

September 6, 2022

Comment: CMS-1770-P

Proposed Rule: Revisions to Payment Policies under the Medicare Physician Fee Schedule Quality Payment Program and Other Revisions to Part B for CY 2023

Fight Colorectal Cancer (Fight CRC) is the leading patient-empowerment colorectal cancer advocacy organization based in the United States. We are responding to section III.D. of the Revisions to Payment Policies under the Medicare Physician Fee Schedule Quality Payment Program and Other Revisions to Part B for CY 2023. Thank you for the opportunity to provide comments.

Colorectal cancer (CRC) is the second-leading cause of cancer death among men and women in the United States and preventive screenings are necessary to reduce CRC incidence and mortality.¹ In 2019, just 67.1% of eligible adults were screened for colorectal cancer.² One of the major barriers to completing colorectal cancer screening are out-of-pocket costs, especially for seniors, many of whom survive on a fixed income.³ Medicare beneficiaries have delayed or refrained from completing a colonoscopy to avoid unexpected financial expenditures. Ensuring that patients who have a colonoscopy following a positive non-invasive test will not face a burdensome bill will improve screening compliance and ultimately save lives.

Fight CRC is grateful for all of the work the Centers for Medicare and Medicaid Services (CMS) has done to reduce barriers to colorectal cancer screening, such as the implementation of section 122 of the FY21 Consolidated Appropriations Act (CAA) to reduce, over time, co-insurance for colorectal cancer screening tests that require further procedures during the same clinical encounter. Further, our organization fully supports section III.D. of the Revisions to Payment Policies under the Medicare Physician Fee Schedule Quality Payment Program and Other Revisions to Part B for CY 2023, to reduce the screening age to 45 years old and to expand coverage to include follow-on screening colonoscopy after a positive non-invasive test.

¹ Siegel, R. L., Miller, K. D., Goding Sauer, A., Fedewa, S. A., Butterly, L. F., Anderson, J. C., Cercek, A., Smith, R. A., & Jemal, A. (2020). Colorectal cancer statistics, 2020. *CA: a cancer journal for clinicians*, 70(3), 145–164. <https://doi.org/10.3322/caac.21601>

² Closing Gaps in Cancer Screening: Connecting People, Communities, and Systems to Improve Equity and Access. A Report from the President's Cancer Panel to the President of the United States. Bethesda (MD): President's Cancer Panel; 2022. Colorectal Cancer Companion Brief. Retrieved from https://prescancerpanel.cancer.gov/report/cancerscreening/pdf/PresCancerPanel_CancerScreening_CB_Colorectal_Feb2022.pdf.

³ Fendrick, A. M., Prinic, N., Miller-Wilson, L. A., Wilson, K., & Limburg, P. (2021). Out-of-Pocket Costs for Colonoscopy After Noninvasive Colorectal Cancer Screening Among US Adults With Commercial and Medicare Insurance. *JAMA network open*, 4(12), e2136798. <https://doi.org/10.1001/jamanetworkopen.2021.36798>

Fight CRC strongly supports expanding CRC screening coverage by reducing the minimum age for CRC screening tests from 50 to 45 years of age for certain Medicare covered CRC screening tests.

Fight CRC supports reducing the screening age for average risk individuals from 50 to 45 years of age for Medicare beneficiaries. This change will bring CMS into alignment with the United States Preventive Services Task Force (USPSTF), the Centers for Disease Control and Prevention (CDC), the U.S. Multi-Society Task Force on Colorectal Cancer, the American Cancer Society and others. While colorectal cancer incidence rates in individuals over 50 have largely stabilized or declined due to significant advancements in preventive screening, incidence rates for early-onset colorectal cancer (*individuals diagnosed at ages 20 to 49*) have been consistently increasing.⁴ Colorectal cancer is trending to be the leading cause of cancer death for Americans ages 20-49 by 2030.⁵ Reducing the Medicare screening age to 45 will improve health outcomes through prevention and early detection.

Fight CRC strongly supports expanding the regulatory definition of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result.

Colorectal cancer screening is not a single test, but a multi-step process. A non-invasive test alone is not enough to confirm a positive diagnosis. Therefore, it is medically necessary for patients who receive a positive result on a non-invasive test to complete a follow-on colonoscopy in order for screening to be achieved.

Removing cost-sharing for follow-on colonoscopy is accordant with guidelines issues by USPSTF, the FAQ guidance issued by the U.S. Departments of Health and Human Services, Labor, and Treasury as well as the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, the American College of Radiology, and the National Colorectal Cancer Roundtable who have all stated in their guidance that follow-on colonoscopy after a positive stool test is an integral part of the screening process that should be covered by health insurers with no patient-cost sharing. A recent study by the National Cancer Institute showed that after a positive non-invasive screening test, the risk of death from colorectal cancer was two times higher among people who did not have a follow-on colonoscopy.⁶ Removing the cost barrier to

⁴ American Cancer Society. (2020). Colorectal Cancer Facts & Figures 2020-2022. American Cancer Society. Retrieved from <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>

⁵ Rahib L, Wehner MR, Matrisian LM, Nead KT. Estimated projection of U.S. cancer incidence and death to 2040. *JAMA Netw Open*. 2021;4(4):e214708. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/33825840>

⁶ Zorzi, M., Battagello, J., Selby, K., Capodaglio, G., Baracco, S., Rizzato, S., Chinellato, E., Guzzinati, S., & Rugge, M. (2022). Non-compliance with colonoscopy after a positive faecal immunochemical test doubles the risk of dying from colorectal cancer. *Gut*, 71(3), 561–567. <https://doi.org/10.1136/gutjnl-2020-322192>

follow-on colonoscopy is important for both early detection and increasing access to care for communities of color who are diagnosed with CRC at later stages and have worse survival outcomes.

Fight CRC asks CMS to advance the revision further to allow for future innovation by removing “stool-based” from the regulation.

The landscape of colorectal cancer screening tools and technology is rapidly expanding. There are a multitude of new, non-invasive tests, including blood tests, that are on the horizon. These tests, when positive, will also require a follow-on colonoscopy in order for screening to be complete. Changing the language to be inclusive of future non-invasive screening tests recommended by the USPSTF and covered by Medicare will allow patients to access all approved screening modalities and eliminate delays for patients that need follow-on colonoscopies after positive non-invasive tests.

Fight CRC asks CMS to advance the revision further by providing coding and reporting guidance to physicians for follow-on colonoscopy.

We encourage CMS to provide guidance to physicians for coding follow-on screening colonoscopy after a positive non-invasive screening test result. We believe the follow-on screening colonoscopy should be coded and reported the same way as a screening colonoscopy and we urge CMS to issue guidance confirming that follow-on colonoscopies should be coded as a screening colonoscopy using the appropriate HCPCS G-code (G0121 or G0105).

We appreciate the opportunity to provide comments and appreciate the commitment of CMS to removing barriers to colorectal cancer screening. It is critical that patients have access to the full continuum of colorectal cancer screening options and that cost is not a barrier to completing screening. The removal of cost-sharing for colonoscopy following a positive non-invasive CRC screening test, will help meaningfully increase access to CRC screening and save lives. If you have any questions or concerns please contact Molly McDonnell, Director of Advocacy at Molly@fightcolorectalcancer.org or (908) 421-0068.



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