

January 6, 2026

Dr. Mehmet Oz
Administrator, Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

SUBMITTED ELECTRONICALLY VIA PARTNERSHIP FOR QUALITY MEASUREMENT WEBSITE

RE: Feedback on Release of 2025 Measures Under Consideration (MUC) List - Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management (ID# MUC2025-034)

Dear Dr. Oz:

Novartis Services, Inc. ("Novartis") appreciates the opportunity to submit comments in response to the 2025 Centers for Medicare and Medicaid Services (CMS) Measures Under Consideration (MUC) List.

We strongly support the American Heart Association's Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management (ID# MUC2025-034) quality measure,¹ a widely-supported measure that could benefit the millions of patients, families, and caregivers impacted by Atherosclerotic Cardiovascular Disease (ASCVD) as well as the health care systems and taxpayers carrying the significant cost burden of this disease. As such, we urge CMS to recommend and implement this measure into the appropriate quality reporting programs through calendar year (CY) 2027 rulemaking.

We offer comments below on the critical link between managing LDL-C and improving health outcomes for the millions of patients living with ASCVD, the lack of alignment between the latest clinical recommendations on LDL-C management and the current quality measure landscape, and how this measure aligns with the Administration's goals to address and prevent chronic illness.

Well-established clinical consensus recognizes LDL-C management as critical to reducing the risk of ASCVD – a costly, prevalent, and deadly form of CVD putting millions of seniors at high risk.

Cardiovascular disease (CVD) – including heart disease and stroke – is the leading cause of death in the US and the single largest cause of mortality ahead of all other diseases.^{2,3} According to the Centers for Disease Control and Prevention (CDC), CVD accounted for 919,032 deaths in 2023 – approximately 1 in 3 of total U.S. deaths.⁴

¹ CMS, [Pre-Rulemaking MUC Lists and Recommendation Reports | The Measures Management System](#).

² AHA, [2025 Heart Disease and Stroke Disease Statistics Fact Sheet](#).

³ CDC, [Heart Disease Facts | Heart Disease | CDC](#).

⁴ *Id.*

ASCVD, characterized by a formation of plaque build-up in the arterial walls, is a complex, high-risk, and costly form of CVD impacting an estimated 26 million people across the United States.^{5,6,7,8,9} Not only does ASCVD result in approximately two million hospitalizations and 400,000 deaths in the US annually, but estimates place the cost burden of ASCVD to exceed \$500 billion in direct and indirect costs to the government and taxpayers between 2015-2035.^{10,11,12,13} ASCVD is currently the leading cause of CV-related death, and its prevalence is expected to rise by 30% in the US through 2035 – putting millions more Americans at high risk of disease progression, poor outcomes, and reduced life expectancy in the future.^{14,15,16,17,18}

Well-established research and evidence-based recommendations demonstrate that LDL-C is a primary cause of ASCVD and managing elevated LDL-C is central to both preventing and reducing the risk of ASCVD events – such as heart attack and stroke – and their recurrence.^{19,20,21} As cited by CMS in the 2025 MUC list outline, elevated LDL-C levels contribute to ASCVD risk and, once identified, can be addressed via lipid management – concurrently, studies support that lowering LDL-C correlates both with reducing the risk of ASCVD (primary prevention) and with reducing the risk of major cardiovascular events for those already diagnosed with ASCVD (secondary prevention).²²

As key multi-society clinical management guidelines have increasingly emphasized the importance of getting patients to optimal target LDL-C levels over the last decade, we believe the proposed LDL-C measure will fill an important gap by promoting LDL-C management to help patients achieve guideline-recommended goals and lower their ASCVD risk as well as improve overall population health.^{23,24}

Despite clinical consensus, the majority of ASCVD patients have uncontrolled LDL-C and require additional clinical support in achieving target levels.

Millions of patients with ASCVD who are at risk have uncontrolled LDL-C levels and would benefit from additional drivers like the proposed LDL-C measure that creates incentives to manage LDL-C for an extended period. This gap between ASCVD clinical care and appropriate goal-directed LDL-C management has direct consequences to patients – 60% of patients with ASCVD have uncontrolled LDL-C (at levels ≥ 70 mg/dL) and approximately 3.65 million deaths in 2021 were directly attributable to high-levels of LDL-C (a nearly 20%

⁵ AHA, [ASCVD Overview](#).

⁶ AHA, 2025 Fact Sheet.

⁷ Roth GA et al. *J Am Coll Cardiol*. 2020;76(25):2982-3021

⁸ Virani SS et al. *AHA Circulation*. 2021;143(8):e254-e743.

⁹ Ritchey MD et al. *MMWR Morb Mortal Wkly Rep*. 2018;67:974-982.

¹⁰ Roth GA et al.

¹¹ Virani SS et al.

¹² Ritchey MD et al.

¹³ Rohan K et al. *J Am Heart* 2020;9(19):e017793.

¹⁴ Toppila I et al. *Clin Cardiol*. 2022 Apr;45(4):342-351.

¹⁵ Bhatt DL et al. *JAMA* 2010 Sep 22;304(12):1350-7.

¹⁶ Steen DL et al. *J Am Heart* 2022 May 3;11(9):e022198.

¹⁷ Nair R et al, *J Am Heart* 2021 Aug 17;10(16):e019270.

¹⁸ AHA, [Cardiovascular disease: a costly burden for America. Projections through 2035 \(2017\)](#).

¹⁹ Grundy SM et al. *J Am Coll Cardiol*. 2018;73(24):3168-3209.

²⁰ Ference BA et al. *Eur Heart J*. 2017;38(32):2459-2472.

²¹ Boekholdt SM et al. *J Am Coll Cardiol*. 2014;64(5):485-494.

²² Grundy SM et al.

²³ Stone NJ, et al. *J Am Coll Cardiol*. 2013;63(25):2889-2934.

²⁴ Grundy SM et al.

increase from the prior decade).^{25,26} The proposed LDL-C measure creates broader awareness and an incentive for clinicians to engage patients in LDL-C management as a health improvement priority.

A recent study using the Family Heart database of 3.6 million US adults with ASCVD found a substantial gap between guideline-recommended LDL-C management and real-world clinical care.²⁷ While nearly all (99.1%) very high-risk ASCVD patients for whom lifestyle modifications have not been sufficient could potentially reach a goal LDL-C (<70 mg/dL) with a combination of statin and non-statin lipid lowering therapies (LLTs), the GOULD national registry of patients with ASCVD and elevated LDL-C demonstrate a significant gap around education for patients unaware of their underlying disease risk as well as clinical recommendations for available LLT treatment interventions, resulting in only 1 in 3 patients achieving LDL-C levels of <70mg/dL.^{28,29,30} Finally, despite multi-society guidelines recommending regular lipid measurement to assess therapeutic adherence and response for lowering LDL-C, studies show that less frequent LDL-C testing means that patients often do not receive optimal treatment.^{31,32}

As such, implementing the proposed LDL-C measure could realign system-wide incentives to clinical guidelines to fill this care gap for ASCVD patients at risk through promoting identification of patients with ASCVD, appropriately managing their LDL-C levels (including lipid testing as well as LLT medication interventions and adherence), and providing an objective and evidence-based measure to evaluate outcomes.

Implementing the proposed LDL-C measure would address the current gap in the quality landscape between clinical consensus and LDL-C monitoring and management.

Despite the urgent health care gap and clear consensus that lowering LDL-C has a direct impact on ASCVD clinical outcomes, there are currently no existing quality measures which drive LDL-C management, which creates a lack of alignment between clinical consensus and quality improvement in the US health care system.³³ Given the clear and pressing need to improve the quality of care for this significant at-risk Medicare population, implementing the proposed LDL-C measure will fill this gap and create system incentives for further treatment.

The Merit-Based Incentive Payment System (MIPS) currently includes measures associated with other ASCVD risk factors (e.g., diabetes, high blood pressure, smoking) but importantly does not include measures around LDL-C management.³⁴ For example, while the Statin Therapy for the Prevention and Treatment of CVD measure does focus on LDL-C management and goal attainment per latest clinical recommendations, it only evaluates statin adherence and prescribing (excluding other nonstatin LLTs which are also part of clinical guideline-recommended treatment options proven to help patients reach target LDL-C goals) and does not include ongoing lipid panel testing requirements.³⁵

The proposed LDL-C measure, however, incorporates both the process of monitoring patients appropriately and evaluating whether the target LDL-C outcome was achieved, giving clinicians and patients the latitude to

²⁵ Shah NP et al. *J Am Heart.* 2025; 25: 50-58.

²⁶ AHA, 2025 Fact Sheet..

²⁷ MacDougall DE, et al. *J Am Prev Cardiol.* 2025; 24 (2025):101354.

²⁸ Gu J et al. *J Clin Lipidol.* 2022; 16(6):901-905.

²⁹ Mhaimeed O et al. *Am J Prev Cardiol.* 2024; 18;18:100649.

³⁰ Cannon CP et al. *JAMA Cardiol.* 2021;6(9):1060-1068.

³¹ Grundy SM et al.

³² Tran C et al. *J Clin Lipidol.* 2022;16(4):491-497.

³³ CMS, [Measure Inventory Tool](#).

³⁴ *Id.*

³⁵ CMS, [Quality: Traditional MIPS Requirements - QPP](#).

develop a shared, patient-centered care plan with goal-directed interventions in alignment with the patient's preferences and priorities.³⁶

Implementing an LDL-C monitoring and management measure aligns with the Administration's MAHA goals to address chronic illnesses.

The proposed LDL-C measure closely aligns with the MAHA goal to address the chronic disease epidemic through early detection, intervention, and management.³⁷ Novartis applauds the Administration's focus on these goals and incentivizing the adoption of holistic, patient-centered care through outcomes measures. By implementing quality measures like the proposed LDL-C measure in value-based programs where doctors are empowered to tackle such significant drivers of poor health like ASCVD, patients are then empowered to prioritize their own health and wellness, leading to better overall health and more affordable care nationwide.

As the agency considers future MIPS rulemaking and where current MUC measures may be most impactful, Novartis believes the proposed LDL-C measure should be included in both the Value in Primary Care and Advancing Care for Heart Disease MIPS Value Pathways to drive incentives for primary care providers to assess patients at risk of CVD early and adequately manage associated risk factors.³⁸

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Novartis appreciates CMS's efforts to gather feedback on new quality improvement measures which have the potential to help improve outcomes related to ASCVD and other chronic illnesses which impact millions of Medicare seniors. Given the critical unmet need highlighted above around successfully driving long-term LDL-C management, we strongly recommend CMS implement MUC2025-034 as part of the CY 2027 MIPS quality-focused rulemaking cycle.

We thank CMS for the continued engagement, and we look forward to working with the agency on future integration of these measures as well as other policy solutions to improve care outcomes in Medicare. We would be happy to provide further information regarding our comments above.

Please feel free to contact us at lisa-2.nelson@novartis.com or via phone at (202) 876-5548 if we can provide any further assistance.

Sincerely,

Cesar Cerezo, MD, PhD
Vice President, US Medical Team Head - CV, Renal, and Metabolism (CRM)

³⁶ CMS, Pre-Rulemaking MUC Lists and Recommendation Reports.

³⁷ CMS, [2025 MUC List Overview](#).

³⁸ CMS, [MVP Reporting Option - QPP](#).