wellman H, Yel N, et al. Abstract 4136978: Six-month Changes in Lipid Management in the Veterans Affairs Lipid Optimization Reimagined Quality Improvement (VALOR-QI) Program. *Circulation*. 2024;150(Suppl 1) https://doi.org/10.1161/circ.150.suppl_1.4136978

Williams MS, Levine GN, Kalra D, et al. 2025 AHA/ACC clinical performance and quality measures for patients with chronic coronary disease: a report of the American College of Cardiology/American Heart Association Joint Committee on Performance Measures. *Circ Cardiovasc Qual Outcomes*. Published online April 30, 2025. doi:10.1161/HCQ.000000000000140

Wong ND, Budoff MJ, Ferdinand K, et al. Atherosclerotic cardiovascular disease risk assessment: an American Society for Preventive Cardiology clinical practice statement. *Am J Prev Cardiol*. 2022;10:100335

3. Reliability/Validity

What testing has been performed at the level of implementation? (MIPS requires full measure testing at the individual clinician level (and may also need to be tested at the group level) for MIPS Clinical Quality Measures (CQMs) and Electronic Clinical Quality Measures (eCQMs) collection types. Administrative claims measures tested at the group level require a reliability threshold to be implemented at the group level.)

- Please provide testing results including the N value, Bonnie test case results, correlation coefficient and any other pertinent information or values to be considered.
- Reliability Testing Results at the accountable entity level
- Face Validity Testing Results, Clinician Sites
- Empiric Validity Testing Results at the accountable entity level
- Data Element/Patient Encounter Level Testing
- Exclusion Frequency
- What were the minimum sample sizes used for reliability results?

Other Information

- Is it risk adjusted? If so, how?
- What benchmarking information is available?
- Collection Type: Specify the data collection type.
- Specify measure stage of development.
- For Patient Reported Outcome Performance Measures:
 - The survey or tool has been tested and doesn't require modifications based on results?

- Patient/encounter level testing for each critical data element doesn't require changes to the tool base on the results?

Performance Gap: The eligible population included patients who met the denominator criteria and were seen by providers from the four reporting health systems (Bay Area Community Health (California), M Health Fairview (Minnesota), Franciscan Missionaries of Our Lady Health System (Louisiana), Wellstar Health (Georgia)). The analysis includes data from January 1, 2024 to December 31, 2024. The data criteria (i.e., identification of race from case list and age/sex from patient list) was applied consistently and limited to only qualified NPIs, which resulted in different n for measure denominators.

A total of 286 NPIs and 28690 eligible patient encounters in the monitoring group were analyzed for this measure. The LDL-C monitoring group performance scores ranged from 30.0% to 100.0%, with a mean of 64.9%; decile scores were 1st – 69.9%, 2nd – 76.3%, 3rd – 71.0%, 4th – 66.3%, 5th – 63.9%, 6th – 59.8%, 7th – 59.1%, 8th – 62.4%, 9th – 58.6%, and 10th – 60.9%.

A total of 215 National Provider Identifiers (NPIs) and 11617 eligible patient encounters in the LDL-C management group. The LDL-C management group performance scores ranged from 18.2% to 85.7%, with a mean of 46.8%; decile scores were 1st – 39.1%, 2nd – 41.3%, 3rd – 41.4%, 4th – 45.4%, 5th – 45.3%, 6th – 47.6%, 7th – 45.6%, 8th – 48.7%, 9th – 57.2%, and 10th – 57.3%.

Summarize Data and Samples: The analysis includes data from January 1, 2024 to December 31, 2024 uploaded to GWTG-Outpace Registry. The Outpace registry is a clinical quality improvement tool that pulls in patient-level data from existing electronic health records and displays organizations performance against various clinical quality measures tied to mitigating risk factors for cardiovascular disease. This registry experience eliminates the barrier of manual data abstraction and provides real time data results for quality improvement and research strategies. The two measures were implemented in the Outpace registry in August 2022. Data was received from 11 health systems which represent patients with visits at over 150+ physical locations. As of April 2025, data has been received on over 610,000 patients from all 11 health systems. Four sites were selected from 2024 participating sites., The eligible population included patients met denominator criteria seen by providers from the 4 reporting health systems (Bay Area Community Health (California), M Health Fairview (Minnesota), Franciscan Missionaries of Our Lady Health System (Louisiana), Wellstar Health (Georgia)) between January 1, 2024, and December 31, 2024. The eligible population included patients met denominator criteria seen by providers from the 4 reporting health systems (Bay Area Community Health, M Health Fairview, Franciscan Missionaries of Our Lady Health System, Wellstar Health) between January 1, 2024, and December 31, 2024.

Across 15348 patients in the LDL-C monitoring group, the population was 5298 (34.5%) female and 10050 (65.5%) male. Age distribution ranged from a minimum of 18 to a maximum of 99, with a median age of 69, 124 (0.8%) aged 18–39, 4841 (31.5%) aged 40–64, and 10383 (67.7%) aged 65 and older. Race data showed 12330 (80.3%) White, 1665 (10.8%) Black or African American, 334 (2.2%) Asian, 38 (0.2%) American Indian or Alaska Native, 15 (0.1%) Native Hawaiian or Other Pacific Islander, 41 (0.3%) Mixed-race and 925 (6.0%) Unknown. This data set captures all patients seen in an ambulatory setting and common diagnoses include hypertension, cardiovascular disease and accompanying comorbid diagnoses.

Across 8370 patients in the LDL-C management group, the population was 2837 (33.9%) female and 5533 (66.1%) male. Age distribution ranged from a minimum of 18 to a maximum of 98, with a median age of 69, 59 (0.7%) aged 18–39, 2601 (31.1%) aged 40–64, and 5710 (68.2%) aged 65 and older. Race data showed 6810 (81.4%) White, 816 (9.7%) Black or African American, 191 (2.3%) Asian, 22 (0.3%) American Indian or Alaska Native, 8 (0.1%) Native Hawaiian or Other Pacific Islander, 14 (0.2%) Mixed-race and 509 (6.1%) Unknown. This data set captures all patients seen in an ambulatory setting and common diagnoses include hypertension, cardiovascular disease and accompanying comorbid diagnoses.

Reliability Testing Results: At the NPI level, SNR reliability testing was conducted using performance scores and measure denominators for each provider.

In the LDL-C monitoring group, the estimated between-NPI variance in performance scores was 0.017. The resulting reliability scores across NPIs ranged from 0.581 to 1.000, with a mean reliability of 0.833. A total of 286 NPIs were evaluated. 249 (87.1%) NPIs had reliability scores above the commonly accepted threshold of 0.7, indicating that observed performance differences are likely to reflect true variation rather than random noise.

In the LDL-C management group, the between-NPI variance in performance scores was 0.017. The resulting reliability scores across NPIs ranged from 0.585 to 0.961, with a mean reliability of 0.759. A total of 215 NPIs were evaluated. 155 (72.1%)

NPIs had reliability scores above the commonly accepted threshold of 0.7, indicating that observed performance differences are likely to reflect true variation rather than random noise.

The LDL-C monitoring group, the mean reliability across all NPIs was 0.833, with scores ranging 0.581 to 1.000. Entities in higher deciles consistently showed higher reliability scores, indicating greater stability and confidence in performance measurement. 87.1% of NPIs had reliability above the 0.7 threshold, which supports the inference that the measure can reliably distinguish performance differences across providers. These findings provide evidence that the measure is sufficiently robust for use in quality improvement and accountability applications.

The LDL-C management group, the mean reliability across all NPIs was 0.759, with scores ranging 0.585 to 0.961. Entities in higher deciles consistently showed higher reliability scores, indicating greater stability and confidence in performance measurement. 72.1% of NPIs had reliability above the 0.7 threshold, which supports the inference that the measure can reliably distinguish performance differences across providers. These findings provide evidence that the measure is sufficiently robust for use in quality improvement and accountability applications.

Validity: As part of the ACC/AHA joint measure development process, a Technical Expert Panel (TEP) is formed that includes representatives of the clinical team, clinicians from diverse geographical regions and practice settings, clinician(s) with expertise in quality improvement, and/or clinician(s) who have data extraction or registry expertise. During the measure development process, the ACC/AHA conducted informal face validity assessments of the measure with our TEP (e.g., a yes/no vote conducted either via email survey and/or during teleconference meeting(s) to confirm the measure should move to the next level of testing). In 2011, a joint ACCF/AHA/AMA-PCPI TEP identified the need for measurement and approved the LDL-C monitoring measure. [Drozda] In 2025, Williams, et al. reaffirmed the need for measurement in the chronic coronary disease (CCD) population and included a LDL-C management measure. [Williams]

Two measures addressing lipid monitoring and lipid management were implemented in the AHA's OUTPACE registry in August 2022. AHA has received data from 11 practices providing over 610,000 unique patients for measure calculation. In 2024, given a continued gap in performance, the AHA team evaluated combining the concepts into one measure for CMS submission. The combined measure draft was reviewed with a focus group of 23 patients and hosted a public comment period to gather additional clinician and specialty society input. Seventeen patient respondents indicated the measure is meaningful with 15 responding yes to the question "Will a measure confirming your doctor completed a lipid panel once during the year be meaningful to you?" and 16 responding yes to the question "Will a measure confirming LDL-C control of less than 70 in the year be meaningful to you?". There was an insufficient number of respondents to face validity survey questions (n=3 with 100% confirming measures what is intended) with respondents opting to provide narrative responses on the draft measure. Comments received supported the measure concept was meaningful and addresses an important clinical gap. Given the support for continued measure development the AHA then focused efforts and resources on full empirical testing of the measure. Empirical testing results are included below.

We conducted clinician score-level validity testing among a sample of Outpace practices by analyzing the correlation of performance scores between the new monitoring measure and QPP128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan. We chose to use QPP128 because it is a validated measure that used by CMS in the Quality Payment Program. Furthermore, it aligns with the new monitoring measure in that it is an effective clinical care focused on ensuring an annual evaluation of a clinical process.

Fully validated data were available on performance scores for both measures for 243 clinicians participating in the registry during the 2024 12-month measurement period.

When correlating each clinician's measure performance, we found a correlation coefficient (r) of 0.577. The results indicate a moderate positive correlation between the two measures demonstrating the empiric validity of the new monitoring measure as a meaningful assessment of quality of care.

We conducted clinician score-level validity testing among a sample of Outpace practices by analyzing the correlation of performance scores between the new management measure and QPP122: Hemoglobin A1c (HbA1c) Poor Control (>9%). We chose to use QPP122 because it is a validated measure that is CBE endorsed and used by CMS in the Quality Payment Program. Furthermore, it aligns with the new management measure in that it is an effective clinical care and intermediate outcome measure focused on ensuring a patient's biomarker falls within an acceptable range.

Fully validated data were available on performance scores for both measures for 155 clinicians participating in the registry during the 2024 12-month measurement period.

When correlating each clinician's measure performance, we found a correlation coefficient (r) of 0.568. The results indicate a moderate positive correlation between the two measures demonstrating the empiric validity of the new management as a meaningful assessment of quality of care.

Equity: This new measure provides an opportunity to address disparities in care as it has been identified that women have a lower likelihood of attaining LDL-C goals than men. [Gavina]. Safford, et al. found differences in treatment and outcomes based on race and gender. [Safford] Further, differences in lipid control have been found based on insurance status. [Egan]

- Egan BM, Li J, Sarasua SM, et al. Cholesterol Control Among Uninsured Adults Did Not Improve from 2001-2004 to 2009-2012 With Both Publicly and Privately Insured Adults Doubled. *Journal of the American Heart Association*. 2017;6(11):e006105.
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Endorsement

Provide the Consensus-Based Entity (CBE) (i.e., Partnership for Quality Measures (PQM)) endorsement status (and CBE ID) and/or other endorsing body. If the measure is only endorsed for paper records, please note endorsement for only the data source being submitted.

This measure has not been submitted for CBE endorsement

Summary

Alignment with CMS Meaningful Measures Initiative or MACRA (if applicable).

This measure is patient-centered and meaningful to patients, focuses on improving LDL-C outcome, provides a significant opportunity for improvement, and aligns across payers.

Relevance to MIPS or other CMS programs.

MIPS focuses on quality, cost, and improving healthcare processes. This measure assesses how well clinicians monitor and manage LDL-C over time and identifies patients who have achieved improved outcomes based on evidence-based care

Rationale: Use of measure for inclusion in program (specialty society, regional collaborative, other).

In the MIPS program, this measure will drive improved outcomes across specialties for patients with clinical ASCVD. The measure is used in the AHA Get With The Guidelines – Outpace™ registry and has demonstrated improvements for patients in ambulatory settings.

Public reporting (if applicable).

Not applicable

Preferable relevant peer-reviewed journal for publication.

Circulation

Rationale as to how the measure correlates to existing cost measures and improvement activities, as applicable and feasible.

This measure is related to and would support the following cost and improvement activities

- IA_PM_14 Implementation of methodologies for improvement in longitudinal care management for high risk patients
- IA_CC_9 Implementation of practices/processes for developing regular individual care plans

- IA_CC_2 Implementation of improvements that contribute to more timely communication of test results
- COST_HF_1 Heart Failure
- MSPB_1 Medicare Spending Per Beneficiary (MSPB) Clinician
- TPCC_1 Total Per Capita Cost (TPCC)