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January 5, 2026,

On behalf of the California Colorectal Cancer Coalition (C4) Board of Directors, we appreciate the opportunity to submit comments in response to *MUC2025-043: Rate of Timely Follow-up on Positive Stool-based Tests for Colorectal Cancer Detection*.

The California Colorectal Cancer Coalition (C4) Board of Directors strongly supports CMS' effort to implement a novel measure to ensure timely follow up on positive non-invasive tests for colorectal cancer detection required to confirm or exclude the presence of colorectal cancer. C4 is a statewide, 501-c(3) all-volunteer non-profit organization consisting of academic clinicians (family and internal medicine, gastroenterology, general research, oncology, nurse practitioner specialists, and pathology), physicians representing Kaiser and safety net organizations, public health practitioners (nonprofits and state health department), CRC survivors and cancer advocates, cancer genetic counselor, CA region of the American Cancer Society, clinicians working for or with FQHC, and CA tribal nations advocates. We are united in our purpose of working towards everyone having a life free from the burden of colorectal cancer. C4 is committed to ensuring that all Californians have the awareness, education, and access needed to prevent, detect, and treat this disease. To this end, improving accountability for colonoscopy completion will provide a critical incentive to improve timely access to care for patients.

To optimize the reach and effectiveness of the novel measures, we recommend the following modifications:

1. Modify the title to: "*Timely follow-up on non-invasive tests for colorectal cancer detection"*. Rationale: The Food and Drug Administration (FDA) has recently approved both novel stool and blood-based noninvasive tests for CRC detection, and Medicare has issued a coverage decision that is in favor of coverage of one of the novel blood-based tests, Shield. To optimize impact, we recommend that the measure cover all non-invasive tests for CRC detection, and that throughout the measure description, reference is made to both stool and blood-based noninvasive tests for CRC detection.

2. Modify the denominator to reflect inclusion of FDA approved non-invasive tests as follows: Identify all stool-based colorectal cancer screening tests (i.e., high-sensitivity guaiac fecal occult blood test, fecal immunochemical test, *ColoSense* or Cologuard) *and all blood-based colorectal cancer screening tests (Shield)* 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].

3. Modify the denominator exclusions to remove the exclusion of inpatient and emergency department tests. Rationale: some patients with positive non-invasive tests done in inpatient and emergency department tests may have increased risk for CRC. Further, inclusion of inpatient and emergency department tests will encourage test stewardship to limit use within inpatient and emergency settings. Reference: Arjun Gupta, Zhouwen Tang, Deepak Agrawal, Eliminating in-Hospital Fecal Occult Blood Testing: Our Experience with Disinvestment, The American Journal of Medicine (2018), https://doi.org/10.1016/j.amjmed.2018.03.002.

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4. Modify the denominator exception details to exclude people with colonoscopy within 1 year prior, rather than 3 years prior to the abnormal non-invasive result. Rationale: An abnormal stool test result still confers increased risk for colorectal cancer in people with a prior colonoscopy.

5. Modify the rationale section to note that the FDA has recently approved a blood-based test for screening, as well as to note recently published data on suboptimal rates of colonoscopy follow up after an abnormal blood-based CRC detection test. Rationale: FDA has approved a blood-based test (Shield) for colorectal cancer screening followed by colonoscopy for an abnormal result (insert reference for coverage decision here). A recent study of 6068 individuals who had a blood-based Shield test, reported that just 49% of the 228 individuals with a positive result completed colonoscopy within 6 months, and that individuals with Medicare Advantage insurance were less likely to complete colonoscopy compared with privately insured individuals (odds ratio 0.26, 95% CI 0.11–0.67; Zaki Gastroenterology 2025;169:1301–1303).

Suggested Modifications

Title: Timely follow-up on non-invasive tests for colorectal cancer detection.

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.
No changes

- Denominator Details:

    a. 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) [http://cts.nlm.nih.gov/fhir/ValueSet/2.16.840.1.113762.1.4.1206.56].

    b. Modify to include blood-based tests and other FDA approved tests: Identify all stool-based colorectal cancer screening tests (i.e., high-sensitivity guaiac fecal occult blood test, fecal immunochemical test, ColoSense or Cologuard) and all blood-based colorectal cancer screening tests (Shield) 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].

        - Retain stool or blood tests with positive results.

        - Retain stool or blood 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].

        - The Patients with at least one positive stool or blood test result are included in the target population.

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- Denominator exclusions

  Rationale: Exclude positive stool-based colorectal cancer screening tests that were not an index test within the calendar year. Exclude index positive stool or blood 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- or blood-based colorectal cancer screening test result in the measurement period (i.e., calendar year) for each patient to define the index positive stool or blood tests and index test result dates [value set “Colorectal Screening” OID 2.16.840.1.113762.1.4.1206.57].

    - [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 or blood tests where the patient had a prior positive stool test result less than 1 year before the index positive stool or blood test result date.

    - Exclude index positive stool or blood 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 or blood 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 or blood 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].

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- Denominator exceptions
    - Exclude index positive stool or blood 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 1 year 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 or blood 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].

Overall Rationale

In 2023, colorectal cancer was the fourth 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 52,900 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- and blood-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, FIT-RNA) as noninvasive screening options, and colonoscopy as the reference standard for follow-up in patients with a positive stool-based test result [3, 4, 5]. Further, FDA has approved a blood-based test (Shield) for colorectal cancer screening followed by colonoscopy for an abnormal result. 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% 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]. A recent study of 6068 individuals who had a blood-based Shield test, reported that just 49% of the 228 individuals with a positive result completed colonoscopy within 6 months, and that individuals with Medicare

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Advantage insurance were less likely to complete colonoscopy compared with privately insured individuals (odds ratio 0.26, 95% CI 0.11–0.67; Zaki Gastroenterology 2025;169:1301–1303).

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.

On behalf of the C4 Board of Directors, we are encouraged by the efforts to add this important quality measure but hope our recommended modifications are taken into consideration as the measure is finalized.

Sincerely,

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