2025 Pre-Rulemaking Measure Review Preliminary Assessment

MUC ID	Title
MUC2025-043	Rate of Timely Follow-up on Positive Stool-based Tests for Colorectal Cancer Detection
Measure Steward & Developer	**Proposed CMS Programs**
Brigham and Women's Hospital	Merit-based Incentive Payment System (MIPS) Link: Merit-based Incentive Payment System (MIPS)

Measure Overview
Rationale: Colorectal cancer is the second leading cause of cancer mortality in the United States for men and women combined.[1] In 2025, around 107,320 patients will be diagnosed with colorectal cancer and 53,010 are expected to die from it. Early detection and removal of colorectal polyps and early-stage cancers prevents disease progression and improves the odds of survival.[2] Noninvasive screening tests (e.g., stool-based tests) are available to detect markers of abnormal growths. However, delays in follow-up colonoscopy reduce the benefits of screening by leading to missed opportunities for timely intervention. Multiple guidelines recommend using stool-based tests (i.e., high-sensitivity gFOBT, FIT, FIT-DNA) as noninvasive screening options, and colonoscopy as the gold standard for follow-up in patients with a positive stool-based test result.[3,4,5] An American Gastroenterological Association (AGA) Clinical Practice Update commentary recommended that at least 95% of patients receive a colonoscopy within 6 months of a positive noninvasive test result to complete the full screening process.[6] Existing literature supports this timeframe as patients who received their colonoscopies after the 6-month mark had a significantly higher risk of being diagnosed with more advanced stages of cancer.[7] Rates of timely follow-up in the U.S. are far below the benchmark recommended by the AGA. A 2023 study examining 39 U.S. health care organizations reported follow-up colonoscopy rates around 50%

[1] Key Statistics for Colorectal Cancer. American Cancer Society. Accessed October 31, 2024. https://www.cancer.org/cancer/types/colon-rectal-cancer/about/key-statistics.html.
[2] 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; 317(16):1631-1641. doi:10.1001/jama.2017.3634. PMID: 28444278.
[3] Rex DK, Boland CR, Dominitz JA, et al. Colorectal Cancer Screening: Recommendations for Physicians and Patients from the U.S. Multi-Society Task Force on Colorectal Cancer. Am J Gastroenterol. 2017; 112(7):1016-1030. doi:10.1038/ajg.2017.174. PMID: 28555630.
[4] Lopes G, Stern MC, Temin S, et al. Early Detection for Colorectal Cancer: ASCO Resource-Stratified Guideline [published correction appears in JCO Oncol Pract. 2022 Nov; 18(11):775-778. doi: 10.1200/OP.22.00580]. J Glob Oncol. 2019; 5:1-22. doi:10.1200/JGO.18.00213. PMID: 30802159.
[5] US Preventive Services Task Force, Davidson KW, Barry MJ, et al. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement [published correction appears in JAMA. 2021 Aug 24; 326(8):773. doi: 10.1001/jama.2021.12404]. JAMA. 2021; 325(19):1965-1977. doi:10.1001/jama.2021.6238. PMID: 34003218.
[6] Burke CA, Lieberman D, Feuerstein JD. AGA Clinical Practice Update on Approach to the Use of Noninvasive Colorectal Cancer Screening Options: Commentary. Gastroenterology. 2022; 162(3):952-956. doi:10.1053/j.gastro.2021.09.075. PMID: 35094786.
[7] Mutneja HR, Bhurwal A, Arora S, Vohra I, Attar BM. A delay in colonoscopy after positive fecal tests leads to higher incidence of colorectal cancer: A systematic review and meta-analysis. J Gastroenterol Hepatol. 2021; 36(6):1479-1486. doi:10.1111/jgh.15381. PMID: 33351959.

Measure Overview
within 180 days of a positive stool-based test.[8] A follow-up study in 2024 reported rates of around 56.1% within the same timeframe.[9] Existing endorsed clinical quality measures report on the percentage of patients who received initial screening for colorectal cancer.[10,11] This eCQM 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 health care delivery and quality in medical facilities and health systems across the U.S.
CMS-provided program rationale: CMS is considering adding this measure to the MIPS quality measure set as a new measure for future performance years. MIPS does not have any related measures that examine timely follow-up for positive stool-based colorectal screening tests; therefore, the quality of patient care benefits from promoting early detection of colorectal cancer. This measure is fully tested and developed at both the facility and clinician level. This process measure represents a gap in MIPS and CMS priority areas of digital measurement and expands on current colonoscopy screening measures to drive quality improvement. Additionally, the measure may be considered for potential inclusion in the Gastroenterology Care MIPS Value Pathway (MVP).
Description: This electronic clinical quality measure (eCQM) reports the percentage of patients aged 45 to 75 years with at least one positive stool-based colorectal cancer screening test (i.e., high-sensitivity guaiac fecal occult blood test, fecal immunochemical test, or Cologuard) during the measurement period (i.e., calendar year) who completed a colonoscopy within 180 days after their index (i.e., first) positive stool-based test result date.
Measure background: New measure never reviewed by the Measure Applications Partnership (MAP) Workgroup or PRMR; never used in a Medicare program.
Numerator: Patients in the denominator population who completed a colonoscopy within 180 days after their index (i.e., first) positive stool-based colorectal cancer screening test result date. Numerator Details: If documented, extract the first colonoscopy occurring within 180 days after the index positive stool test result date for each patient [value set: “Colonoscopy” OID 2.16.840.1.113883.3.464.1003.108.12.1020]. Patients that completed a colonoscopy within 180 days are included in the numerator population. **Exclusions:** N/A
Denominator: Patients aged 45 to 75 years with at least one positive stool-based colorectal cancer screening test result date during the measurement period (i.e., calendar year). Only the first positive stool test result (i.e., index screening test) is included in the measure calculation. Denominator Details: Identify all stool-based colorectal cancer screening tests (i.e., high-sensitivity guaiac fecal occult blood test, fecal immunochemical test, or Cologuard) with result dates in the measurement period (i.e., calendar year) [value set “Colorectal Screening” OID 2.16.840.1.113762.1.4.1206.57].

[8] Mohl JT, Ciemins EL, Miller-Wilson LA, Gillen A, Luo R, Colangelo F. 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; 6(1):e2251384. Published 2023 Jan 3. doi:10.1001/jamanetworkopen.2022.51384. PMID: 36652246.
[9] Ciemins EL, Mohl JT, Moreno CA, Colangelo F, Smith RA, Barton M. Development of a Follow-Up Measure to Ensure Complete Screening for Colorectal Cancer. JAMA Netw Open. 2024; 7(3):e242693. Published 2024 Mar 4. doi:10.1001/jamanetworkopen.2024.2693. PMID: 38526494.
[10] #0034 Colorectal Cancer Screening (COL). NQF: Quality Positioning System. Updated March 26. 2023. Accessed May 24, 2024. https://www.qualityforum.org/Qps/QpsTool.aspx#qpsPageState=%7B%22TabType%22%3A1.
[11] Quality ID #113 (NQF 0034). Centers for Medicare & Medicaid Services. Accessed October 31, 2024. https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2023_Measure_113_MIPSCQM.pdf.

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Measure Overview	
Retain stool tests with positive results. Retain stool tests where patients were aged between 45 and 75 years on the positive stool test result date [value set "Birth Date" OID 2.16.840.1.113883.3.560.100.4]. Patients with at least one positive stool test result are included in the target population. **Exclusions:** Exclude positive stool-based colorectal cancer screening tests that were not an index test or were conducted in the inpatient or emergency department setting. Exclude index positive stool tests from the denominator population where patients had a history of colorectal cancer or total colectomy, or recently received hospice or palliative care. Denominator Exclusions Details: Identify the first positive stool-based colorectal cancer screening test result in the measurement period (i.e., calendar year) for each patient to define the index positive stool tests and index test result dates [value set “Colorectal Screening” OID 2.16.840.1.113762.1.4.1206.57]. Exclude index positive stool tests conducted in inpatient or emergency department settings [value sets: “Encounter Inpatient” OID 2.16.840.1.113883.3.666.5.307; “Emergency Department Evaluation and Management Visit” OID 2.16.840.1.113883.3.464.1003.101.12.1010]. Exclude index positive stool tests where the patient had a prior positive stool test result less than 1 year before the index positive stool test result date. Exclude index positive stool tests where patients had a documented history of colorectal cancer before the index positive stool test result date [value set: “Malignant Neoplasm of Colon” OID 2.16.840.1.113883.3.464.1003.108.12.1001]. Exclude index positive stool tests where patients had a documented history of total colectomy before the index positive stool test result date [value set: “Total Colectomy” OID 2.16.840.1.113883.3.464.1003.198.12.1019]. Exclude index positive stool tests where patients received hospice or palliative care within 1 year before or 180 days after the index positive stool test result date [value sets: “Hospice Care Ambulatory” OID 2.16.840.1.113883.3.526.3.1584; “Hospice Diagnosis” OID 2.16.840.1.113883.3.464.1003.1165; “Hospice Encounter” OID 2.16.840.1.113883.3.464.1003.1003; “Palliative Care Encounter” OID 2.16.840.1.113883.3.600.1.1575; “Palliative Care Diagnosis” OID 2.16.840.1.113883.3.464.1003.1167; “Palliative Care Intervention” OID 2.16.840.1.113883.3.464.1003.198.12.1135]. **Exceptions:** Exclude index positive stool tests from the denominator population only if the patients are not in the numerator population in cases where the patients completed a prior recent colonoscopy or died during the 180-day follow-up period. Denominator Exceptions Details: Exclude index positive stool tests (only if patient not in the numerator population) where patients completed a colonoscopy within 3 years before the index positive stool test result date [value set: “Colonoscopy” OID 2.16.840.1.113883.3.464.1003.108.12.1020]. Exclude index positive stool tests (only if patient not in the numerator population) where patients were deceased within 180 days after the index positive stool test result date [value set “Expired” OID 2.16.840.1.113762.1.4.1047.438].	
Substantive changes from prior version (if applicable): N/A	
Measure type: Process	**Measure is a composite:** No **Measure is digital and/or an eCQM:** Yes **Measure is a paired or group measure:** No
Level of analysis: Facility, Individual Clinician	**Data source(s):** Digital-Electronic Health Record (EHR) Data
Care setting(s):	**Risk adjustment or stratification:** No

Measure Overview	
Ambulatory/office-based care Hospital outpatient department (HOD)	
CBE endorsement status: Endorsed	**CBE endorsement history:** Endorsed with conditions during the Fall 2024 cycle. When the measure returns for maintenance (3 years), the measure developer should have: • Conducted additional validity testing (data element in additional EHR); and • Continued to monitor (e.g., qualitative assessments, empirical analyses) for unintended consequences (e.g., reduced access to colonoscopies) during implementation.
Is measure currently used in CMS programs? No	**Measure addresses statutorily required area?** No

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Evaluation

Meaningfulness

Importance	
Type of evidence:	Clinical Guidelines or U.S. Preventive Services Task Force (USPSTF) Guidelines; Empirical data; Peer-Reviewed Original Research; Peer-Reviewed Systematic Review [MERIT Submission Form]
Importance: As outlined in the literature cited for the measure rationale, early detection of colorectal cancer through screening greatly improves survival rates and reduces costs. Increasing screening rates can significantly lower mortality and Medicare spending. Noninvasive stool tests (gFOBT, FIT, FIT-DNA) are cost effective and combining them with follow-up colonoscopy yields better outcomes. However, many patients with positive stool tests do not receive timely follow-up colonoscopy, increasing their risk of late-stage cancer. This eCQM aims to improve timely follow-up by reporting the percentage of patients that completed the multi-step colorectal cancer screening process after an initial positive stool-based test result. During CBE endorsement review, the committee found the evidence supporting the importance of this measure to be sufficient.	
Rating: Met; Prior CBE Endorsement	

Conformance
Measure alignment with conceptual intent: This measure is intended to report the percentage of patients that completed the multi-step colorectal cancer screening process after an initial positive stool-based test result. The measure is patient based and complements the Colorectal Cancer Screening measure already in use in CMS programs, including MIPS. The measure's numerator, denominator, and exclusions are clearly defined and directly support the intent of this measure. Specifically, the numerator includes patients who completed a colonoscopy within 180 days after their index (i.e., first) positive stool-based colorectal cancer screening test result date from among the denominator population of patients aged 45 to 75 years with at least one positive stool-based colorectal cancer screening test result date during the measurement period.
Rating: Met; Prior CBE Endorsement

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Feasibility	
eCQM feasibility testing/analysis conducted: Yes	Yes, eCQM testing was performed [MERIT submission form; eCQM Feasibility Scorecard]
Feasibility: All data elements are in defined fields in electronic sources and align with United States Core Data for Interoperability (USCDI)/USCDI+ Quality standards making the measure highly feasible. The measure was tested in three EHRs. The feasibility scorecard addresses the following domains: • Data availability: Data element exists in a structured format in this EHR. • Data accuracy: Information is from authoritative source and/or is highly likely to be correct. • Data standards: Data element is coded in a nationally accepted terminology standard or can be mapped to that terminology standard. • Workflow: The data element is routinely collected during clinical care and requires no, or limited, additional data entry from a clinician or other provider, and no EHR interface changes. Feasibility testing did not identify any data elements that required additional review within Epic, Oracle Health, or Allscripts. During CBCE endorsement review in 2024, the committee found the feasibility of this measure to be sufficiently demonstrated.	
Rating: Met; Prior CBE Endorsement	

Validity	
Validity testing method(s):	Face validity [MERIT Submission Form, Peer-reviewed journal article template]
Testing level(s)	Facility
Was this measure tested in the same target population as the CMS program?	Yes
Validity: A technical expert panel (TEP) consisting of six members, representing the patient experience and expertise in medicine, measure development, quality and safety of care, cancer screening, health services research, and EHRs, reviewed the measure. The majority of TEP members agreed that the measure can be used to distinguish good from poor quality care at the hospital (i.e. facility) level. Committee members may wish to consider if face validity in combination with prior CBE endorsement is sufficient to support use of this measure within MIPS. The developers provided patient/encounter level testing. Manual chart reviews were conducted on random samples to validate the accuracy of the eCQM's automated patient allocations into numerator, denominator, or exclusions. Reviewers, blinded to the eCQM results, assessed full charts and found 100% agreement, Kappa scores of 1.0, and PPVs of 100%, indicating strong validity of the eCQM.	

Validity
During CBE endorsement review in 2024, the committee found the validity of this measure to be sufficiently demonstrated.
Threats to validity: Threats to validity were not identified in the submission materials. Empirical validity testing was not completed for this measure.
Rating: Met; Prior CBE Endorsement

Reliability	
Reliability testing method(s):	Signal-to-Noise and Random Split-Half Correlation [MERIT Submission Form, Peer-reviewed journal article template]
Testing level:	Facility (Facility Group), Individual Clinician
Reliability discussion: Signal-to-noise reliability was calculated at the group level across six facility groups in one hospital system. The minimum reliability for the most recent year (2023) is 0.859 and 100% of the six facility groups have a reliability greater than 0.6. The developer calculated a Spearman's rank correlation between two randomly split halves of the data and reported a correlation of 0.83. In the original MERIT submission, ICC was calculated as the percentage of variation in facility-level scores attributable to facility-level signal variation, with 95% confidence intervals for each split sample. Battelle noted during review that this was not the type of ICC that measures correlation between the two split samples. These initial ICC values were very low: 0.006 for the test sample and 0.019 for the validation sample in 2020. These results conflicted with the signal-to-noise and Spearman rank results. In response to this issue noted during PA collaboration, the developer revised testing methods during the MERIT submission window to align with recommendations and calculated a different type of ICC to assess the correlation between the two spilt samples. The ICC calculation now aligns with the intended approach and is consistent with the Signal-to-Noise Ratio (SNR) and Spearman correlation results. These results are shown in Table 1, provided by the developer below. At the individual clinician level, the overall median SNR was 0.451 (95% CI: 0.383, 0.519) for the 11 clinicians with a denominator of at least 20 index positive stool-based tests across all years (2018-2023). The minimum SNR was 0.363 and the maximum SNR was 0.576. The developers note in their submission that "based on these data and supported by stakeholder consultations, this eCQM is not recommended for use at the individual clinician level." During CBE endorsement review in 2024, the committee found the reliability of this measure to be sufficiently demonstrated.	
Additional reliability analyses: No additional reliability analyses were performed.	
Rating: Met; Prior CBE Endorsement	

Table 1. Intraclass Correlation Coefficients (ICC), Overall and by Year from 2018 to 2023 for Six Facility Groups in Health System 1

Measurement Year	Test-Validation Correlation	95% CI
Overall	0.909	(0.632, 0.983)
2018	0.129	(0.000, 0.998)
2019	0.106	(0.000, 0.998)
2020	0.534	(0.069, 0.946)
2021	0.369	(0.025, 0.929)
2022	0.655	(0.185, 0.941)
2023	0.706	(0.240, 0.948)

Usability	
Usability considered in application:	Yes, the submission materials briefly discuss the measure's usability within relevant programs.
Usability discussion: This measure has usability in MIPS. The measure has been tested at the facility level and was feasible to implement into EHR systems. A patient representative on the TEP raised concerns about the challenges of scheduling a colonoscopy, citing difficulties navigating the health care system. This feedback highlights potential barriers to timely follow-up care, particularly for patients who may face complex or fragmented referral and scheduling processes. The developer did not identify any unintended consequences. However, this measure is currently specified in FHIR, which may result in implementation barriers within MIPS if program updates are delayed in future. During CBE endorsement review in 2024, the committee found the use/usability of this measure to be sufficiently demonstrated.	
Rating: Met; Prior CBE Endorsement	

Appropriateness of Scale

Appropriateness of Scale	
Similar or related measures in program(s):	Colorectal Cancer Screening in MIPS
Measure balance, burden, and value across target populations/measured entities: The related clinical quality measure quantifies the	

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Appropriateness of Scale
percentage of screen-eligible patients that initiated the colorectal cancer screening process. This eCQM submitted for consideration complements the existing MIPS colorectal cancer screening measure by reporting the percentage of patients that completed the multi-step colorectal cancer screening process after an initial positive stool-based test result. The developer notes that rates of timely follow-up are lower among historically disadvantaged and medically underserved communities, further emphasizing the necessity of tailored interventions to increase colonoscopy uptake for all patient populations. The results of this measure can help facilities identify areas of improvement that may be specific to their setting and the communities being served. Facilities, health systems, and other stakeholders may also use this measure to develop targeted interventions to increase colonoscopy uptake in populations with lower rates of timely follow-up. **Considerations for the committee:** Based on clinical and professional experience, the committee should consider the distribution of benefits and risks/burdens of the measure within the proposed program population.

Time-to-Value Realization

Time-to-Value Realization	
Plan for near- and long-term impacts after implementation:	None specified
Measure implementation impacts over time: The developer briefly mentions long- and near-term impacts of the measure as an eCQM in a patient population. There may be need for further examination of near- and long-term impacts of this measure after implementation across clinician and patient populations. **Considerations for the committee:** • What are the potential near- and long-term impacts of this measure on measured entities, proposed CMS program, and patient populations? • Will benefits and burdens associated with this measure be realized within an appropriate implementation time frame?’ • How will this measure mature through revisions in the future if added to the MIPS measure set?	