January 6, 2026

Guardant Health Comments on MUC2025-043: Rate of Timely Follow-up on Positive Stool-based Tests for Colorectal Cancer Detection

Dear PRMR Clinician Committee,

Guardant Health appreciates the opportunity to comment on the electronic clinical quality measure (eCQM), *Rate of Timely Follow-up on Positive Stool-based Tests for Colorectal Cancer Detection* (MUC2025-043) included on the List of Measures Under Consideration (MUC), including consideration of this measure for use in the Merit-based Incentive Payment System (MIPS). Guardant Health agrees that timely follow-up after an abnormal non-invasive colorectal cancer (CRC) screening result is a critical component of high-quality CRC screening. Ensuring appropriate follow-up colonoscopy is essential to realizing the full benefit of non-invasive screening and improving early detection of colorectal cancer.

In July 2024, Shield™ became the first blood-based test approved by the U.S. Food and Drug Administration (FDA) as a primary screening option for colorectal cancer [1] that meets the requirements for Medicare coverage [2]. More recently, Shield™ was included in the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for colorectal cancer screening [3]. New modalities of testing, such as blood-based screening, have the potential to overcome many of the access and adherence barriers associated with current screening methods by incorporating CRC screening into routine medical care. For example, real-world clinical experience with blood-based colorectal cancer screening shows an over 90 percent test completion rate, demonstrating the potential of blood-based screening to improve adherence and reach individuals who remain unscreened with currently available options [4].

CMS has recognized the value of blood-based CRC screening as part of the screening continuum. As noted in the CY 2025 Physician Fee Schedule Final Rule, blood-based tests may be more accessible for certain patients [5]. Importantly, CMS policy ensures that Medicare beneficiaries do not face out-of-pocket costs for a follow-up colonoscopy after a positive blood-based screening test [5], reinforcing that blood-based testing is fully integrated into covered CRC screening pathways.

Similar to other non-invasive CRC screening tests, a patient with a positive (abnormal) blood-based screening result should be referred for diagnostic colonoscopy. However, completion rates for follow-up colonoscopy after abnormal non-invasive screening remain suboptimal. Quality measurement can play a meaningful role in improving outcomes by encouraging providers, health systems, and plans to ensure patients who choose non-invasive screening fully complete the screening process.

Because stool-based tests are no longer the only FDA-approved and Medicare-covered non-invasive CRC screening modality, Guardant Health respectfully recommends that this measure be expanded to include timely follow-up after abnormal blood-based colorectal cancer screening results. Expanding the measure would ensure that clinicians and health systems participating in programs such as MIPS are not disincentivized from using FDA-approved, Medicare-covered screening tools that can help close persistent screening gaps. To reflect this broader and future-facing approach, we also recommend revising the measure title to "*Timely Follow-up on Non-invasive Screening Tests for Colorectal Cancer Detection*." This would allow the measure to remain clinically relevant as additional non-invasive screening technologies become available.

Guardant Health is deeply committed to expanding access to high-quality, convenient screening tools that enable earlier detection of colorectal cancer, when it is more easily treated. We thank you for the opportunity to comment on this measure under consideration.

Sincerely,

Jennifer N. Higgins

Senior Vice President, Global Public Affairs

[1] FDA Premarket Approval – Shield™ (P230009) (July 26, 2024), available here: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230009

[2] National Coverage Determination (NCD). Colorectal Cancer Screening Tests 210.3, available here: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=281

[3] NCCN Guidelines Version 2.2025 Colorectal Cancer Screening.

[4] Graham-Adderton, C., Guerra, C. E., Ngo-Metzger, Q., Hoang, T., & Raymond, V. M. (2025). Implementation of blood-based colorectal cancer screening: real-world adherence and outcomes. Current medical research and opinion, 41(10), 1915–1920. https://doi.org/10.1080/03007995.2025.2582257

[5] Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments, available here: https://www.federalregister.gov/documents/2024/12/09/2024-25382/medicare-and-medicaid-programs-cy-2025-payment-policies-under-the-physician-fee-schedule-and-other