



November 13, 2020

Tamara Syrek Jensen, J.D.  
Director, Coverage & Analysis Group  
Centers for Medicare & Medicaid Services  
Mailstop S3-02-01  
7500 Security Blvd.  
Baltimore, MD 21244

Sent electronically

**Re: Proposed Decision Memo for Screening for Colorectal Cancer - Blood-Based Biomarker Tests (CAG-004454N)**

Dear Ms. Syrek Jensen:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions across the health care spectrum, thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the recently released proposed decision memo for screening of colorectal cancer (CRC) among Medicare beneficiaries using blood-based biomarker tests.<sup>1</sup> PMC appreciates CMS utilizing the National Coverage Analysis (NCA) process to prioritize cancer screening and to develop a proposed decision memo as part of the NCA process that is forward-thinking in establishing coverage for some new screening tests that come to market. The proposed decision memo recognizes that blood-based tests can improve early detection and personalized treatment of multiple cancers, including CRC, and it establishes a coverage approach that could reduce delays in beneficiaries' access to innovative screening tests that receive approval from the U.S. Food and Drug Administration (FDA).

Personalized medicine is an evolving field that uses diagnostic tools to identify specific biological markers, often genetic, to help determine which medical treatments and procedures will be best for each patient. By combining this information with an individual's medical history, circumstances, and values, personalized medicine allows doctors and patients to develop targeted prevention and treatment plans.

Personalized medicine is helping to shift the patient and provider experiences away from trial-and-error treatments of late-stage diseases in favor of more streamlined approaches to disease prevention and treatment, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC's members are leading the way in personalized medicine and recommend that patients who may benefit from this approach undergo appropriate testing and tailored treatment as soon as possible during their clinical experiences.

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## Statement of Neutrality

Many of PMC's members will present their own responses to CMS and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the proposed decision memo for screening for CRC using blood-based biomarker tests.

## Burden of Colorectal Cancer and Value of Earlier Detection

The Colorectal Cancer Alliance estimates that there are more than one million CRC survivors in the United States today.<sup>ii</sup> The survival rate for CRC has been increasing in part due to increased awareness, screening and improved treatment options. Earlier detection and treatment are particularly important for the older adult population. For colon cancer, the median age of diagnosis is 68 years of age in men and 72 years of age in women. For rectal cancer, the median age at diagnosis is 63 in both men and women.<sup>iii</sup>

Despite strides made to increase survival rates, CRC remains the second leading cause of cancer death among men and women combined in the United States. Nearly half of CRC cases and deaths would be preventable with improved screening.<sup>iv</sup> Molecular screening tests, including blood-based cancer tests, are emerging as an additional way to screen for cancer. This broad category of tests will continue to evolve. Many tests in development have the potential to be options for patients who otherwise would not be screened with available screening tools such as colonoscopy, sigmoidoscopy, and fecal occult blood testing. PMC appreciates CMS recognizing the value of earlier detection and seeking to address a major factor contributing to gaps in screening<sup>v</sup>, namely patient concerns over coverage for a test, with the policy outlined in the proposed decision memo.

## Considerations for Final Coverage Determination

PMC applauds CMS for responding to stakeholder feedback provided upon opening the NCA, which emphasized opportunities that blood-based tests present for improving early detection and treatment of CRC. When issuing a final coverage determination, PMC urges CMS to consider the following issues in order to allow more streamlined coverage of new blood-based tests as they are approved.

PMC understands that CMS is proposing to cover "blood-based biomarker test as an appropriate colorectal cancer screening test once every 3 years, or at the interval designated in FDA label if the FDA indicates a specific test interval," for patients age 50-85 years "when performed in a *Clinical Laboratory Improvement Act (CLIA)*-certified laboratory and when ordered by a treating physician." A 3-year screening interval reflects current evidence for frequency of testing using an FDA-approved stool-based DNA test but may not be appropriate for blood-based testing where testing intervals have not yet been established. CMS indicates that it will cover blood-based CRC screening tests at another screening interval if it is designated in the FDA label for a new blood-based CRC screening test. However, the frequency of a test is not always dictated by an FDA label. For this reason, CMS' final coverage decision should allow for test frequency to be adjusted based on professional society recommendations or test-

specific data (e.g., modeling studies). Additionally, PMC encourages CMS to align its screening age requirements with current recommendations for CRC screening. The American Cancer Society now recommends certain CRC screening modalities for individuals at age 45<sup>vi</sup> and the U.S. Preventive Services Task Force (USPSTF) proposed a Grade B recommendation for certain CRC screening modalities for patients between ages 45 and 49.<sup>vii</sup> We believe any CRC screening tests, including blood-based biomarker tests, that are supported by relevant professional societies and fulfill criteria established by the final coverage determination should be covered for patients as young as age 45.

In order to increase beneficiary access without having to reconsider the final coverage determination, CMS is also proposing a pathway for future coverage if specific threshold test performance criteria are met. A test must have “proven performance characteristics for a blood-based screening test with both sensitivity greater than or equal to 74 percent and specificity greater than or equal to 90 percent in the detection of CRC compared to the recognized standard, as minimal threshold levels, based on pivotal studies included in FDA labeling.” Recognizing the unique balance of benefits and harms for cancer screening tests and the opportunity to increase screening adherence with new technology, PMC has concerns with the performance criteria in this coverage policy. PMC urges CMS to discuss these concerns further with stakeholders and then consider removal of this criteria in the final NCD issued by the agency.

Along with the proposed performance criteria, a test would need to be included as a screening option in at least one professional society guideline, professional society consensus statement, or USPSTF recommendation to meet the requirement for coverage. Given the pace of development in this space and the length of time necessary to issue guidelines, CMS should consider alternative pathways for professional societies to provide feedback on whether tests meet the performance criteria aside from inclusion in guidelines. These pathways may include endorsement letters from professional society leadership and/or editorial publication from professional society leadership in peer-reviewed journals.

## Conclusion

Thank you for releasing the proposed decision memo on blood-based biomarker tests for CRC screening and for considering our comments. PMC welcomes the opportunity to serve as a resource for you in continuing to shape coverage policies that impact beneficiary access to personalized medicine tests and treatments so that they achieve the goal we share with CMS of delivering appropriate, efficient, and accessible health care to patients. If you have any questions about the content of this letter, please contact me at 202-499-0986 or [cbens@personalizedmedicinecoalition.org](mailto:cbens@personalizedmedicinecoalition.org).

Sincerely yours,



Cynthia A. Bens  
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<sup>i</sup> Centers for Medicare & Medicaid Services. *Proposed Decision Memo for Screening for Colorectal Cancer - Blood-Based Biomarker Tests*. October 16, 2020. <https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=299>.

<sup>ii</sup> Colorectal Cancer Alliance. *Statistics and Risk Factors*. <https://www.ccalliance.org/colorectal-cancer-information/statistics-risk-factors>. Accessed November 13, 2020.

<sup>iii</sup> Colorectal Cancer Alliance. *Statistics and Risk Factors*. <https://www.ccalliance.org/colorectal-cancer-information/statistics-risk-factors>. Accessed November 13, 2020.

<sup>iv</sup> Centers for Disease Control and Prevention. *Vital Signs Colorectal Cancer*. July 2011. <https://www.cdc.gov/vitalsigns/cancerscreening/colorectalcancer/index.html>.

<sup>v</sup> Colorectal Cancer Alliance. *Screening FAQs*. <https://www.ccalliance.org/screening-prevention/screening-faqs>. Accessed November 13, 2020.

<sup>vi</sup> American Cancer Society. *Guideline for Colorectal Cancer Screening*. <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html>. Accessed November 13, 2020.

<sup>vii</sup> U.S. Preventive Services Task Force. *Draft Recommendation Statement Colorectal Cancer Screening*. October 27, 2020. [https://uspreventiveservicestaskforce.org/uspstf/draft-recommendation/colorectal-cancer-screening3#:~:text=In%20the%20current%20draft%20recommendation,years%20\(B%20grade%20recommendation\)](https://uspreventiveservicestaskforce.org/uspstf/draft-recommendation/colorectal-cancer-screening3#:~:text=In%20the%20current%20draft%20recommendation,years%20(B%20grade%20recommendation)).