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September 6, 2022

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare and Medicaid Services 7500 Security Boulevard Baltimore, MD 21244

RE: CMS-1770-P, Revisions to Payment Policies under the Medicare Physician Fee Schedule Quality Payment Program and Other Revisions to Part B for CY 2023

Dear Administrator Brooks-LaSure:

The Prevent Cancer Foundation[®] is the only U.S. nonprofit organization focused solely on saving lives across all populations through cancer prevention and early detection. Through research, education, outreach and advocacy, we help people reduce their risk for cancer or detect their cancer early enough to be successfully treated.

Thank you for the opportunity to submit comments for your consideration on the Revisions to Payment Policies under the Medicare Physician Fee Schedule Quality Payment Program and Other Revisions to Part B for CY 2023. We are writing in regard to the provisions expanding coverage for colorectal cancer (CRC) screening.

Colorectal cancer 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.¹¹ One of the major barriers to completing colorectal cancer screening are out-of-pocket costs, especially for older Americans, many of whom survive on a fixed income.¹¹¹ 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.

We commend the Centers for Medicare and Medicaid Services (CMS) for working to reduce barriers to colorectal cancer screening, including reducing, over time, out-of-pocket costs for colonoscopies when a polyp is detected and removed. We fully support 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 followon screening colonoscopy after a positive non-invasive stool-based test.

CMS' proposal to expand Medicare coverage of certain CRC screening tests by lowering the minimum eligible age to 45 years

We support reducing the screening age for average risk individuals from 50 to 45 years of age for Medicare beneficiaries. 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.^{iv} Reducing the Medicare screening age to 45 will improve health outcomes through prevention and early detection.

CMS' proposal on follow-on screening colonoscopy after a positive blood-based test

We also support expanding the regulatory definition of CRC screening tests to include a followon 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. 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-up colonoscopy.^v Removing the cost barrier to follow-up 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.

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. To that end, we ask that CMS consider revising the regulation to remove "stool-based" to allow for future innovation in non-invasive screening tests. 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 U.S. Preventive Services Task Force 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.

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.

Thank you again for the opportunity to review and comment on the Medicare Physician Fee Schedule Quality Payment Program and Other Revisions to Part B for CY 2023. If you have any questions about our comments, please contact Director of Policy and Advocacy, Caitlin Kubler, at <u>Caitlin.Kubler@preventcancer.org</u>.

Sincerely,

Jody Hoyos, MHA President and Chief Operating Officer

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

ⁱⁱ 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.p df.

ⁱⁱⁱ Fendrick, A. M., Princic, 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

^{iv} 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

^v Zorzi, M., Battagello, J., Selby, K., Capodaglio, G., Baracco, S., Rizzato, S., Chinellato, E., Guzzinati, S., & Rugge, M. (2022). Noncompliance 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