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January 6, 2026

BY ELECTRONIC FILING
(p4qm.org/prmr-measures)

RE: Merck Comments on 2025 Measures Under Consideration (MUC) List

Merck Sharp & Dohme LLC, a subsidiary of Merck & Co. Inc., Rahway, NJ, U.S.A. (collectively, “Merck”), appreciates the opportunity to submit comments to the Partnership for Quality Measurement (PQM) on the Centers for Medicare & Medicaid Services’ (CMS’s) 2025 Measures Under Consideration (MUC) List. As a global health care leader in pharmaceutical, vaccine, and biologics development, Merck is committed to harnessing the best science and state-of-the-art medicine to produce essential medicines and vaccines.

Merck supports the inclusion of the following proposed measures under consideration for the Merit-based Incentive Payment Program: MUC2025-034 (Low-Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management); MUC2025-042 (Rate of Timely Follow-up on Abnormal Screening Mammograms for Breast Cancer Detection); and MUC2025-043 (Rate of Timely Follow-up on Positive Stool-based Tests for Colorectal Cancer Detection). We value the opportunity to provide input on the measures proposed for review and have outlined our measure-specific feedback below for your evaluation and consideration.

MUC2025-034: Low-Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management (MIPS)

Merck is highly supportive of the proposed “Low-Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management” measure (MUC2025-034) and commends CMS for advancing evidence-based atherosclerotic cardiovascular disease (ASCVD) care. ASCVD remains the leading cause of death in the United States, driving significant morbidity, mortality, and health care costs.¹ This measure fills a critical gap in current CMS quality metrics, which have historically focused on statin prescribing and adherence rather than on monitoring and achieving

¹ Virani SS, Alonso A, Aparicio HJ, et al. Heart disease and stroke statistics—2021 update: a report from the American Heart Association. *Circulation*. 2021 Feb 23;143(8):e254-743.

guideline-directed LDL-C targets.² Elevating LDL-C monitoring and management has the potential to catalyze better outcomes for patients as care teams confirm treatment effectiveness and intensify therapy when needed to achieve LDL-C targets.

The measure appropriately aligns with American College of Cardiology/American Heart Association (ACC/AHA) cholesterol management guidelines that emphasize LDL-C reduction to lower ASCVD risk.³ Robust evidence has demonstrated LDL-C is a modifiable, causal risk factor for ASCVD⁴ and LDL-C reductions lead to proportional reductions in major cardiovascular events.⁵ Despite this, persistent gaps in real-world practice exist. Among Medicare beneficiaries, only about 30% receive LDL-C testing within 90 days following myocardial infarction,⁶ even though timely LDL-C measurement and control are associated with improved survival and better adherence to therapy.⁷ The measure steward's validity and reliability testing using their Get With The Guidelines – Outpace™ registry also indicate there is meaningful room for improvement, with mean performance for monitoring at 46.8% (range 30% - 100%) and management at 64.9% (range 18.2% - 85.7%). These data underscore both the need and opportunity for a national measure to raise performance across diverse settings.

To enhance the measure's clinical relevance and population-health impact, Merck recommends CMS consider exploring risk-based stratification for the measure. The current measure specifications support treating to an LDL-C target of <70mg/dL for those with clinical ASCVD. The 2022 ACC Expert Consensus Decision Pathway supports an LDL-C target of <70mg/dL for those with clinical ASCVD who are considered not at very high-risk; however, an LDL-C target of <55mg/dL is recommended for those at very high-risk for future events.^{3,8} Clinical practice guidelines define very high-risk for future events as either two or more major ASCVD events or one major ASCVD event and multiple high-risk conditions. One study estimated about 82% of U.S. adults with ASCVD fall within the very-high ASCVD risk category.⁹ Exploring stratified

² Virani SS, Aspry K, Dixon DL, et al. The importance of low-density lipoprotein cholesterol measurement and control as performance measures: a joint clinical perspective from the National Lipid Association and the American Society for Preventive Cardiology. *Am J Prev Cardiol.* 2023;13:100472. doi:10.1016/j.ajpc.2023.100472

³ Grundy SM, Stone NJ, Bailey AL, et al. 2018

AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2019;73(24):e285-e350. doi:10.1016/j.jacc.2018.11.003

⁴ Ference BA, Ginsberg HN, Graham I, et al. Low-density lipoproteins cause atherosclerotic cardiovascular disease. 1. Evidence from genetic, epidemiologic, and clinical studies. A consensus statement from the European Atherosclerosis Society Consensus Panel. *Eur Heart J.* 2017 Aug 21;38(32):2459-72.

⁵ Baigent C, Blackwell L, Emberson J, et al. Efficacy and safety of more intensive lowering of LDL cholesterol: a meta-analysis of data from 170,000 participants in 26 randomised trials. *Lancet.* 2010 Nov 8;376(9753):1670-81.

⁶ Colantonio LD, Wang Z, Jones J, et al. Low-density lipoprotein cholesterol testing following myocardial infarction hospitalization among Medicare beneficiaries. *JACC Adv.* 2023;3(1):100753. doi:10.1016/j.jacadv.2023.100753

⁷ Solomon MD, Leong TK, Levin E, et al. Cumulative adherence to secondary prevention guidelines and mortality after acute myocardial infarction. *J Am Heart Assoc.* 2020;9(6):e014415. doi:10.1161/JAHA.119.014415

⁸ Writing Committee, Lloyd-Jones DM, Morris PB, et al. 2022 ACC expert consensus decision pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol.* 2022 Oct 4;80(14):1366-418.

⁹ Alanaeme CJ, Bittner V, Brown TM, et al. Estimated number and percentage of US adults with atherosclerotic cardiovascular disease recommended add-on lipid-lowering therapy by the 2018 AHA/ACC multi-society cholesterol guideline. *Am Heart J Plus: Cardiol Res Pract.* 2022;21:100201. doi:10.1016/j.ahjo.2022.100201

performance reporting for those at very-high-risk with an LDL-C target of <55 mg/dL could identify gaps and guide targeted quality improvement efforts that could affect the majority of U.S. adults currently living with ASCVD.

Overall, Merck urges CMS to implement the “LDL-C Monitoring and Management” measure in the Merit-based Incentive Payment System (MIPS) program. In addition, Merck recommends CMS consider enhancements to the measure by exploring risk-based stratification for the very high-risk clinical ASCVD population with an LDL-C target of <55mg/dL.

MUC2025-042: Rate of Timely Follow-up on Abnormal Screening Mammograms for Breast Cancer Detection (MIPS)

Merck supports the proposed “Timely Follow-up on Abnormal Screening Mammograms for Breast Cancer Detection” measure (MUC2025-042), recognizing its potential to enhance the quality of care in breast cancer. Breast cancer was the second most common cause of cancer deaths among women in the U.S. in 2023.¹⁰ Research has highlighted the importance of timely follow-up care for breast cancer after receiving abnormal screening mammograms, as delays can lead to further progression of the disease and worsening outcomes.¹¹ Five-year survival for breast cancer is about 99.6% when diagnosed at a localized stage but drops to roughly 32.9% for metastatic disease.¹²

The measure specifications align with clinical practice guidelines, which emphasize the importance of timely follow-up care and appropriate diagnostics that can lead to earlier, treatment opportunities.¹³ However, gaps in timely follow-up on abnormal screening mammograms are significant; one systematic review found 7.2%-33% did not have any follow-up within 3 months and 27.3%-71.6% within 6 months.¹⁴ The wide variability in the lack of follow-up post-abnormal screening may indicate barriers limiting mammography facilities from carrying out complete diagnostic resolution within a timely manner for all patients. This quality measure can be used to address quality gaps by monitoring timeliness and completeness of care to improve breast cancer screening and diagnostic processes.

Overall, Merck encourages CMS to implement the “Timely Follow-up on Abnormal Screening Mammograms for Breast Cancer Detection” measure in the MIPS program. We are encouraged that CMS is continuing to prioritize care improvements for patients at risk of, or living with, cancer.

¹⁰ U.S. Cancer Statistics Working Group. United States Cancer Cases and Death Statistics At a Glance. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute. Published June 2025. Accessed December 16, 2025. <https://gis.cdc.gov/Cancer/USCS/>.

¹¹ Reece JC, Neal EF, Nguyen P, et al. Delayed or failure to follow-up abnormal breast cancer screening mammograms in primary care: a systematic review. *BMC Cancer*. 2021 Apr 7;21(1):373.

¹² Centers for Disease Control and Prevention. U.S. Cancer Statistics Female Breast Cancer Stat Bite. U.S. Department of Health and Human Services. Published June 2, 2025. Accessed December 18, 2025. <https://www.cdc.gov/united-states-cancer-statistics/publications/breast-cancer-stat-bite.html>.

¹³ Monticciolo DL, Malak SF, Friedewald SM, et al. Breast cancer screening recommendations inclusive of all women at average risk: update from the ACR and Society of Breast Imaging. *J Am Coll Radiol*. 2021 Sep 1;18(9):1280-8.

¹⁴ Reece JC, Neal EF, Nguyen P, et al. Delayed or failure to follow-up abnormal breast cancer screening mammograms in primary care: a systematic review. *BMC Cancer*. 2021 Apr 7;21(1):373.

MUC2025-043: Rate of Timely Follow-up on Positive Stool-based Tests for Colorectal Cancer Detection (MIPS)

Merck supports the proposed “Timely Follow-up on Positive Stool-based Tests for Colorectal Cancer Detection” measure (MUC2025-043), recognizing its potential to enhance the quality of care in colorectal cancer. Colorectal cancer is the fourth leading cause of cancer mortality in the U.S. for men and women combined in 2023.¹⁵ Early detection and removal of colorectal polyps and early-stage cancers prevents disease progression and improves the odds of survival.¹⁶

This measure, aligned with established clinical guidelines, emphasizes the importance of prompt diagnostic evaluation and can enable the initiation of effective therapies at a stage when they can have the greatest impact. Delays in ongoing evaluation and appropriate actions for patients with colorectal cancer may lead to later-stage diagnosis, resulting in limited treatment options and poorer outcomes.^{17,18} Early detection and linkage to treatment are critical to improving survival rates and quality of life for patients.¹⁹ However, gaps in timely follow-up on positive stool-based tests are significant, with follow-up rates being reported near 50% in the literature.²⁰ This quality measure can be used to measure rates of timely completion of the full screening process after positive non-invasive colorectal cancer screening stool-based test results to help improve the quality of health care delivery and patient outcomes.

Overall, Merck encourages CMS to implement the “Timely Follow-up on Positive Stool-based Tests for Colorectal Cancer Detection” measure in the MIPS program. We are encouraged that CMS is continuing to prioritize care improvements for patients at risk of, or living with, cancer.

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We appreciate your consideration of these comments and look forward to seeing how these important measures can be incorporated into the MIPS program to enhance patient care and outcomes. Please feel free to contact us with any questions or if we may provide additional information.

¹⁵ U.S. Cancer Statistics Working Group. United States Cancer Cases and Death Statistics At a Glance. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute. Published June 2025. Accessed December 16, 2025. <https://gis.cdc.gov/Cancer/USCS/>.

¹⁶ Corley DA, Jensen CD, Quinn VP, et al. Association between time to colonoscopy after a positive fecal test result and risk of colorectal cancer and cancer stage at diagnosis. *JAMA*. 2017 Apr 25;317(16):1631-41.

¹⁷ Waddell O, Keenan J, Frizelle F. Challenges around diagnosis of early onset colorectal cancer, and the case for screening. *ANZ J Surg*. 2024 Oct;94(10):1687-92.

¹⁸ Murchie P, Raja EA, Brewster DH, et al. Time from first presentation in primary care to treatment of symptomatic colorectal cancer: effect on disease stage and survival. *Br J Cancer*. 2014 Jul;111(3):461-9.

¹⁹ Bresalier RS, Grady WM, Markowitz SD, et al. Biomarkers for early detection of colorectal cancer: the early detection research network, a framework for clinical translation. *Cancer Epidemiol Biomarkers Prev*. 2020 Dec 1;29(12):2431-40.

²⁰ Mohl JT, Ciemins EL, Miller-Wilson LA, et al. Rates of follow-up colonoscopy after a positive stool-based screening test result for colorectal cancer among health care organizations in the US, 2017-2020. *JAMA Netw Open*. 2023 Jan 3;6(1):e2251384.

Sincerely,

A handwritten signature in black ink, appearing to read "Björn J. Oddens". The signature is written in a cursive style with a long horizontal stroke at the end.

Björn J. Oddens, MD, PhD