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April 05, 2022

Joseph Chin, MD
Deputy Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

Submitted Electronically to NCDRequest@cms.hhs.gov

Re: National Coverage Reconsideration for Screening Computed Tomography Colonography (CTC) for Colorectal Cancer (CAG-00396N)

Dear Dr. Chin,

On behalf of the undersigned organizations representing radiologists and the colon cancer community, we formally request the Centers for Medicare and Medicaid Services (CMS) reconsider the existing May 2009 National Coverage Determination (NCD) on Screening Computed Tomography Colonography (CTC) for Colorectal Cancer (CAG-00396N) in light of new evidence and the updated [United States Preventive Services Task Force \(USPSTF\) recommendation](#) that endorses CTC as a colorectal cancer screening option and expands screening for colorectal cancer in all adults ages 45 to 75 years. Please refer to the appendix which includes abundant evidence that supports the inclusion of CTC as a Medicare benefit.

There have been pivotable events since the last appeal of the ACR to the CMS Coverage and Analysis Group to include CT colonography as a covered exam for colorectal cancer screening in Medicare beneficiaries. These include 1) the COVID-19 pandemic which has significantly increased the backlog of

HEADQUARTERS
1891 Preston White Drive
Reston, VA 20191
703-648-8900

GOVERNMENT RELATIONS
505 Ninth St. N.W.
Suite 910
Washington, DC 20004
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50 South 16th St., Suite 2800
Philadelphia, PA 19102
215-574-3150

**AMERICAN INSTITUTE FOR
RADIOLOGIC PATHOLOGY**
1100 Wayne Ave., Suite 1020
Silver Spring, MD 20910
703-648-8900

persons in need of screening; 2) the acknowledgment of leaders and organizations in healthcare along with the general public of the continued pervasive healthcare inequities faced by many racial minorities and certain socioeconomic groups, including increased incidence and mortality from colorectal cancer; 3) President Biden’s revitalization of the “Cancer Moonshot” initiative to reduce cancer death by 50% for all people, and 4) the USPSTF has once again thoroughly reviewed the evidence of colorectal cancer (CRC) screening exams and determined CTC to be amongst the screening tests that should be recommended for all persons of average risk for CRC. The modification of the NCD for Medicare patients to include CTC in the context of these events warrants your focused consideration. CTC remains the only USPSTF and American Cancer Society (ACS) recommended test to not be covered by Medicare or traditional Medicaid for primary screening. As the Affordable Care Act requires private insurers to cover all USPSTF-approved screening services without patient cost-sharing, patients lose access to this screening option once they become Medicare age.

Accredited U.S. programs have reported sizable monthly screening deficits for lung (nearly 45% of facilities), breast (55%), and colorectal cancer (81%). Overall median percentage drops in monthly screenings were nearly 2% for breast cancer, climbing as high as 18% for colorectal screenings.¹ Due to the COVID-19 pandemic, there was a delay of over 18,000 CRC screening exams from 2020–2021.² The CRC screening rates have been slow to return to the baseline which was already suboptimal with close to 30% of candidates remaining unscreened. Evidence-based modeling predicts it would take approximately 3,800 more exams per week for 52 weeks to return to the pre-COVID-19 suboptimal baseline screening numbers.³ To compound the issue, there was a shortage of gastroenterologists available to perform optical colonoscopy before the pandemic which has further increased post-pandemic with some physicians having retired during the pandemic.⁴ With the recent update to USPSTF guidelines now recommending that screening for those at average risk begin at age 45 instead of 50, it is more important than ever that patients have access to a variety of screening options and that we can quickly identify patients most in need of a colonoscopy. CTC offers another option for a “direct visualization” screening exam as CT scanners are widely available geographically and the ratio of radiologists required to read several screening exams per day can improve access and screening capacity. Specifically, CTC offers more access to direct visualization tests which as indicated by both the prior and recent USPSTF’s review has a significantly higher sensitivity for precursor polyp detection. Polyp identification and subsequent removal provide an opportunity for the “prevention” of cancers as compared to the stool-based test options which have a lower sensitivity for detection of precursor polyps and are more appropriate for early cancer detection. The March 2022 report from the Medicare Payment Advisory Commission report to Congress identified colorectal cancer as one of the most expensive conditions to treat per Medicare beneficiary. Offering another screening option that can prevent the development of colorectal cancer could lower these treatment costs.⁵

¹ Joung RH, et al. A national quality improvement study identifying and addressing cancer screening deficits due to the COVID-19 pandemic. *Cancer*. 2022 Mar 21. doi: 10.1002/cncr.34157. Epub ahead of print. PMID: 35307815.

² J. D. Camp. COVID-19 and CRC Screening. (2020, June). Colorectal Cancer Screenings Saves Lives. Retrieved from <https://www.loveyourbuns.org/blog/2020/6/10/covid-19-and-crc-screening>.

³ Mast C, Deckert J, Muñoz del Río, A. (2022, January). Troubling Cancer Screening Rates Still Seen Nearly Two Years Into the Pandemic. <https://epicresearch.org/articles/troubling-cancer-screening-rates-still-seen-nearly-two-years-into-the-pandemic>.

⁴ Newitt, P. Gastroenterology's biggest threats. (2021, October). Retrieved from <https://www.beckersasc.com/gastroenterology-and-endoscopy/gastroenterology-s-biggest-threats.html>.

⁵ Medicare Payment Advisory Commission. March 2022 Report to Congress. Retrieved from https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf

The healthcare access challenge for minority populations to direct visualization exams continues to contribute to health inequity since minority populations are not provided with the same opportunity for cancer prevention. An opportunity to reach the same healthcare outcomes as the majority is the very definition of a health inequity that we could impact positively for colorectal cancer. Secondary benefits of the easier access to CTC during the pandemic are multifold and include a decreased need for personal protective equipment (PPE), fewer healthcare workers exposed per screening candidate, and lower risk for exposure to aerosolized virus transmission, as no anesthesia or sedation is needed. We have learned from the projected 52,000 more CRC deaths in 2022 that cancer screenings need to be considered necessary exams that should not be delayed.⁶

Previous discussions with the coverage group revealed a perspective that the NCD included enough options for Medicare patients to complete CRC screening. Another valuable lesson medical professionals have come to accept is that we cannot take a “one size fits all” approach to healthcare given the diversity of thought, culture and historical experiences in our patients. What may be an option for the majority is not necessarily a viable or reasonable option for minority populations. As such, ACS has adopted an approach to provide all the options recommended by the USPSTF as the solution to increase screening. The ACR agrees with that approach, and we ask that CTC be included amongst those options provided to the Medicare population. The need for a driver or car transportation, the need to take a day off from work, and the need for anesthesia or sedation for someone with a fear-based in cultural background are all important barriers to screening that may be faced by someone outside of the majority. The opportunity for prevention through a direct visualization test should not be off the table of options. Lack of Medicare and Medicaid coverage for CTC is a contributor to inequities in healthcare for colorectal cancer screening.

The use of CTC as a CRC screening exam is evidence-based. The cited peer-reviewed literature provides continued and new evidence confirming the efficacy and safety of CTC and fully supports the inclusion of CTC as a validated option for colorectal cancer screening for Medicare beneficiaries. Medicare noncoverage of this valuable colorectal cancer screening test has a disproportionate impact on Black patients and other racial minorities. We strongly urge CMS to extend national coverage for this preventive service. CTC is an untapped resource that will be beneficial to broadening screening options and mitigating increasing screening demands secondary to the continued significant increase in the size of the Medicare population. It provides a proven safe and minimally invasive exam to both screen for CRC and saves lives. CTC has an ideal profile for a safe screening structural examination of the colon. We urge CMS to provide coverage for CTC for all Medicare candidates and to help bridge the gap in reaching the ACS “80% In Every Community!” campaign. As emphasized by the ACS, all qualified screening test options are needed to raise screening rates, and offering more choices increases the overall likelihood of screening, which continues to be at a plateau and has been negatively affected due to COVID-19. Medicare patients deserve the same options afforded to the commercially insured. They deserve to exercise “choice” in selecting their appropriate screening test with options that include CTC.

Our organizations, thank CMS for reconsidering this NCD based on additional supporting evidence provided in the appendix and stakeholder concerns and feedback. We appreciate this opportunity to comment on this important lifesaving preventive service for the Medicare population. We look forward to

⁶ American Cancer Society. Key Statistics for Colorectal Cancer. Retrieved from <https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html>

working with you during this process to provide additional evidence, stakeholder feedback and expert opinions on the CTC screening NCD. To further explore any questions regarding our formal NCD reconsideration request, please contact Alicia Blakey, MS, Principal Economic Policy Analyst, at ablakey@acr.org.

Sincerely,

American College of Radiology
Black Women's Health Imperative
Colorectal Cancer Alliance
Colon Cancer Coalition
Prevent Cancer Foundation
The Blue Hat Foundation

Cc:

William T. Thorwarth Jr., MD, FACR, ACR Chief Executive Officer
Judy Yee, MD, FACR, Chair, ACR Colon Cancer Committee
Katie Keysor, ACR Senior Director Economic Policy
Gregory N. Nicola, MD, FACR, Chair, ACR Commission on Economics
Andrew B. Rosenkrantz, MD, Chair, ACR Commission on Body Imaging
Sammy Chu, MD, FACR, Chair, ACR Contractor Advisory Committee Network

Enclosures

Appendix: Evidence to Support Inclusion of CT Colonography Screening Test for Colorectal Cancer

Per the Federal Register Notice regarding the Medicare Program, Revised Process for Making Medicare National Coverage Determinations, Section IV. B-J, instructions for the Formal Reconsideration Request of an Existing NCD, listed below are the required items included in this NCD (CAG-00396N) reconsideration request:

I. Relevance, Usefulness, and Medical Benefits of CTC to the Medicare Population

Colorectal cancer is the third leading cause of cancer death for both men and women, with an estimated 52,980 deaths in the US from colorectal cancer in 2021. Colorectal cancer is most frequently diagnosed among persons aged 65 to 74 years. It is estimated that 10.5% of new colorectal cancer cases occur in persons younger than 50 years. The incidence of colorectal cancer (specifically adenocarcinoma) in adults aged 40 to 49 years has increased by almost 15% from 2000-2002 to 2014-2016. In 2016, 26% of eligible adults in the US had never been screened for colorectal cancer and in 2018, 31% were not up to date with screening.⁷

Data from the 2020 Behavioral Risk Factor Surveillance System (BRFSS), which asked people across the United States whether they had been screened for colorectal cancer, found that about 7 in 10 U.S. adults aged 50 to 75 are up to date with colorectal cancer screening. 64 million adults aged 50 to 75 were screened in 2020, however 19.9% of the surveyed adults had never been screened for colorectal cancer.⁸ 2020 is the first year the survey asked questions about fecal immunochemical test (FIT)-DNA and CTC.

Several studies have evaluated the performance of CTC in the Medicare population. Namely, in the original prospective ACRIN trial of 2,531 asymptomatic patients at 15 centers in the US, a sub-analysis of 477 participants aged 65 years and older representing the Medicare population was published.⁹ Prevalence of large (1 cm and greater) adenomas in the older age group was 6.9% (33/477) compared to 3.7% (76/2064) in the younger age group, with no difference in the prevalence of right- vs. left-sided lesions between groups. Per patient sensitivity in the older vs. younger age groups for larger neoplasms was 81% vs. 92% ($p=0.05$), respectively and for polyps 6 mm and greater was 72% vs. 81% ($p=0.04$). Overall, there were no statistically significant differences in measures between the older and younger populations. Two other studies found similar colonoscopy referral rates of 14.5% to 15% from a positive CTC (based on a 6 mm threshold at CTC).^{10, 11}

⁷ US Preventive Services Task Force, Davidson KW, Barry MJ, Mangione CM, Cabana M, Caughey AB, Davis EM, Donahue KE, Doubeni CA, Krist AH, Kubik M, Li L, Ogedegbe G, Owens DK, Pbert L, Silverstein M, Stevermer J, Tseng CW, Wong JB. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2021 May 18;325(19):1965-1977. doi: 10.1001/jama.2021.6238. Erratum in: *JAMA*. 2021 Aug 24;326(8):773. PMID: 34003218.

⁸ Use of Colorectal Cancer Screening Tests. (2022, February). 2020 Behavioral Risk Factor Surveillance System. <https://www.cdc.gov/cancer/colorectal/statistics/use-screening-tests-BRFSS.htm>

⁹ Johnson CD, Herman BA, Chen MH, et al. The National CT Colonography Trial: assessment of accuracy in participants 65 years of age and older. *Radiology* 2012;263:401-408.

¹⁰ Macari M, Nevsky G, Bonavita J, et al. CT colonography in senior versus non-senior patients: extracolonic findings, recommendations for additional imaging, and polyp prevalence. *Radiology*. 2011 Jun;259(3):767-74.

¹¹ Kim DH, Pickhardt PJ, Hanson ME, Hinshaw JL. CT colonography: performance and program outcome measures in an older screening population. *Radiology* 2010;254:493-500

II. Statutorily Defined Benefit Category

The ACR recognizes that to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B and must not be otherwise excluded from coverage. Section 4104 of the Balanced Budget Act of 1997 provides for coverage of screening colorectal cancer procedures under Medicare Part B.¹² Medicare covers: (1) annual fecal occult blood tests (FOBTs); (2) flexible sigmoidoscopy over 4 years; (3) screening colonoscopy for persons at average risk for colorectal cancer every 10 years, or for persons at high risk for colorectal cancer every 2 years; (4) barium enema every 4 years as an alternative to flexible sigmoidoscopy, or every 2 years as an alternative to colonoscopy for persons at high risk for colorectal cancer; and, (5) other procedures the Secretary finds appropriate based on consultation with appropriate experts and organizations.

Under this law, CMS may determine coverage of other types of colorectal cancer screening tests that are not specifically identified in the law or regulations as it determines to be appropriate, in consultation with appropriate organizations. We request CMS to conduct a National Coverage Analysis (NCA) to evaluate the available evidence for screening CTC and determine a national coverage determination is warranted.

III. Design, Purpose, and Method of Screening CTC for Colorectal Cancer

CTC uses X-rays and computers to produce images of the entire colon, which are displayed on a computer screen for the doctor to analyze. CTC uses low radiation dose CT scanning to obtain images of the inside of the colon that otherwise can only be seen with the more invasive colonoscopy. During CT colonography, the doctor inserts a small tube a short distance into the rectum to allow for inflation with carbon dioxide or air. Automated carbon dioxide is preferred because it provides better inflation and less discomfort. The doctor takes CT images of the patient's abdomen and examines them for polyps and other abnormalities using advanced computer software. Patients do not need sedation for this exam. The patient will, however, still need to thoroughly cleanse their colon before the test. Patients may also be asked to drink oral contrast 1-2 days before the test. Contrast makes the patient's stool look different than polyps.¹³

It is important to differentiate CTC from stool-based tests. Whereas stool-based tests are meant to identify the presence of cancer, CTC accurately identifies precancerous polyps and cancers. CTC is a structural test that can identify the presence and location of polyps and even early-stage cancers when it can be prevented or more easily treated.

IV. Screening Recommendations Supporting Inclusion of CTC

In May 2021, the USPSTF released its final recommendation which replaces the 2016 USPSTF recommendation on screening for colorectal cancer. In 2016, the USPSTF recommended screening for colorectal cancer starting at age 50 years and continuing until age 75 years (A recommendation). In addition, the USPSTF concluded that the decision to screen for colorectal cancer in adults aged 76 to 85 years should be an individual one, taking into account the patient's overall health and prior screening history (C recommendation) and that screening should be discontinued after age 85 years. CTC is one of several screening options clearly endorsed (again) by the updated USPSTF recommendation.

¹² Sec. 4104. Coverage of colorectal screening. <https://www.govinfo.gov/content/pkg/CRPT-105hrpt217/pdf/CRPT-105hrpt217.pdf>

¹³ Colorectal Cancer Screening.(2022, February). RadiologyInfo.org. <https://www.radiologyinfo.org/en/info/screening-colorectal>

In the current 2021 recommendation, while continuing to recommend colorectal cancer screening in adults aged 50 to 75 years (A recommendation), the USPSTF now recommends offering screening starting at age 45 years (B recommendation).¹⁴ Currently, the USPSTF supports stool-based and direct visualization screening tests. Among the direct visualization tests, a colonoscopy every 10 years or CTC every 5 years have greater estimated life-years gained than flexible sigmoidoscopy every 5 years. These changes allow millions of Americans to receive private insurance coverage for this vital screening. Although the Affordable Care Act requires commercial insurance coverage of screening CTC, Medicare does not cover the test. Expanding Medicare coverage will help medical providers save more lives and will allow patients the same access to screening CTC that they have under commercial plans when they transition to Medicare coverage.

This recommendation update directly aligns with the 2018 American Cancer Society (ACS) published guideline for colorectal cancer screening, which concluded that adults aged 45 years and older with an average risk of colorectal cancer should undergo regular screening using one of a variety of available screening options, including CTC every 5 years.¹⁵ ACS recommends that adults begin screening at age 45, preferably with a test that allows for **both** cancer prevention and detection.

The two most preferred tests that offer both cancer prevention and detection include:

- CT colonography (virtual colonoscopy), repeated every five years.
- Colonoscopy, repeated every 10 years.

Less preferred screening tests include:

- Double-contrast barium enema, repeated every five years.
- Flexible sigmoidoscopy, repeated every five years.

Tests that allow for cancer detection only include:

- Fecal occult blood test (gFOBT) or fecal immunochemical test (FIT) every year.
- Stool DNA test every three years.

Since 2009, CMS has barred coverage of this valuable screening test despite the updated recommendations mentioned above. We strongly encourage Medicare to follow the lead of the USPSTF and ACS and allow beneficiaries access to this lifesaving exam.

V. Racial/Ethnic Disparities in Screening

CTC has been found to be a preferred screening test option in vulnerable patients. A study evaluating preferences for colorectal cancer screening among racially and ethnically diverse patients found that ratings of CTC were significantly higher than ratings of colonoscopy, sigmoidoscopy, and fecal occult blood testing in Black and LatinX patients.¹⁶ Recent census survey data indicates that more Blacks and Hispanics

¹⁴ US Preventive Services Task Force, Davidson KW, Barry MJ, Mangione CM, Cabana M, Caughey AB, Davis EM, Donahue KE, Doubeni CA, Krist AH, Kubik M, Li L, Ogedegbe G, Owens DK, Pbert L, Silverstein M, Stevermer J, Tseng CW, Wong JB. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2021 May 18;325(19):1965-1977. doi: 10.1001/jama.2021.6238. Erratum in: *JAMA*. 2021 Aug 24;326(8):773. PMID: 34003218.

¹⁵ Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA Cancer J Clin*. 2018;68:250-281.

¹⁶ Hawley ST, Volk RJ, Krishnamurthy P, et al. Preferences for colorectal cancer screening among racially/ethnically diverse primary care patients. *Med Care* 2008;46:S10-6.

are being screened with CTC compared to whites, 2.5% versus 0.9% respectively.¹⁷ Census data also shows a nearly 1/2 million lower incidence of CRC per year for White Americans in comparison to Black Americans with overall screening rates for Black Americans down by 6-18% compared to White Americans.¹⁸ Expanding Medicare coverage of CTC is an opportunity to help reduce gaps in care and improve health care disparities for minorities.

The Atlanta VA Medical Center has been performing colorectal cancer screening with CTC for many years. Researchers looked at the performance of CTC in an African American cohort (n=2490) of the Atlanta VA's CTC screening program and found that CTC was an effective screening modality with a per-patient CTC positive rate of 9.8% for polyps measuring 6 to 9 mm, 5.4% for polyps measuring 10 to 29 mm, and 1.3% for masses \geq 30 mm. The referral rate to optical colonoscopy was 13.9%.¹⁹ CTC is an effective screening modality for African American adults and could potentially improve rates of colorectal cancer screening in this underserved population.

While USPSTF is tasked with providing guidelines that guide the average-risk population, the guidelines do not adequately address the incidence and mortality variability based on race/ethnicity and gender differences. Black adults have the highest incidence of and mortality from colorectal cancer compared with other races/ethnicities. From 2013 to 2017, incidence rates for colorectal cancer were 43.6 cases per 100 000 Black adults, 39.0 cases per 100 000 American Indian/Alaska Native adults, 37.8 cases per 100 000 White adults, 33.7 cases per 100 000 Hispanic/ Latino adults, and 31.8 cases per 100 000 Asian/Pacific Islander adults.²⁰ It is suggested the USPSTF further examine the variance in incidence, mortality, and screening rates for the: Black American Population, Latinx, and Indigenous Populations to make specific considerations for subpopulations.

Medicare noncoverage of this valuable colorectal cancer screening test may have a disproportionate impact on black patients and other racial minorities. A recent study using the ACR's CTC registry evaluated the use of screening CTC examinations by age comparing individuals of Medicare-eligible age to younger cohorts to determine if the association between use of CTC and Medicare-eligible age varies by race. The CTC registry contained data on 12,648 screening examinations. Between ages 52 and 64, the number of screening examinations increased; each additional age year was associated with a 5.3% ($P < .001$) increase in the number of screenings. However, after age 65, the number of screening examinations decreased at -6.9% per additional year of age above 65 compared with the trend between ages 52 and 64 ($P < .001$). The modal age group for CTC use was 65 to 69 years in white and 55 to 59 in black individuals.²¹ The study concluded after age 65, the number of screening CTC examinations decreased, likely due, at least in part, to lack of Medicare coverage.

¹⁷ National Cancer Institute Cancer Trends Progress Report. (2021, July). Colorectal Cancer Screening. Retrieved from https://progressreport.cancer.gov/detection/colorectal_cancer.

¹⁸ May FP, Whitman CB, Varlyguina K, Bromley EG, Spiegel BM. Addressing Low Colorectal Cancer Screening in African Americans: Using Focus Groups to Inform the Development of Effective Interventions. *J Cancer Educ.* 2016 Sep;31(3):567-74. doi: 10.1007/s13187-015-0842-z. PMID: 25963898; PMCID: PMC4644112.

¹⁹ Moreno CC, Fibus TF, Krupinski EA, Kim DH, Pickhardt PJ. Addressing racial disparity in colorectal cancer screening with CT colonography: experience in an African-American cohort. *Clin Colorectal Cancer* 2018;17(2):e363-e367.

²⁰ Howlander N, Noone AM, Krapcho M, et al. SEER Cancer Statistics Review, 1975-2017. National Cancer Institute. Published April 15, 2020. Accessed March 30, 2021. https://seer.cancer.gov/csr/1975_2017/

²¹ Moreno CC, Yee J, Dachman AH, Duszak R Jr, Goldman L, Horný M. Use of Screening CT Colonography by Age and Race: A Study of Potential Access Barriers Related to Medicare Noncoverage Based on Data From the ACR's National CT Colonography Registry. *J Am Coll Radiol.* 2021 Jan;18(1 Pt A):19-26. doi: 10.1016/j.jacr.2020.09.043. Epub 2020 Oct 18. PMID: 33086049.

In December 2021, based on the input received through the Center for Medicaid and CHIP Services (CMCS) annual review process, CMCS has added two new measures that now include the Colorectal Cancer Screening measure to the 2022 Adult Core Set. This measure supports efforts by CMS to assess healthcare disparities and address health equity, as colorectal cancer is one of the leading causes of cancer deaths in the United States; research found disparities in screening rates for those with Medicaid versus commercially insured.²² The ACR supports the inclusion of this measure in the Core Set. We encourage CMS to follow suit and expand access to CTC for Medicare beneficiaries.

VI. Younger Age Onset of Colorectal Cancer

A disturbing increase in the incidence of colorectal cancer and particularly rectal cancer in younger individuals has come to light in the last decade²³ and has led to a lowering of the screening age recommendation in 2018 by the ACS to age 45 from 50.²⁴ In addition to the 26.1-27.3 million CRC screen-eligible Americans at the age of 50-74, we now add 17.2-18.0 million screen-eligible younger Americans aged 45 to 49, representing a 60% increase from roughly 27-44 million people.²⁵ By 2030, CRC is projected to be the #1 cancer killer in the 20-49-year-old age group.²⁶ However, from 2014-2019 there has been only a corresponding 10% increase in the number of practicing gastroenterologists to accommodate this increased need for colonoscopy.²⁷ While this younger cohort would not normally be covered by CMS if otherwise healthy, this data strongly indicates an enormous potential further strain of limited screening resources now available. Herein lies a tremendous opportunity for expansion of CTC as an additional acceptable screening test and perhaps the “(best test is the) **one that gets done.**” We urge CMS to endorse CTC and to recognize this dire need for an empiric increase in resources brought on by this frightening trend in “young-onset colorectal cancer.”²⁸

VII. NCD reconsideration recommendations to address previous concerns raised by CMS:

Quality & Safety of CTC

²² CMCS Informational Bulletin. (2021, December). 2022 Updates to the Child and Adult Core Health Care Quality Measurement <https://www.medicare.gov/federal-policy-guidance/downloads/cib121021.pdf>

²³ Siegel RL, Fedewa SA, Anderson WF, Miller KD, Ma J, Rosenberg PS, Jemal A. Colorectal Cancer Incidence Patterns in the United States, 1974-2013. *J Natl Cancer Inst.* 2017 Aug 1;109(8):djw322. doi: 10.1093/jnci/djw322. PMID: 28376186; PMCID: PMC605923.

²⁴ Wolf AMD, Fontham ETH, Church TR, Flowers CR, Guerra CE, LaMonte SJ, Etzioni R, McKenna MT, Oeffinger KC, Shih YT, Walter LC, Andrews KS, Brawley OW, Brooks D, Fedewa SA, Manassaram-Baptiste D, Siegel RL, Wender RC, Smith RA. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA Cancer J Clin.* 2018 Jul;68(4):250-281. doi: 10.3322/caac.21457. Epub 2018 May 30. PMID: 29846947.

²⁵ Piscitello A, Edwards DK 5th. Estimating the Screening-Eligible Population Size, Ages 45-74, at Average Risk to Develop Colorectal Cancer in the United States. *Cancer Prev Res (Phila).* 2020 May;13(5):443-448. doi: 10.1158/1940-6207.CAPR-19-0527. Epub 2020 Feb 6. PMID: 32029430.

²⁶ Rahib L, Wehner MR, Matrisian LM, Nead KT. Estimated Projection of US Cancer Incidence and Death to 2040. *JAMA Netw Open.* 2021;4(4):e214708. doi:10.1001/jamanetworkopen.2021.4708

²⁷ Lupis, JC. 20 Statistics About the US Gastroenterology Market. (2021, July). Global Health Advisors. Retrieved from <https://www.ghadvisors.net/research-reports/20-statistics-about-the-us-gastroenterology-market/>

²⁸ Done JZ, Fang SH. Young-onset colorectal cancer: A review. *World J Gastrointest Oncol.* 2021 Aug 15;13(8):856-866. doi: 10.4251/wjgo.v13.i8.856. PMID: 34457191; PMCID: PMC8371519.

CTC has a highly favorable safety profile. Radiation doses of CTC has been reduced to levels similar to annual background levels and much lower than that of a double-contrast barium enema (which is currently covered by Medicare) with continuing progress being made to further reduce doses.^{29, 30, 31, 32}

The risk of perforation is effectively 0% in the screening population (less than 0.02% in the 2016 USPSTF's systematic review) to 0.04% in symptomatic patients.^{33, 34, 35, 36} The low complication risks of CTC make it ideal for older patients, patients with chronic disease, and patients with significant co-morbidities (i.e. the Medicare population).

In 2008, the ACR National Radiology Diagnostic Registry (NRDR) established quality metrics for CTC which have been continuously adopted by those performing CTC into 2021. The metrics are both process measures for diagnostic adequacy of the exam and use of a low radiation dose protocol, along with outcomes measures of positive predictive value (PPV) for large polyps, the incidence of extracolonic findings, and rate of perforation.³⁷ As per the 2019 American College of Radiology Practice Parameters for CTC, polyps 6 mm or greater should be detected and reported by CTC. The recommendation in positive cases is to undergo follow-up colonoscopy for polypectomy in suitable patients and in negative cases a surveillance interval of five years before the next screening CTC.³⁸

Consistency and standardization in reporting findings at CTC have been aided by a reporting structure called the CT Colonography Reporting and Data System (C-RADS), which was developed in 2005.³⁹ C-RADS was modeled after the successful development of BI-RADS (used in mammography) and standardizes the reporting of colonic findings by lesion size, morphology, and location. Importantly, it also develops a per-patient category scale summarizing all colorectal findings, ranging from C0 (incomplete/limited study) to C4 (suspected or known cancer). The C-RADS reporting structure has become widely accepted in clinical practice. In addition to the use of the C-RADS reporting structure for quality assurance, significant efforts by the ACR Incidental Findings Committee have led to numerous

²⁹ Boellaard TN, Venema HW, Streekstra GJ, et al. Effective radiation dose in CT colonography: is there a downward trend? *Acad Radiol.* 2012 Sep;19(9):1127–33.

³⁰ Fletcher JG, Silva AC, Fidler JL, et al. Noncathartic CT colonography: Image quality assessment and performance and in a screening cohort. *Am J Roentgenol.* 2013;201(4):787–94.

³¹ Graser A, Stieber P, Nagel D, et al. Comparison of CT colonography, colonoscopy, sigmoidoscopy and faecal occult blood tests for the detection of advanced adenoma in an average risk population. *Gut.* 2009 Feb;58(2):241–8.

³² Neri E, Faggioni L, Cerri F, et al. CT colonography versus double-contrast barium enema for screening of colorectal cancer: comparison of radiation burden. *Abdom Imaging.* 2010;35(5): 596-601.

³³ Graser A, Stieber P, Nagel D, et al. Comparison of CT colonography, colonoscopy, sigmoidoscopy and faecal occult blood tests for the detection of advanced adenoma in an average risk population. *Gut.* 2009 Feb;58(2):241–8.

³⁴ Bellini D, Rengo M, De Cecco CN, Iafrate F, Hassan C, Laghi A. Perforation rate in CT colonography: a systematic review of the literature and meta-analysis. *Eur Radiol.* 2014;24(7):1487-96.

³⁵ Sosna J, Blachar A, Amitai M, et al. Colonic perforation at CT colonography: assessment of risk in a multicenter large cohort. *Radiology.* 2006;239(2):457-63.

³⁶ Pickhardt PJ. Incidence of colonic perforation at CT colonography: review of existing data and implications for screening of asymptomatic adults. *Radiology.* 2006;239(2):313-6.

³⁷ National Radiology Data Registry (2018, July). CT colonography registry. Retrieved from <https://www.acr.org/Practice-Management-Quality-Informatics/Registries/CT-Colonography-Registry>.

³⁸ American College of Radiology. ACR-SAR-SCBT-MR Practice Parameter for the Performance of Computed Tomography (CT) Colonography in Adults (Resolution 3). Revised 2019. <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/CT-Colonog.pdf>

³⁹ Zalis ME, Barish MA, Choi JR, et al. CT colonography reporting and data system: a consensus proposal. *Radiology* 2005; 236:3–9.

guidelines regarding standardization and optimizing the reporting of incidental findings in radiology.
40,41,42,43,44

Extracolonic Findings at CTC

In addition to the colorectal scores, a similar scale for reporting and management of the extracolonic findings (ECF) was developed and is being incorporated into the ACR CTC quality registry. ECF were raised as a concern by CMS as a source of additional concern for patients and a potential cost burden due to CTC, but it is critical to understand the actual issues of ECF. ECF have led to debate and significant misunderstanding in terms of their incidence and impact in screening cohorts at CTC. Although relatively higher rates have been reported in symptomatic patients, including patients with colon cancer and metastatic disease^{45,46,47}, low rates of clinically significant ECF of 4.5 to 16% have been reported in large screening cohorts.⁴⁸ The vast majority of these findings are incidental and do **not** require additional workup.

It is important to recognize that the reporting of many common findings, such as gallstones or kidney stones, which may or may not be already known, most often do not require further intervention in asymptomatic patients. This issue is not specific to CTC. In a retrospective study of low dose CTC (for purposes of screening or after incomplete colonoscopy), 204 non-Medicare patients (mean age 52) were compared to 250 Medicare patients (mean age 69).⁴⁹ In this study, the percentage of patients with at least one reported ECF was 55.4% in the non-Medicare group and 74.0% in the Medicare group. However, the percentage of patients who were recommended for additional imaging tests based on these findings was **4.4%** in the non-Medicare group and **6.0%** in the Medicare group. Overall, 92% of the Medicare group and 91.8% of the non-Medicare group had ECF that were of low clinical significance (C-RADS scores of

⁴⁰ Berland LL, Silverman SG, Gore RM, et al. Managing incidental findings on abdominal CT: white paper of the ACR incidental findings committee. *J Am Coll Radiol* 2010; 7:754-773.

⁴¹ Patel MD, Ascher SM, Paspulati RM, et al. Managing Incidental Findings on Abdominal and Pelvic CT and MRI, Part 1: White Paper of the ACR Incidental Findings Committee II on Adnexal Findings. *J Am Coll Radiol* 2013;10:675-681.

⁴² Heller MT, Harisinghani M, Neitlich JD, Yeghiayan P, Berland LL. Managing Incidental Findings on Abdominal and Pelvic CT and MRI, Part 3: White Paper of the ACR Incidental Findings Committee II on Splenic and Nodal Findings. *J Am Coll Radiol* 2013;10:833-839.

⁴³ Sebastian S, Araujo C, Neitlich JD, Berland LL. Managing Incidental Findings on Abdominal and Pelvic CT and MRI, Part 4: White Paper of the ACR Incidental Findings Committee II on Gallbladder and Biliary Findings. *J Am Coll Radiol* 2013;10:953-956.

⁴⁴ Doshi AM, Kiritsy M, Rosenkrantz AB. Strategies for avoiding recommendations for additional imaging through a comprehensive comparison with prior studies. *J Am Coll Radiol* 2015;12:657-663.

⁴⁵ Kahn KY, Xiong T, McCafferty I et al. Frequency and impact of extracolonic findings detected at computed tomography in a symptomatic population. *British J of Surgery* 2007;94:355-361.

⁴⁶ Flicker MS, Tsoukas AT, Hazra A. Economic impact of extra-colonic findings at computed tomographic colonography. *J Comput Assist Tomogr* 2008;32:497-503.

⁴⁷ Hellstrom M, Svensson MH, and Lassin A. Extracolonic and incidental findings on CT colonography (virtual colonoscopy). *AJR* 2004; 182:631-638.

⁴⁸ Pickhardt PJ, Choi JR, Hwang I, et al. Computed Tomographic Virtual Colonoscopy to Screen for Colorectal Neoplasia in Asymptomatic Adults. *N Engl J Med* 2003;349:2191-2200.

⁴⁹ Macari M, Nevsky G, Bonavita J, et al. CT colonography in senior versus nonsenior patients: extracolonic findings, recommendations for additional imaging, and polyp prevalence. *Radiology*. 2011 Jun;259(3):767-74.

E1 and E2). These low percentages are highly relevant for your current review of ECF on CTC in moving forward and to debunk the myth of high percentages of ECF on CTC requiring follow-up.

A large meta-analysis of ECF in CTC was published in 2018 including 44 studies of both screening and symptomatic cohorts (49,676 patients) from 1994 to 2017.⁵⁰ The pooled rate of potentially important findings was 4.9% (95% CI 3.7-6.4%). Importantly, with longer-term follow-up of extracolonic findings, this estimate declined over time, averaging a 9% decrease per year since 2006, and was significantly lower with the use of the C-RADS reporting system for CTC. The overall pooled rates of recommended workup were 4.0% for potentially important ECF.

A screening cohort of 2,490 Black adults (85% male) reported a rate of 4% for E4 (potentially important) findings in patients 50 to 80 years old.⁵¹ Another series of over 3,000 low-risk but symptomatic patients was published in 2017, with a rate of 2.0% for E4 ECF findings.⁵² These large series continue to demonstrate the low rates of clinically significant ECF at CTC.

A study comparing ECF rates in screening and diagnostic CTC patient cohorts found low rates in both. 4.6% of patients with E3/E4 findings in the screening cohort demonstrated clinically significant outcomes, compared with 4.0% in the diagnostic cohort, including a total of three extracolonic malignancies (0.8%) and three abdominal aortic aneurysms (0.8%).⁵³ The distribution of extracolonic findings and clinical outcomes were not statistically significantly different between screening and diagnostic CTC populations.

In a 2021 systematic review for USPSTF, 27 studies reported on ECF identified on CTC were reviewed and cited. Approximately 1.3% to 11.4 % of CTCs had potentially important extracolonic findings C-RADS category E4 that necessitated diagnostic follow-up. Additionally, 3.4% to 26.9% of CTCs had C-RADS category E3 findings, some of which may require additional workup because of incompletely characterized findings.⁵⁴ In a 2016 systematic review for the USPSTF, 21 studies reporting on ECF identified on CTC in asymptomatic cohorts were reviewed and cited.⁵⁵ Peer-reviewed screening studies determined a combined rate of E3 and E4 findings of 10% to 15%. Pooler et al. evaluated 7,952 patients who underwent CTC and found an E4 rate of only 2.5%; almost all the 202 E4 patients had confirmed

⁵⁰ Pickhardt PJ, Correlate L, Morra L, Regge D, Hassan C. Extra-colonic findings at CT colonography: systematic review and meta-analysis. *AJR* 2018;211:25-39.

⁵¹ Moreno CC, Fibus TF, Krupinski EA, Kim DH, Pickhardt PJ. Addressing racial disparity in colorectal cancer screening with CT colonography: experience in an African-American Cohort. *Clin Colorectal Cancer*. 2018 Jun;17(2):e363-e367. doi: 10.1016/j.clcc.2018.02.007. Epub 2018 Feb 20.

⁵² Netz FRS, Pickardt PJ, Heijnen MLG, Simons PCD. Detections of potentially relevant extra-colonic findings at CT colonography in a low risk symptomatic patient population. *Abdom Radiol* 2017;42:2799-2806).

⁵³ Taya M, McHargue C, Ricci ZJ, Flusberg M, Weinstein S, Yee J. Comparison of extracolonic findings and clinical outcomes in a screening and diagnostic CT colonography population. *Abdom Radiol*. 2018 Sep 12. doi: 10.1007/s00261-018-1753-3. [Epub ahead of print]

⁵⁴ Lin JS, Perdue LA, Henrikson NB, Bean SI, Blasi PR. Screening for Colorectal Cancer: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. *JAMA*. 2021 May 18;325(19):1978-1998. doi: 10.1001/jama.2021.4417. Erratum in: *JAMA*. 2021 Jul 20;326(3):279. PMID: 34003220.

⁵⁵ Evidence Summary: Colorectal Cancer: Screening. U.S. Preventive Services Task Force. August 2016.

<https://www.uspreventiveservicestaskforce.org/Page/Document/evidence-summary/colorectal-cancer-screening>

findings after workup, demonstrating a clear advantage for the detection of ECF.⁵⁶ The most prevalent E4 findings were extracolonic tumors and abdominal aortic aneurysms. Hassan et al. demonstrated that there were substantial gains in life-years with using a CTC screening strategy compared to CRC screening with colonoscopy, given that the frequency of finding unsuspected abdominal aortic aneurysms and extracolonic malignancies on CTC may exceed the detection rate of CRC in a screening population.⁵⁷ The ACR Incidental findings committee published a comprehensive White Paper in 2010 regarding the management of incidental findings at abdominal CT.⁵⁸ This manuscript outlined important algorithms of how to follow or ignore common incidental findings based on size and morphology in both the general population and patients with limited life expectancy and/or co-morbidity. Since its publication, numerous other publications of this committee have been published,^{59, 60, 61, 62} with algorithms widely promoted at national radiology meetings and incorporated into the “Choosing Wisely” and “Image Wisely” national campaigns.^{63, 64}

One issue not often addressed, but which must be included in discussions on the efficacy of CTC is the benefits of extracolonic diagnoses. There are serious findings that could be discovered to the patient’s benefit, including extracolonic cancers and abdominal aortic aneurysms (AAA). Veerappan et al. reported that the prevalence of EC cancers was equivalent to unsuspected colorectal cancers in their large screening series (n=2,277).⁶⁵ Similar results were seen in a larger screening cohort of over 10,000 patients where the extracolonic cancer prevalence was 0.35% whereas the colorectal cancer prevalence was 0.21%.⁶⁶ The AAA prevalence has been reported at 0.5% (up to 1% in screening males).⁶⁷ The benefits of screening for AAA have already been established for older males — and these can be accurately detected at CTC due to its cross-sectional nature. Hassan et al. modeled the impact of incorporating the impact of extracolonic neoplasms and AAA into CTC screening.⁶⁸ This group demonstrated that there were substantial gains in

⁵⁶ Pooler BD, Kim DH, Pickhardt PJ. Potentially important extracolonic findings at screening CT colonography: incidence and outcomes data from a clinical screening program. *AJR Am J Roentgenol* 2016;206:313-8.

⁵⁷ Hassan C, Pickhardt PJ, Laghi A, et al. Computed tomographic colonography to screen for colorectal cancer, extracolonic cancer, and aortic aneurysm: model simulation with cost-effectiveness analysis. *Arch Intern Med* 2008;168:696-705.

⁵⁸ Berland LL, Silverman SG, Gore RM, et al. Managing incidental findings on abdominal CT: white paper of the ACR incidental findings committee. *J Am Coll Radiol* 2010; 7:754-773.

⁵⁹ Patel MD, Ascher SM, Paspulati RM, Shanbhogue AK, Siegelman ES, Stein MW, Berland LL. Managing Incidental Findings on Abdominal and Pelvic CT and MRI, Part 1: White Paper of the ACR Incidental Findings Committee II on Adnexal Findings. *J Am Coll Radiol* 2013;10:675-681

⁶⁰ Sebastian S, Araujo C, Neitlich JD, Berland LL. Managing Incidental Findings on Abdominal and Pelvic CT and MRI, Part 4: White Paper of the ACR Incidental Findings Committee II on Gallbladder and Biliary Findings. *J Am Coll Radiol* 2013;10:953-956.

⁶¹ Gore RM, Pickhardt PJ, Morteale KJ, Fishman EK, Horowitz JM, Fimmel CJ et al. Management of Incidental Liver lesions on CT: A white paper of the ACR incidental findings committee. *JACR* 2017;14:1429-1437.

⁶² Doshi AM, Kiritsy M, Rosenkrantz AB. Strategies for avoiding recommendations for additional imaging through a comprehensive comparison with prior studies. *J Am Coll Radiol* 2015;12:657-663.

⁶³ Choosing Wisely. <http://www.choosingwisely.org/>

⁶⁴ Image Wisely. <http://www.imagewisely.org/>

⁶⁵ Veerappan GR, Ally MR, Choi JR, et al. Extracolonic findings on CT colonography increases yield of colorectal cancer screening. *AJR*. 2010;195:677-686.

⁶⁶ Pickhardt PJ, Hanson ME. Incidental adnexal masses detected at low-dose noncontrast CT in asymptomatic women over 50 years of age: implications for clinical management and ovarian cancer screening. *Radiology* 2010; 257:144–150.

⁶⁷ Pickhardt PJ, Hanson ME, Vanness DJ, et al. Unsuspected extracolonic findings at screening CT colonography: clinical and economic impact. *Radiology*. 2008;249:151-159.

⁶⁸ Hassan C, Pickhardt PJ, Laghi A, et al. Computed tomographic colonography to screen for colorectal cancer, extracolonic cancer, and aortic aneurysm: model simulation with cost-effectiveness analysis. *Arch Intern Med*. 2008;168:696-705.

life years by CTC screening because of the coincident ability of CTC to detect AAA in addition to detecting colorectal high-risk lesions.

Patient cohorts targeted for CTC

CTC is a minimally invasive test, thus it may be more appealing for specific screening candidates, such as those who are risk-averse or those who refuse more invasive testing. Conscious sedation is not needed and, therefore, no recovery time is required for CTC and no additional sedation-related costs are incurred. CTC is thus suited to any outpatient setting and does not require nursing resources. Patients can drive themselves to and from the procedure, allowing them to immediately return to work or other activities without requiring coordination with another person to transport them. The use of CTC for CRC testing offers effective screening, patient-centered advantages, and lower costs compared with optical colonoscopy, and may be particularly appealing to the currently unscreened population with commercial health insurance. If the availability of CT colonography expands to meet the increased demand for it, CT colonography could cost up to 50% less than optical colonoscopy per screening year.⁶⁹

Given the above, CTC can be a valuable option not only to average-risk patients eligible for CRC screening but also to specific cohorts that may be less well suited for other direct visualization tests. One example is candidates with prior incomplete optical colonoscopy (often due to excessive colonic tortuosity or narrowed sigmoid colon due to diverticulosis). Other examples include patients at risk to undergo colonoscopy (typically from anesthesia or bleeding risks) and some patients with hernias. Older patients, with co-morbidities, can be at higher risk for more invasive screening. Finally, there are patients who refuse to undergo cancer screening. As previously mentioned, several studies have demonstrated the potential of these key procedural differences to increase screening compliance and uptake as well as decrease societal costs and inconvenience.

Cancer screening has been shown to save lives, but there are significant gaps in screening uptake and access to care, including among many populations that often are medically underserved. Published in Feb. 2022, The President's Cancer Panel report, Closing Gaps in Cancer Screening, lays out recommendations focused on connecting people, communities, and systems to increase equity and access. These recommendations are highly relevant to colorectal cancer including facilitating equitable access to cancer screening tests.⁷⁰ Additionally, President Biden's relaunch of the Cancer Moonshot program has a goal of reducing the death rate from cancer by at least 50% over the next 25 years. This is achievable if Medicare coverage supports early detection and cancer screening. There are multiple effective options for colorectal cancer screening including CTC, a validated direct visualization test able to identify pre-cancerous polyps with high sensitivity. We strongly believe there is ample evidence to conclude that CTC is an appropriate colorectal cancer screening test for the Medicare population. This letter provides clear justification for adding CTC to the existing covered CRC screening exams across the diverse and all too frequently unscreened Medicare population.

⁶⁹ Sawhney TG, Pyenson BS, Rotter D, Berrios M, Yee J. Computed Tomography Colonography Less Costly Than Colonoscopy for Colorectal Cancer Screening of Commercially Insured Patients. *Am Health Drug Benefits*. 2018 Oct;11(7):353-361. PMID: 30647823; PMCID: PMC6306102.

⁷⁰ 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. https://prescancerpanel.cancer.gov/report/cancerscreening/pdf/PresCancerPanel_CancerScreening_Feb2022.pdf

The COVID-19 pandemic significantly postponed preventative screening in 2020, with a reported drop of colorectal cancer screening up to 86% relative to screening rates prior to 2020. As the pandemic has fluctuated in 2021 into 2022, safety protocols remain important to screen patients. CTC offers an efficient and safe whole colon structural exam similar to colonoscopy and not offered by stool-based tests, with key advantages to decrease risk and use of personal protective equipment (PPE). CTC has continued to be performed during this time as an urgent or semi-urgent test for certain key indications, including the urgent screening of patients for colorectal cancer prior to organ transplantation.⁷¹

As the pandemic continues and areas of the country continue to experience additional COVID-19 surges, clinicians are experiencing that screening rates are not returning to pre-pandemic baselines. A recent study found that rates of breast and colon cancer screenings remain slightly below historical baselines, down 2.7% and 3.4% respectively. These rates equate to an estimated 68,000 missed breast cancer screenings, 27,000 missed colon cancer screenings, and 9,000 missed cervical cancer screenings from January 2021 through October 2021. To make up for the missed colon cancer screenings in 2020 and 2021, rates would need to exceed the historical weekly average by over 3,800 screenings a week.⁷² Further delays in cancer screening could lead to delayed cancer diagnoses, which will increase morbidity and mortality and exacerbate existing health care disparities, as well as increase health care costs. Ongoing efforts to increase patient access to affordable screenings are critical to our nation's COVID recovery.

⁷¹ Moreno CC, Yee J, Ahmed FS, Barish MA, Brewington C, Dachman AH, Gollub MJ, Kim DH, McFarland E, Pickhardt PJ, Reddy S, Zalis M, Chang KJ. CT Colonography's Role in the COVID-19 Pandemic: A safe(r), socially-distanced total colon examination *Abdominal Radiology* 2021;46:486-490.

⁷² Mast C, Deckert J, Muñoz del Río, A. (2022, January). Troubling Cancer Screening Rates Still Seen Nearly Two Years Into the Pandemic. <https://epicresearch.org/articles/troubling-cancer-screening-rates-still-seen-nearly-two-years-into-the-pandemic>