

POLICY TITLE	VIRTUAL COLONOSCOPY/CT COLONOGRAPHY
POLICY NUMBER	MP-5.045

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**I. POLICY**

Computed tomography (CT) colonography (also known as virtual colonoscopy) may be considered **medically necessary** in patients for whom a conventional colonoscopy is indicated but who are unable to undergo conventional colonoscopy for medical reasons or in patients with an incomplete conventional colonoscopy because of colonic stenosis or obstruction.

Except as noted in the policy statement above, CT colonography is considered **not medically necessary** for the purposes of colon cancer screening because the clinical outcomes with this screening strategy have not been shown to be superior to other approaches including optical colonoscopy.

*Cross-reference:*  
 NA

**II. PRODUCT VARIATIONS**

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[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

- [N] Capital Cares 4 Kids
- [N] PPO
- [N] HMO
- [N] SeniorBlue HMO
- [N] SeniorBlue PPO

- [N] Indemnity
- [N] SpecialCare
- [N] POS
- [Y] FEP PPO\*

\* Refer to FEP Medical Policy Manual MP-6.01.32 Virtual Colonoscopy/CT Colonography The FEP Medical Policy manual can be found at: [www.fepblue.org](http://www.fepblue.org)

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**III. DESCRIPTION/BACKGROUND**

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Computed tomography (CT) colonography, also known as “virtual colonoscopy,” is an imaging technique of the colon involving thin-section helical CT to generate high-resolution 2-dimensional axial images of the colon. Three-dimensional images, which resemble the endoluminal images obtained with conventional endoscopic colonoscopy, are then reconstructed off line. CT colonography has been investigated as an alternative to conventional endoscopic (“optical”) colonoscopy, specifically as an alternative screening technique for colon cancer. While CT colonography requires a full bowel preparation, similar to conventional colonoscopy, no sedation is required, and the examination is less time consuming. However, the technique involves gas insufflation of the intestine, which may be uncomfortable to the patient, and training and credentialing of readers may be needed to achieve optimal performance.

CT colonography may be indicated in patients who have contraindications to conventional colonoscopy or in patients who have incomplete conventional colonoscopy because of colonic obstruction or stenosis. Contraindications to conventional colonoscopy may also include continuous anticoagulation therapy or high anesthesia risk.

**IV. RATIONALE**

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Colon cancer screening prevents morbidity from colon cancer by the detection of early colon cancers and the detection and removal of cancer precursors such as polyps. The detection of cancer and removal of polyps initially or ultimately require an optical colonoscopy.

Computed tomography (CT) colonography (“virtual colonoscopy”) is an imaging procedure that can identify cancers or polyps. The effectiveness and efficiency of virtual colonoscopy is dependent on its capability to accurately identify cancer or polyps, so that all or most patients who have such lesions are appropriately referred for colonoscopy for ultimate diagnosis and treatment and that polyps or cancer are not falsely identified.

**Diagnostic accuracy of CT colonography**

The diagnostic characteristics of CT colonography as a colon cancer screening test have been investigated in many studies in which patients who are referred for optical colonoscopy agree to first undergo a CT colonography. Using a second-look unblinded colonoscopy aided by the results of the CT colonography as the reference standard, the diagnostic characteristics of CT colonography and the blinded colonoscopy can be calculated and compared. The sensitivity of CT colonography is a function of the size of the polyp; sensitivity is poorer for smaller polyps. A 2004 TEC Assessment (1) found variable sensitivity and specificity of CT

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colonography at that time, with many studies showing poor sensitivity. A subsequent meta-analysis of studies that examined the diagnostic performance of CT colonoscopy showed variation between studies but increasing sensitivity for larger polyps. (2) Sensitivity was 48% for detection of polyps smaller than 6 mm, 70% for polyps 6 to 9 mm, and 85% for polyps larger than 9 mm. Characteristics of the CT scanner explained some of the variation between studies. In contrast, specificity was homogeneous (92% for detection of polyps smaller than 6 mm, 93% for polyps 6 to 9 mm, and 97% for polyps larger than 9 mm).

Diagnostic performance of CT colonography is highly dependent on the technology and techniques used. Thus, many of the older studies reviewed may no longer represent currently possible diagnostic performance of the test. A large study published in 2003 showed diagnostic test performance of CT colonography for polyps to be equivalent to that of optical colonoscopy. (3) Other studies showed variable performance, with 2 large studies showing much lower sensitivity than optical colonoscopy. (4, 5) Results from the largest study of a screening population (n>2,500), the American College of Radiology Imaging Network (ACRIN) 6,664 trial, (6) were recently published and reviewed in a 2009 TEC Assessment. (7) This study used 16- to 64-row detector CT scanners, stool-tagging techniques, and minimum training standards for interpreters of the test. The results of this study showed 90% sensitivity of CT colonography for polyps 10 mm or larger and 86% specificity; positive and negative predictive values were 23% and 99%, respectively.

The results of the ACRIN trial may have been dependent on the technical standards required for performance of the test and the training and skill of the interpreters of the test. If these practices can be replicated in the community, then it is likely that improved health outcomes similar to those in the trial can be achieved. Standards of performance and interpretation of CT colonography consistent with those reported in the ACRIN trial will be necessary for CT colonography to be an effective screening test.

A meta-analysis published in 2011 by de Haan et al. (8) of diagnostic characteristics of CT colonography in screening populations showed summary sensitivities and specificities that were similar to prior studies. Estimated sensitivities for polyps or adenomas 10 mm or larger were 83.3% and 97.9%, respectively.

The diagnostic accuracy of CT colonography compared to colonoscopy was assessed in a 2012 study by Zalis et al., using a laxative-free bowel preparation technique for CT colonography. (9) For adenomas 10 mm or larger, the sensitivity of CT colonography was similar but slightly lower than colonoscopy. For smaller adenomas, the sensitivity of CT colonography was lower than colonoscopy.

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Conclusions. There is some variability in the diagnostic accuracy of CT colonography in the literature; this is likely due to the improvement in technical performance over time. The most recent studies have reported that diagnostic accuracy for CT colonography is high and in the same range as optical colonoscopy for polyps greater than 10 mm.

**CT colonography in patients with contraindications to optical colonoscopy**

CT colonography may also be indicated in patients who have contraindications to conventional colonoscopy or in patients who have incomplete conventional colonoscopy because of colonic obstruction or stenosis. A case series by Yucel and colleagues (10) reported on 42 patients older than 60 years (mean: 71 years; range: 60–87 years) referred for CT colonography because of contraindications to the conventional procedure (n=12) or incomplete colonoscopy (n=30). Contraindications included anticoagulation therapy (n=8), increased anesthesia risk (n=3), or poor tolerance for colonoscopy preparation (n=1). The most common reasons for incomplete colonoscopy included diverticular disease, colonic redundancy, adhesions, and residual colonic content. Optimal distension of the entire colon was achieved in 38 patients (90%), and 39 (93%) of the patients had abnormal findings. Extracolonic findings potentially requiring further evaluation or treatment were observed in 26 patients (62%).

**Impact of CT colonography on health outcomes**

There is no direct evidence that evaluates the impact of CT colonography on health outcomes compared to optical colonoscopy. Modeling studies, generally done as part of cost-effectiveness analyses, can provide some insights into the health outcome benefits of CT colonography, as well as provide relevant data on cost-effectiveness.

Given the chain of logic and other underlying evidence that supports the practice of accepted colon cancer screening techniques such as optical colonoscopy, a 90% sensitivity of CT colonography for detection of polyps 10 mm or larger is consistent with an improvement in health outcomes. The 86% specificity of CT colonography would result in some false-positive tests, which, in turn, would result in some unnecessary follow-up colonoscopies. However, compared with optical colonoscopy, there are several other types of health outcomes that may differ in terms of convenience, cost, detection of unrelated health problems, and radiation exposure. These are difficult to quantify and are probably small in magnitude compared to the health benefit of identifying and removing cancer precursors.

As a companion piece to the 2009 clinical TEC Assessment on CT colonography, (7) a 2009 TEC Special Report provided a critical appraisal of cost-effectiveness analyses of CT

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colonography to inform this policy document. (11) Seven published studies were selected. (12-18)

Two studies completely simulated assumptions that are consistent with current diagnostic capability of CT colonography and recommended practice guidelines. (16, 18) In the study by Zauber et al., (18) colonoscopy was slightly more effective and was less expensive than CT colonography. This was based on a model using 1,000 individuals who were 65 years-old. In spite of a somewhat lower per procedure cost, the strategy using CT colonography was found to be more expensive because CT colonography was performed every 5 years (compared to every 10 years for optical colonography), and patients with polyps 6 mm or larger were referred for optical colonoscopy for polyp removal. In this model, the payment for colonoscopy without polypectomy was \$500 and for CT colonography was \$488. In the study by Scherer et al., (16) the model was based on 1,000 individuals aged 50 years. In this analysis, the only model for CT colonography that was more effective than every 10-year optical colonoscopy was CT colonography every 5 years, with removal of polyps 6 mm or larger. Using these assumptions, this CT colonography approach saved 118.5 lives compared to 116.8 for every 10-year optical colonoscopy; the costs of the two approaches were \$2.95 million and \$1.86 million, respectively. In this analysis, the costs of each procedure were comparable, \$523 for CT colonography compared to \$522 for optical colonoscopy without polypectomy. Thus, the outcomes using CT colonography were comparable to optical colonoscopy, yet the CT colonography strategy was more costly. In this study, a sensitivity analysis showed that when the cost of CT colonography was 0.36 that of colonoscopy, CT colonography became less expensive.

A published cost-effectiveness analysis (19) performed by the same authors as a previously published analysis, (12) but applied to a simulated Medicare-age population 65 years and older, reached similar conclusions as the previously published analysis, which also incorporates the benefits of aortic aneurysm screening. Another cost-effectiveness analysis of several colon cancer screening techniques by Heitman et al. (20) compared several colon cancer screening techniques. This review reported that CT colonography was similar in effectiveness to several other established screening techniques but was more expensive and was, therefore a dominated, or unpreferred strategy.

Lansdorp-Vogelaar et al. (21) conducted a systematic review of cost-effectiveness studies of colon cancer screening techniques and found 55 publications relating to 32 unique cost-effectiveness models. CT colonography was evaluated in 8 models. Although CT colonography was deemed cost-effective compared with no screening, it was dominated (i.e., both more expensive and less effective) by established screening strategies in 5 of the

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analyses. They found one study in which CT colonography would be the recommended screening strategy at a cost per life-year gained of less than \$50,000.

None of the aforementioned studies included the costs of anesthesia; costs for colonoscopy may be particularly high when anesthesiologists provide pain control. (MPRM policy 7.02.01 concludes that “Use of monitored anesthesia care is considered not medically necessary for gastrointestinal endoscopic procedures in patients at average risk related to use of anesthesia and sedation.”)

In general, in these cost-effectiveness analyses, colonoscopy was the more effective screening test. CT colonography was a dominant option (more effective and less costly) only in the 1 study that added CT colonography’s benefit of detection of aortic aneurysm and extracolonic cancers. (12) This study also incorporated long-term radiation effects. (12) This benefit of detecting extra-colonic disease was calculated to account for up to 20% of the total health benefit achieved. Most of the benefit was estimated to be from early detection of aortic aneurysms. Screening for aneurysm using ultrasound has been demonstrated to be effective in older (i.e., age 65 or older) men and has been recommended for older male smokers. Screening for the other cancers assumed to be detected has not been shown to be effective. Further research is needed to bolster the data supporting considerable benefit of CT colonography regarding aortic aneurysm, especially in older individuals, and extracolonic cancer detection, as well as the costs and potential health risks of false-positive findings.

Hanly et al. published a systematic review of cost-effectiveness studies of CT colonography in 2012. (22) They concluded that CT colonography is cost-effective compared to no screening. They could not reach a conclusion regarding a comparison to colonoscopy, due to differences in study parameters and assumptions. They note that in early studies colonoscopy dominated CT colonography; that is, was both more effective and less expensive. More recent studies have had variable results, dependent on the threshold for colonoscopy referral and whether the costs and effects of acting upon extra-colonic findings seen on CT colonography are accounted for.

Due to differing assumptions, current studies vary in their evaluation of the comparative costs and effects of CT colonography and colonoscopy with currently available data and practice guidelines. Overall benefit without consideration of costs appears to be similar between the two tests regarding colon cancer prevention. Most studies did not consider the potential benefits of aortic aneurysm detection and extracolonic cancer detection. CT colonography was generally more expensive and in many studies less effective as a screening strategy than colonoscopy, and in other studies only slightly more effective.

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Conclusions. There are no long-term comparative studies that directly report on outcomes of CT colonography compared to optical colonoscopy. The determination of comparative outcomes of CT colonography and optical colonoscopy is complex, due to the differing patterns of follow-up associated with each strategy. Studies of cost-effectiveness have modeled outcomes of the two procedures and generally conclude that outcomes are similar, or that optical colonoscopy results in better outcomes. These analyses assume equal participation rates between the two strategies.

**Impact of CT colonography on colon cancer screening adherence**

Compliance with recommendations for optical colonoscopy is suboptimal. CT colonography has been proposed as an alternative colon cancer screening technique that may improve patient compliance, compared to optical colonoscopy. A literature survey of studies which attempt to determine whether the availability of CT colonography would improve population screening rates found a diffuse literature consisting of survey studies, patient satisfaction studies, and focus group studies. It is unclear how such studies provide a sufficient base of evidence to demonstrate that population adherence to colon cancer screening would improve through CT colonography.

Stoop et al published a randomized controlled trial (RCT) in 2012 that evaluated the impact of CT colonography on colon cancer screening rates. (23) This study was performed in the Netherlands, and members of the general population aged 50-75 years were randomized to an invitation for CT colonography or optical colonoscopy. The CT colonography protocol included a non-cathartic preparation, consisting of iodinated contrast agent given the day before the exam and 1.5 hours before the exam, in conjunction with a low fiber diet. The participation rate in the CT colonography group was 34% (982/2,920), compared to a rate of 22% (1,276/5,924) in the optical colonoscopy group (p<0.0001). The diagnostic yield per patient of advanced polyps was higher in the optical colonoscopy group, at 8.7/100 participants compared to 6.1/100 participants for CT colonography (p=0.02). However, the diagnostic yield of advanced neoplasia per invitee was similar, at 2.1/100 invitees for CT colonography compared to 1.9/100 invitees for optical colonoscopy (p=0.56). These data indicate that the increased participation rates with CT colonography offset the advantages of optical colonoscopy, and that overall outcomes are likely to be similar between the two strategies. It is not known whether the same participation rates would be achieved if CT colonography employed a cathartic preparation, or whether the different preparation regimens affect participation rates.

Conclusions. At least one well-done RCT reports that participation rates are improved with CT colonography compared to optical colonoscopy. The improved screening rate may offset,

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or even outweigh, any benefit of optical colonoscopy on outcomes. However, the available study used a non-cathartic preparation, and it is not certain that similar screening rates would be achieved with a cathartic preparation.

**Summary**

The available evidence supports the conclusion that the diagnostic accuracy of CT colonography is in the same range as optical colonoscopy, with a moderate to high sensitivity and a high specificity for larger polyps. As a result, screening with CT colonography may provide similar diagnostic results to screening using conventional colonoscopy. The majority of modeling studies report that the overall health outcome benefits of a strategy that uses optical colonoscopy likely exceed the benefits of a strategy using CT colonography. However, these analyses assume equal participation rates in screening between the two strategies. Participation in screening may be higher with CT colonography than with optical colonoscopy, and this may ameliorate or offset any improved outcomes associated with optical colonoscopy.

A strategy that employs CT colonography is generally more costly than a strategy that employs optical colonoscopy. This increased cost relates to a more frequent screening interval and the need for subsequent colonoscopy for removal of polyps. Thus, for use in colorectal cancer screening, CT colonography is considered not medically necessary when patients are able to undergo optical colonoscopy. When it is determined at a local level that CT colonography is not more costly than optical colonoscopy, then CT colonography may be considered medically necessary.

For patients who have contraindications to colonoscopy, such as the need for continuous anticoagulation and/or high anesthetic risk, or in patients with an incomplete colonoscopy due to colonic obstruction or stenosis, CT colonography is a reasonable alternative, and therefore may be considered medically necessary.

**Practice Guidelines and Position Statements**

The 2008 edition of colorectal cancer screening guidelines released jointly by the American Cancer Society (ACS), the American College of Radiology, and the U.S. Multisociety Task Force on Colorectal Cancer (24) recognizes two types of screening tests: colon cancer prevention and cancer detection. Colon cancer prevention tests detect both early cancer and adenomatous polyps. The cancer prevention options recommended were flexible sigmoidoscopy every 5 years, colonoscopy every 10 years, double-contrast barium enema every 5 years, or CT colonography every 5 years. For cancer detection, three types of fecal screening tests were supported: annual guaiac-based tests, annual fecal immunochemical



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tests, and stool DNA tests. The ACS endorses colon cancer prevention as the “primary goal of [colorectal cancer] screening” where resources and patient acceptance permit. (24)

In the 2008 clinical guideline statement of the U.S. Preventive Services Task Force (USPSTF) on colorectal cancer screening, (25) the evidence for CT colonography was judged to be insufficient to evaluate the benefits and harms. This guideline was based on concerns about potential harms of radiation exposure and potential for harm due to evaluation of extracolonic findings.

Given that much of the evidence supporting colorectal cancer screening is indirect, it is not so surprising that consensus groups reviewing the same evidence might come to different conclusions, as have the USPSTF and the ACS regarding CT colonography. Although both groups reviewed the same evidence and similar decision models to reach their conclusions, Pignone and Sox (26) suggest that subtle differences in emphasis may underlie the differing conclusions. The USPSTF is more concerned with the potential unknown effects of radiation exposure and workups for extracolonic findings, taking a more longitudinal perspective. The ACS report concentrates on the capability of CT colonography to detect large polyps in a single screening visit as the principal criterion to determine colon cancer prevention. Thus, the ACS report favors screening technologies with superior single-screening detection characteristics over less sensitive tests that have demonstrated efficacy with repeated screening.

A 2006 statement by ACS and the U.S. Multi-Society Task Force on Colorectal Cancer on colonoscopy surveillance after cancer resection recommended that in patients with obstructing colon cancers, CT colonography with intravenous contrast may be used to detect neoplasms in the proximal colon. (27)

A position statement by the American College of Gastroenterology in 2006 (prior to the publication of the ACRIN 6664 trial) also expressed concerns over additional areas of uncertainty such as the radiation risk, interpretation, and management of extracolonic findings, and the cost-effectiveness of CT colonography. (28)

**V. DEFINITIONS**

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**COLONOSCOPY** refers to the visualization of the lower gastrointestinal tract: most often refers to the insertion of a flexible endoscope through the anus to inspect the entire colon and terminal ileum.

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**COMPUTED TOMOGRAPHY** is an x-ray technique that produces a film representing a detailed cross section of tissue structure.

**NONINVASIVE** refers to a device or procedure that does not penetrate the skin or enter any orifice in the body.

**SIGMOIDOSCOPY** refers to the use of a sigmoidoscope (tubular speculum) for examination of the sigmoid colon and the rectum.

**SCREENING** refers to evaluating a patient for diseases such as cancer, heart disease, or substance abuse before they become clinically obvious.

**VI. BENEFIT VARIATIONS**

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

**VII. DISCLAIMER**

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*Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

**VIII. CODING INFORMATION**

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**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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**Covered when medically necessary:**

<b>CPT Codes®</b>							
74261	74262	74263					

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<b>ICD-9-CM Diagnosis Code*</b>	<b>Description</b>
153.0-153.9	MALIGNANT NEOPLASM OF COLON
V76.51	SPECIAL SCREENING FOR MALIGNANT NEOPLASMS, COLON

\*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

**The following ICD-10 diagnosis codes will be effective October 1, 2015:**

<b>ICD-10-CM Diagnosis Code*</b>	<b>Description</b>
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
Z12.11	Encounter for screening for malignant neoplasm of colon

\*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

**IX. REFERENCES**

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**X. POLICY HISTORY**

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<b>MP 5.045</b>	<b>CAC 11/30/10</b> This policy was previously combined in Screening, Diagnosis and Treatment of Colon Cancer. For this review it has been separated into its own policy titled Virtual Colonoscopy/CT Colonography. Adopted BCBSA language.
	<b>CAC 4/24/12</b> Consensus, no policy changes, references updated. FEP variation revised.
	<b>CAC 6/4/13</b> Consensus list review. Administrative code review complete.
	<b>CAC 3/25/14</b> Consensus. No change to policy statements. References updated. Rationale section added.

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