



March 27, 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: National Coverage Analysis (NCA) 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 230 institutions across the health care spectrum, thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the National Coverage Analysis (NCA) for screening of colorectal cancer among Medicare beneficiaries using blood-based biomarker tests.¹ PMC believes that the NCA process will allow CMS to hear from stakeholders on how blood-based tests available today and those in development can improve early detection and treatment of multiple cancers, including colorectal cancer. With these opportunities in mind, PMC urges CMS to take a holistic view when formulating a national coverage determination (NCD) for blood-based tests under this NCA. To allow more streamlined coverage of new blood-based tests as they come to market, we recommend that CMS explore an NCD focused on molecular screening tests, including blood-based colorectal cancer screening assays as a group, rather than an individual company's test.

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 experience 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 NCA for screening for colorectal cancer using blood-based biomarker tests.

Burden of Colorectal Cancer

The Colorectal Cancer Alliance estimates that there are more than one million colorectal cancer survivors in the United States today.ⁱⁱ The survival rate for colorectal cancer has been increasing, due in part to increased awareness, screening and improved treatment options. Cancer is easiest to treat when identified at its earliest stages. 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.ⁱⁱⁱ

Despite strides made to increase survival rates, colorectal cancer remains the second leading cause of cancer death among men and women combined in the United States. The American Cancer Society estimates that more than 53,000 people could die from colorectal cancer this year.^{iv}

Value of Earlier Detection in Colorectal Cancer

Nearly half of colorectal cancer cases and deaths are preventable with screening.^v The U.S. Preventive Services Task Force, the National Comprehensive Cancer Network, the Multi-Society Task Force on Colorectal Cancer, and the American Cancer Society recommend screening for colorectal cancer, including individuals in the Medicare-eligible population.^{vi} Guideline-recommended screening tests include colonoscopy, sigmoidoscopy, fecal occult blood testing by guaiac or immunochemistry, and fecal DNA testing in conjunction with immunochemistry.^{vii} Even with the availability of these screening tools, one in three adults who need colorectal cancer screening remain unscreened.^{viii} Concerns over insurance coverage for a test, patient fears about the test or test preparation, and a lack of time to undergo screening are some factors contributing to gaps in screening.^{ix}

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. As CMS considers whether to draft a proposed NCD for blood-based biomarker tests in colorectal cancer, PMC recommends that the agency take a holistic approach to the NCD. To offer more screening choices for patients, the NCD should not be tied solely to a specific company's test but rather allow for more streamlined coverage of new blood-based cancer tests as they come to market.

Conclusion

Thank you for opening the NCA on blood-based biomarker tests for colorectal cancer 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.

Sincerely yours,



Cynthia A. Bens
Senior Vice President, Public Policy

CC: Carl Li, M.D., M.P.H.
Medical Officer

Kimberly Long
Lead Analyst

ⁱ Centers for Medicare & Medicaid Services. *National Coverage Analysis (NCA) for Screening for Colorectal Cancer- Blood-Based Biomarker Tests*. February 28, 2020. https://www.cms.gov/medicare-coverage-database/details/nca-details.aspx?NCAId=299&ExpandComments=n&lcd_id=16534&bc=gEAAAAAAAAIAAA&

ⁱⁱ Colorectal Cancer Alliance. Statistics and Risk Factors. <https://www.ccalliance.org/colorectal-cancer-information/statistics-risk-factors> Accessed March 25, 2020.

ⁱⁱⁱ Colorectal Cancer Alliance. Statistics and Risk Factors. <https://www.ccalliance.org/colorectal-cancer-information/statistics-risk-factors> Accessed March 25, 2020.

^{iv} American Cancer Society. Key Statistics for Colorectal Cancer. <https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html> Accessed March 25, 2020.

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

^{vi} U.S. Preventive Services Task Force. *Final Recommendation Statement: Colorectal Cancer: Screening*. June 15, 2016. <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/colorectal-cancer-screening2>; National Comprehensive Cancer Network, Colorectal Cancer Screening (Version 2.2019). August 2, 2019. https://www.nccn.org/professionals/physician_gls/pdf/colorectal_screening.pdf; U.S. Multi-Society Task Force on Colorectal Cancer (MSTF). *Colorectal Cancer Screening: Recommendations for Physicians and Patients*. July 2017.

https://journals.lww.com/ajg/Fulltext/2017/07000/Colorectal_Cancer_Screening_Recommendations_for.13.aspx; American Cancer Society. *Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society*. May 30, 2018. <https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21457>

vii Colorectal Cancer Alliance. Types of Screening Chart. <https://www.ccalliance.org/screening-prevention/screening-methods> Accessed March 25, 2020.

viii American Cancer Society. *Colorectal Cancer Facts and Figures 2020-2022*. Accessed March 27, 2020 <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2020-2022.pdf>

ix Colorectal Cancer Alliance. Screening FAQs. <https://www.ccalliance.org/screening-prevention/screening-faqs> Accessed March 25, 2020.