

September 9, 2024

Docket ID: CMS-2024-0256

Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

The undersigned organizations representing the colorectal cancer community are responding to section III.K. of the proposed Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments. We thank you for the opportunity to provide comments.

Colorectal cancer (CRC) is the second-leading cause of cancer death in the United States and preventive screenings are necessary to reduce CRC incidence and mortality. In 2021, fewer than two thirds of eligible adults were up to date with colorectal cancer screening.¹ 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.² Medicare beneficiaries have delayed or refrained from completing a colonoscopy to avoid unexpected financial expenditures. Ensuring that patients who have a colonoscopy following an abnormal non-invasive test will not face a burdensome bill will improve screening compliance and ultimately save lives.

We are grateful for the work that the Centers for Medicare and Medicaid Services (CMS) has done to reduce barriers to colorectal cancer screening, including reducing, over time, out-of-pocket costs for colonoscopies when a polyp is detected and removed, and removing out of pocket costs for a screening colonoscopy following abnormal result on a non-invasive stool-based test.

Comprehensive coverage for colorectal cancer screening is vital. This is particularly important when a follow-up colonoscopy is required after an abnormal, non-invasive test. As non-invasive tests for colorectal cancer advance, they will require a multi-step process to confirm a diagnosis. It is medically essential that patients who receive abnormal results from non-invasive screenings undergo a follow-up colonoscopy to ensure accurate diagnosis and effective screening. A recent study by the National Cancer Institute highlighted a significant concern: individuals who did not receive a follow-up colonoscopy after an abnormal non-invasive screening result were found to have a risk of death from colorectal cancer that was twice as high as those who did.³ This finding underscores the urgent need to eliminate financial barriers to follow-up colonoscopies, as they are pivotal for both the prevention and early detection of colorectal cancer.

¹ Siegel, Rebecca L., Nikita Sandeep Wagle, Andrea Cercek, Robert A. Smith, and Ahmedin Jemal. "Colorectal Cancer Statistics, 2023." *CA: A Cancer Journal for Clinicians* 73, no. 3 (2023): 233–54. <https://doi.org/10.3322/caac.21772>.

² 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>

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

To that end, we support section III.K which expands the regulatory definition of “complete colorectal cancer screening” to include a follow-up screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test returns an abnormal result. As new CRC screening tests are approved and covered by CMS, it is critical that patients also have access to the follow-up colonoscopy to complete the full continuum of screening without cost being a barrier.

We also support section III.K. of the proposed rule to expand coverage to include computed tomography colonography (CTC) procedures. Coverage of additional non-invasive colorectal cancer screening tests will encourage more beneficiaries to get screened in a way that best suits their individual needs.

A standalone CTC however does not constitute a “complete colorectal cancer screening” as the United States Preventive Services Task Force (USPSTF) Colorectal Cancer Screening Recommendations explicitly state that “Abnormal findings identified by flexible sigmoidoscopy or CT colonography screening require follow-up colonoscopy for screening benefits to be achieved”. Considering this, we urge CMS to expand their approach to a "complete CRC Screening" in § 410.37(k) to include follow-up colonoscopies after all Medicare covered non-invasive colorectal cancer screening tests, including CTC, that require a follow-up colonoscopy after an abnormal result. The removal of cost-sharing for colonoscopies following abnormal results from these tests would help meaningfully increase access to care across the full continuum of CRC screening and will save lives.

The landscape of colorectal cancer screening tools and technology is rapidly expanding, and there are many new, non-invasive tests on the horizon. To that end, we ask that as CMS considers future colorectal cancer screening coverage updates, careful consideration is given to whether new screening modalities constitute a “complete colorectal cancer screening” on their own. When necessary, we encourage continued expansion of the definition of what constitutes a “complete colorectal cancer screening” to ensure follow-up colonoscopies are covered when required. Ensuring complete screening coverage for future screening tests that require follow-up after an abnormal result will allow patients to access all approved screening modalities and eliminate delays for patients that need follow-up colonoscopies.

We appreciate the opportunity to provide comments and the commitment of CMS to removing barriers to colorectal cancer screening.

Sincerely,

Fight Colorectal Cancer
AliveandKick'n
American Association of Medical Assistants
American Cancer Society Cancer Action Network
American Medical Group Association
American Society of Colon & Rectal Surgeons
Big Mike's Bottom Line
Cheeky Charity
Colon Cancer Prevention Project
Colon Cancer Stars
Colorectal Cancer Alliance

Crohn's & Colitis Foundation
Digestive Disease National Coalition
FORCE: Facing Our Risk of Cancer Empowered
GI Cancers Alliance
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