

August 5, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 120F
Washington, DC 20201

Dear Secretary Becerra:

On behalf of the 24 undersigned organizations that advocate for broad access to cancer screening, we respectfully request that you expedite the addition of new FDA-approved colorectal cancer screening tests to the policies and educational content used by the Department of Health and Human Services (HHS) and its constituent agencies.

In alignment with the Biden Administration's Cancer Moonshot and a priority focus on expanding cancer prevention and early detection, specifically colorectal cancer screening, this request asks:

1. That the United States Preventive Services Task Force (USPSTF) conduct and complete an early update of its colorectal cancer screening guidelines in 2024, and;
2. That the Centers for Medicare and Medicaid Services (CMS) immediately open a National Coverage Determination (NCD) to include new FDA-approved colorectal cancer screening tests.

Given the increasing rates of colorectal cancer among younger individuals, it is a public health imperative that these two steps be taken as quickly as possible to expand access to all available FDA-approved screening tests for individuals aged 45 and older, whether they are covered by commercial insurance or the Medicare program. Updating the USPSTF colorectal cancer guidelines and the Medicare NCD for colorectal cancer to reflect the availability of new, innovative FDA-approved tests will help ensure that individuals and their health care providers can utilize the test that they deem most appropriate.

As you know, colorectal cancer is the second-most deadly cancer in the United States, and it is of serious concern that the American Cancer Society recently reported that it is now the leading cause of cancer deaths for males under 50 – and the second-leading cause of death for females. In addition, colorectal cancer is on track to be the number one cause of cancer death for males and females under 50 by 2030.

Furthermore, colorectal cancer incidence and mortality rates also highlight racial/ethnic and geographic health disparities. For example, Black Americans and Indigenous communities are at higher risk for colorectal cancer incidence and mortality¹. Healthcare professionals are finding higher rates of advanced colorectal cancer in rural areas compared to urban centers largely due to being diagnosed at later stages². Colorectal cancer can, however, be caught early or even prevented through regular screening. Still, unfortunately, tens of millions of eligible Americans do not get screened due to a lack of access or avoidance of invasive options like colonoscopies.

Further, many people needing a colonoscopy face delays due to the lack of capacity for screening colonoscopies across the country. A recent study estimated 59.2 million individuals eligible for CRC screening

¹ Carethers, John M. Racial and Ethnic Disparities in Colorectal Cancer Incidence and Mortality. *Advances in Cancer Research*. 2021; 151: 197-229.

² Penn State Health News. The Medical Minute: Colon cancer rates higher in rural areas. March 14, 2024.

and only 6.3 million annual colonoscopies available annually for screening³. Moreover, many individuals have difficulty accessing colonoscopy for myriad reasons, including, mobility and/or transportation issues, disabilities, inability to take time off from work for the pre-procedure prep and the procedure itself, etc. With an estimated one in three people who should be screened for colorectal cancer forgoing this preventive measure, millions of Americans awaiting access to a colonoscopy, and increasingly younger people being diagnosed, we urgently need innovative strategies and tools to ensure more people are screened for this preventable disease.

The USPSTF plays an integral role in colorectal cancer prevention and early detection because commercial insurers rely on its recommendations to determine coverage of colorectal cancer screening tests. Many commercial insurers will decline coverage for a preventive screening test unless it is included in USPSTF guidelines, regardless of strong data supporting the effectiveness of the new screening modality. Importantly, colorectal cancer screening modalities that receive an A or B rating from the USPSTF are fully covered by insurance, and this elimination of patient cost-sharing facilitates access and utilization.

The speed of cancer screening and detection innovation is outpacing the USPSTF's average review timelines. Typically, the USPSTF updates its recommendations every five years. According to this schedule, the review process for colorectal cancer screening should have already begun, however, there is no indication of when the estimated two-year review and update process will commence.

Two new colorectal cancer screening options are entering the market. These additional tools are essential for increasing colorectal cancer screening rates, especially among individuals aged 45-49, individuals with disabilities, and those living in underserved and rural communities. Fight Colorectal Cancer (FightCRC), a leading patient advocacy organization, has submitted a formal request to USPSTF to conduct an early update of its colorectal cancer screening guidelines given that these two new, innovative screening tests have received FDA approval. Given the lack of colonoscopy screening capacity alongside colorectal cancer disparities, additional options are urgently needed to help ensure all eligible individuals can get screened for colorectal cancer.

Many clinicians likely will be reticent to prescribe these new tests unless they are included in USPSTF guidelines, ensuring insurance coverage and eliminating patient cost-sharing. Additionally, the Centers for Medicare and Medicaid Services (CMS) must take action to update its coverage and payment policy so that all FDA-approved colorectal cancer screening tests are accessible to Medicare beneficiaries and dually-eligible beneficiaries.

Requests

HHS policies and programs directly affect colorectal cancer screening practices, availability, and access. To that end, we urge you to:

1. **Request that USPSTF immediately commence an early update of its colorectal cancer screening guidelines to evaluate all new FDA-evaluated and approved colorectal cancer screening tests and those for which there is peer-reviewed published evidence about an intervention not previously considered.**^{4 5} We ask that you urge USPSTF to undertake and complete an early update process this year. We recognize that USPSTF is an independent advisory body, but as Secretary, you can request early

³ Fendrick M, Ebner D, Kisiel JB, et al. ELIMINATING THE COLONOSCOPY BACKLOG WITH STOOL-BASED COLORECTAL CANCER SCREENING OPTIONS. Abstract presented at Digestive Disease Week (DDW) 2024 Annual Meeting. Washington, DC. May 17-21, 2024. <https://www.hcplive.com/view/mark-fendrick-md-addressing-the-colonoscopy-backlog-with-new-screening-modalities>

⁴ Multitarget Stool RNA Test for Colorectal Cancer Screening; Erica K. Barnell, MD, PhD^{1,2,3}; Elizabeth M. Wurtzler, PhD³; Julie La Rocca, MS³; et al. <https://jamanetwork.com/journals/jama/fullarticle/2811133>

⁵ A Cell-free DNA Blood-Based Test for Colorectal Cancer Screening: Daniel C. Chung, M.D., Darrell M. Gray II, M.D., M.P.H., Harminder Singh, M.D., Rachel B. Issaka, et al. <https://www.nejm.org/doi/abs/10.1056/NEJMoa2304714>

updates when certain criteria are met. It is important to note that the newest FDA-approved colorectal cancer screening tests fill a gap in the evidence; for example, when USPSTF last completed a guideline review, it did not have evidence of the value of a stool-based nucleic-acid-FIT test for the 45–49-year-old cohort. That has changed with the advent of a newly FDA-approved RNA-FIT colorectal cancer screening test.

2. **Direct CMS to immediately open a NCD process to add new FDA-approved colorectal cancer screening tests.** CMS should expedite the inclusion of these tests in an NCD to ensure that Medicare beneficiaries and dually-eligible individuals have access to a broader range of effective colorectal cancer screening options. With the rising incidence of colorectal cancer among younger individuals, it is particularly important for younger Medicare-Medicaid dual-eligibles, specifically those aged 45-64 – many who are disabled, to have access to highly effective, noninvasive at-home screening tests.

Thank you for considering our requests. These actions will help detect and prevent colorectal cancer for individuals within the Medicare and Medicaid programs as well as those covered by commercial insurance. We stand ready to work with you on these and other efforts to prevent and reduce colorectal cancer. If you need further information, please contact Erin Peterson at erin@coloncancercoalition.org.

Sincerely,

Colon Cancer Coalition
AliveandKick'n
Alliance for Aging Research
American Academy of Physician Associates
American Association of Nurse Practitioners
American College of Surgeons
Butt Check Inc
Cancer Advocacy Group of Louisiana (CAGLA)
Cancer Early Detection Alliance (CEDA)
Cheeky Charity
Colon Cancer Prevention Project
Colon Cancer Stars
Colorectal Cancer Alliance
Colorectal Cancer Equity Foundation
Digestive Disease National Coalition
GI Cancers Alliance
Global Colon Cancer Association
Man Up to Cancer
One Cancer Place
Paltown Development Foundation - Colontown
Prevent Cancer Foundation
Raymond Foundation
Spina Bifida Association
The Gloria Borges WunderGlo Foundation