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VIA ELECTRONIC DELIVERY

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8016

Re: 2025 Measures Under Consideration List

Dear Administrator Oz:

Amgen Inc. (Amgen) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS's) 2025 Measures Under Consideration (MUC) List.[1]

Amgen is a science-based, patient-driven company committed to using science and innovation to dramatically improve patient lives. Amgen is dedicated to improving patient access in the U.S to innovator and biosimilar biological products, and promoting high-quality care for Medicare beneficiaries. Our comments reflect our interest in policies that support appropriate Medicare beneficiary access to preventive care and chronic disease management.

Amgen supports the adoption of the new quality measure MUC2025-034 for atherosclerotic cardiovascular disease (ASCVD) patients titled the "Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management" in the Merit-based Incentive Payment System (MIPS) Quality Program. In the United States, the adult ASCVD population is clinically complex, with a substantial proportion experiencing multiple comorbid conditions—most notably diabetes, hypertension, and chronic kidney disease—which significantly increase cardiovascular risk and underscores the importance of consistent LDL-C monitoring and management.[2]

[1] CMS. Measure Implementation: 2025 Measures Under Consideration List. (December 15, 2025). Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview. Accessed December 15, 2025.
[2] Tian Y, Li D, Cui H, et al. Epidemiology of multimorbidity associated with atherosclerotic cardiovascular disease in the United States, 1999–2018. BMC Public Health. 2024; 24(267). https://doi.org/10.1186/s12889-023-17619-y.

Amgen further recommends CMS adopt this measure in the new CMMI ACCES model as it directly relates to two of the clinical tracks – early cardio-kidney-metabolic conditions (eCKM) and cardio-kidney-metabolic conditions (CKM), which will assess improvement and control of lipids.[3]

We also urge CMS to consider the applicability and value of the LDL-C Monitoring and Management measure in context of the Medicare Advantage and Part D Star Ratings Program and other CMS quality programs. LDL-C is an important modifiable risk factor for cardiovascular disease (CVD) and for the measure's specified population of adult patients with clinical atherosclerotic cardiovascular disease (ASCVD), this is an urgently needed measure for a variety of Federal quality programs.

LDL-C Monitoring and Management (MUC2025-034)

Amgen is supportive of quality measures that are meaningful in preventing disease and ensuring guideline-directed chronic disease management. The LDL-C Monitoring and Management measure under consideration focuses on an important modifiable risk factor for CVD and presents a meaningful opportunity to impact this serious disease for Medicare beneficiaries. CVD is a leading public health threat with trends curving in the wrong direction.[4] The 2018 American Heart Association (AHA)/American College of Cardiology (ACC)/Multisociety cholesterol treatment guidelines recommend monitoring and management of ASCVD patient's lipid levels after treatment initiation and repeated every 3 to 12 months as needed.[5] Additionally, the ACC/AHA chronic coronary disease (CCD) guidelines recommend targeting an LDL-C value of <70 mg/100 ml.[6] Unfortunately, the appropriate monitoring and management of LDL-C levels is not being delivered consistently.

The proposed LDL-C measure aligns with the CMS's priorities for quality and value based care as it would directly address significant quality gaps in prevention and chronic disease management. An analysis of Medicare data between 2016 and 2020 found that only a third of Medicare beneficiaries had LDL-C measured within 90 days after hospital discharge following myocardial infarctions (MI) and 12 months after MI two-thirds of Medicare beneficiaries received LDL-C tests.[7] In VESALIUS-REAL, a global retrospective observational study in high-risk patients without previous MI or stroke, less than 1 in 5 US patients (median age: 65 years) with an LDL-C result achieved LDL-C <70 mg/dL,

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[3] CMS, ACCESS Technical Frequently Asked Questions, available at: https://www.cms.gov/priorities/innovation/access-technical-frequently-asked-questions. Accessed December 18, 2025.

[4] Joynt, KE, et al. Forecasting the Burden of Cardiovascular Disease and Stroke in the United States Through 2050—Prevalence of Risk Factors and Disease: A Presidential Advisory From the American Heart Association. Circulation. 2024;150(4).

[5] Grundy SM, et al. AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2019;18;139(25):e1082-e1143.

[6] Virani, S, Akeroyd, J, Smith, S. et al. Very High-Risk ASCVD and Eligibility for Nonstatin Therapies Based on the 2018 AHA/ACC Cholesterol Guidelines. *JACC*. 2019 Aug, 74 (5) 712–714.

[7] Jones J, Colantonio L, Muntner P, et al. Low-density Lipoprotein Cholesterol Testing Following Myocardial Infarction Hospitalization Among Medicare Beneficiaries. J Am Coll Cardiol. 2023 Mar, 81 (8_Supplement) 1706. https://doi.org/10.1016/S0735-1097(23)02150-2.

demonstrating that most patients had sub-optimal LDL-C management despite being at high risk for cardiovascular (CV) events.[8,9] For high risk ASCVD patients, such as those with recent MI, failure to achieve guideline recommended LDL-C levels leaves patients at risk for another CV event. According to an analysis from statin trials in patients with ASCVD and LDL ≥ 70 mg/dL, an estimated 634,000 ASCVD events could be prevented over 10 years if all US adults with this chronic disease achieved and maintained LDL-C levels below 70 mg/dL.[10] This evidence demonstrates the urgency of a quality strategy for LDL-C management, as neither the appropriate clinical processes for checking LDL-C levels nor the appropriate goal-directed therapy is being delivered consistently. The proposed LDL-C measure can bridge this important quality gap by ensuring guideline-recommended care for monitoring LDL-C levels and for achieving the target clinical outcome, both of which the existing process-only measures have been unsuccessful in addressing.

New evidence continues to show the clear and compelling case for an intensive, goal-directed focus on lowering LDL-C to reduce cardiovascular risk. Amgen recently announced the results of the Phase 3 VESALIUS-CV clinical trial published in the *New England Journal of Medicine* showing that Repatha® (evolocumab) achieved statistically significant and clinically meaningful reductions in major adverse cardiovascular events (MACE) in high-risk adults without a prior heart attack or stroke, when added to optimized statins or other LDL-C lowering treatments.[11] In this landmark study of more than 12,000 patients at high CV risk with atherosclerosis or diabetes who had no prior heart attack or stroke, Repatha demonstrated:

- A 25% relative reduction in the risk of a composite of time to first occurrence of coronary heart disease (CHD) death, heart attack or ischemic stroke;
- A 19% reduction in a broader composite that also included any ischemia-driven arterial revascularization;
- A reduced risk of heart attack by 36%; and
- In a substudy of the VESALIUS-CV trial, Repatha plus optimized lipid lowering therapies substantially lowered LDL-C by an average of 55% as compared to optimized lipid lowering therapies, with a median achieved LDL-C of 45 mg/dL at 48 weeks.
- Only treatment-emergent adverse events that were serious or led to discontinuation were captured in the VESALIUS study. The incidence of serious adverse events was 28.2% in the evolocumab plus optimized lipid lowering therapies arm (n=6125) and 28.9% in the optimized lipid lowering therapies arm (n=6122). The incidence of adverse events leading to study drug discontinuation was 3.3% and 3.7%, respectively.

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[8] Chan Q, et al. Poster presented at: ACC 2025; March 29-31, 2025; Chicago, IL.
[9] Chan Q, et al. Poster presented at ESC; August 29-September 1, 2025; Madrid, Spain/Virtual meeting.
[10] McKinley EC, Bittner VA, Brown TM, et al. The Projected Impact of Population-Wide Achievement of LDL Cholesterol <70 mg/dL on the Number of Recurrent Events Among US Adults with ASCVD. Cardiovascul Drugs and Therapy. 2021.
[11] Bohula EA, Marston NA, Bhatia AK et al. Evolocumab in Patients Without a Previous Myocardial Infarction or Stroke. NEJM. 2025 Nov 8. https://doi.org/10.1056/NEJMoa2514428.

- Serious hypersensitivity reactions including angioedema have occurred with Repatha. Most common adverse reactions include: nasopharyngitis, diabetes, upper respiratory tract infection, influenza, back pain, and injection site reactions. For more information, please refer to the Repatha® Prescribing Information (available at: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Repatha/Repatha-Full-Prescribing-Information-Interstitial.pdf).

CVD is a leading public health threat and every 40 seconds, a heart attack or stroke occurs in the U.S., and 75% of those are first-time events.[12] Recent research shows that more than 99% of people who experience a first-time cardiovascular event have at least one traditional risk factor, including high LDL-C which is one of the most modifiable risk factors for heart attack or stroke.[13] Evidence-based prevention through LDL-C testing and intensive lipid lowering management can significantly improve the health of the nation. Adopting the thoughtfully constructed and rigorously tested LDL-C measure into the MIPS program is a key first step towards a comprehensive quality strategy for preventing the most serious complications of atherosclerotic cardiovascular disease. Other modifiable CVD risk factors such as hypertension and diabetes that involve a routinely-measured outcome have outcome measures (controlling blood pressure and controlling blood sugar). This LDL outcome measure represents the first step on a path toward aligning with CMS's broader approach toward measuring CVD risk, with the ultimate goal of an LDL outcome measure analogous to controlling blood pressure and blood sugar.

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We appreciate your consideration of our comments on the 2025 MUC List. Please do not hesitate to contact Yola Gawlik by phone at (202) 320-1159 or by email at ygawlik@amgen.com if you have any questions regarding our comments.

Sincerely,

Yola Gawlik

Yola Gawlik

Executive Director

Global Government Affairs & Policy

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[12] Martin SS, et al. 2024 Heart Disease and Stroke Statistics: A Report of US and Global Data From the American Heart Association. Circulation. 2024;149;e347-e913. https://doi.org/10.1161/CIR.0000000000001209.

[13] Lee H, Huang X, Khan S, et al. Very High Prevalence of Nonoptimally Controlled Traditional Risk Factors at the Onset of Cardiovascular Disease. *JACC*. 2025 Oct, 86 (14) 1017–1029. https://doi.org/10.1016/j.jacc.2025.07.014.