
Medical Policy



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***Current Policy Effective Date: 5/1/22**
(See policy history boxes for previous effective dates)

Title: Virtual Colonoscopy/CT Colonography

Description/Background

Computed tomography (CT) colonography, also known as “virtual colonoscopy,” is an imaging technique of the colon. CTC has been investigated as an alternative to conventional endoscopic (“optical”) colonoscopy, specifically as an alternative screening technique for colon cancer.

Computed tomography colonography (CTC), 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 offline. CTC has been investigated as an alternative to conventional endoscopic (“optical”) colonoscopy, specifically as an alternative screening technique for colon cancer. While CTC 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.

Medical Policy Statement

The safety and effectiveness of virtual colonoscopy (computed tomography colonoscopy) for specified patient populations have been established. It may be considered a useful diagnostic option for selected indications.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Inclusions:

- For 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.

Exclusions:

- Patient preference for virtual colonoscopy vs. conventional colonoscopy
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CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

74261 74262

Other codes (investigational, not medically necessary, etc.):

74263

Rationale

Both computed tomography (CT) colonography and standard optical colonoscopy can be used for the evaluation of a number of disorders of the colon and rectum, most notably colon cancer and colon cancer precursors, but also conditions such as inflammatory bowel disease and diverticulitis/diverticulosis. CTC has been most extensively studied as part of a colon cancer screening strategy.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

CTC for Colon Cancer Screening

Clinical Context and Test Purpose

Diseases of the colon and rectum for which computed tomography colonography (CTC) may be considered as a diagnostic or screening tool include colorectal cancer (CRC) and

precancerous conditions, diverticulosis and diverticulitis, and inflammatory bowel disease. The most widely studied use of CTC is as an alternative screening technique for colon cancer.

The purpose of CTC in patients who are asymptomatic and undergoing CRC screening to prevent morbidity by detecting early colon cancers and detecting and removing cancer precursors such as polyps. The detection of cancer and removal of polyps ultimately requires an optical colonoscopy. CTC is an imaging procedure that can identify cancers or polyps. The effectiveness and efficiency of CTC depends on its ability to identify cancer or polyps accurately, so that all or most patients who have such lesions are appropriately referred for optical colonoscopy for diagnosis and treatment.

The question addressed in this evidence review is: Does the use of CTC improve the net health outcome in patients who are asymptomatic and undergoing CRC screening?

The following **PICOs** were used to select literature to inform this review.

Populations

The relevant population of interest are individuals who are asymptomatic and eligible for CRC screening.

Interventions

The test being considered is CTC. CTC is performed in an outpatient setting or in a hospital or an imaging facility. Results of CTC are assessed by a radiologist.

Comparators

The following tests are currently being used to make decisions about managing patients who are asymptomatic and undergoing CRC screening: optical colonoscopy, sigmoidoscopy, and fecal occult blood test.

Outcomes

The outcomes of interest are disease-specific morbidity and mortality. Beneficial outcomes relate to true positive testing, which leads to detection of disease that would be otherwise missed. Harmful outcomes result from false-negative testing, which may delay diagnosis and management of CRC.

Study Selection Criteria

For the evaluation of clinical validity of the CTC test, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the technology
- Included a suitable reference standard
- Patient clinical characteristics were described
- Patient selection criteria were described.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Systematic Reviews

The diagnostic characteristics of CTC 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 CTC. Using a second-look unblinded colonoscopy aided by the results of the CTC as the reference standard, the diagnostic characteristics of CTC and the blinded colonoscopy can be calculated and compared. The sensitivity of CTC is a function of the size of the polyp; sensitivity is poorer for smaller polyps.

Lin et al (2016) published a systematic review and meta-analysis of literature on CRC screening, conducted for the U.S. Preventive Services Task Force (USPSTF).¹ The investigators identified 9 prospective diagnostic accuracy studies on CTC (total N=6497 patients). Seven studies involved CTC with bowel preparation and 2 involved CTC without bowel preparation. Five studies, including both without bowel preparation, were rated by USPSTF as good quality and the remaining 4 were considered fair quality. In 4 studies of CTC with bowel preparation, the sensitivity to detect adenomas 6 mm or larger ranged from 73% to 98%, and the specificity ranged from 89% to 91%. The sensitivity of CTC to detect adenomas 10 mm or larger (7 studies) ranged from 67% to 94% and the specificity ranged from 96% to 98%. Four (n=481) of the 9 studies also provided data on colonoscopy. The sensitivity for adenomas 6 mm or larger ranged from 75% to 93%, and the sensitivity to detect adenomas 10 mm and larger ranged from 89% to 98%.

In addition, the Lin et al (2016) systematic review evaluated evidence on harms and extracolonic findings associated with CTC. Eleven fair or good quality prospective studies (total N=10,272 patients) suggested little or no risk of serious adverse effects such as perforation. In contrast, Lin et al estimated that, with optical colonoscopy, the risk of perforation was 4 in 10,000 procedures (95% confidence interval [CI], 2 to 5 in 10,000) and the risk of major bleeding was 8 in 10,000 procedures (95% CI, 5 to 14 in 10,000). Radiation exposure is a potential harm of CTC, and many of the studies did not report the extent of radiation exposure. Using data from 4 studies, Lin estimated that the radiation dose of a full-screening CTC examination was about 4.5 to 7 mSv. However, in more recent studies (i.e., published in 2004 to 2008), the estimated radiation dose was lower, about 1 to 5 mSv. Among studies reporting this outcome, extracolonic findings occurred in 27% to 69% of CTC examinations. Approximately 1% to 11% underwent diagnostic evaluation and 3% required treatment. Extracolonic cancers occurred in about 0.5% of individuals undergoing CTC examinations.

A meta-analysis published in 2014 by Martin-Lopez et al that included 9 studies of colorectal cancer screening, excluding studies that were conducted for the diagnosis of colorectal cancer or in elderly, high-risk, or symptomatic patients.² The patient level pooled sensitivity and specificity of CTC were 66.8% (95% CI, 62.7% to 70.8%) and 80.3% (95% CI, 77.7% to 82.8%), respectively. For colonoscopy, the pooled sensitivity was 92.5% (95% CI, 89.0% to 95%) and pooled specificity was 73.2% (95% CI, 67.7% to 78.1%). In the subgroup with larger lesions, the diagnostic accuracy of the 2 approaches was more similar. For lesions 10 mm or larger, CTC had a pooled sensitivity of 91.2% (95% CI, 86.5% to 94.6%) and a specificity of 87.3% (95% CI, 86.2% to 88.3%). The pooled sensitivity of colonoscopy for lesions 10 mm or larger was 92.9% (95% CI, 86.0% to 97.1%) and the specificity was 91.3% (95% CI, 89.9% to 92.5%)

Randomized Controlled Trials

Regge et al (2017) reported on an RCT in which 5412 individuals were randomized to CTC (n=2674) or flexible sigmoidoscopy (n=2738).³ The detection rate for advanced adenomas did not differ significantly between groups (p=0.52). Detection rates were 133 (5.1%) in the CTC group and 127 (4.7%) in the flexible sigmoidoscopy group. Ten CRCs were identified in the CTC group and 9 in the flexible sigmoidoscopy group. No serious adverse events were reported.

More recently, several large RCTs have compared the diagnostic accuracy of CTC to a different method of CRC screening. In the IJspeert et al (2016) study, 8844 individuals were invited to be screened and 2258 (26%) agreed to participate.⁴ This included 982 (34%) of 2920 randomized to CTC and 1276 (22%) of 5924 randomized to standard colonoscopy. The analysis focused on detection of high-risk sessile serrated polyps (SSPs). SSPs were detected significantly more often in colonoscopy examinations (n=55 [4.3%]) than in CTC examinations (n=8 [0.8%]). For the outcome of all SSPs (high and low risk), significantly more were detected with colonoscopy (n=83 [6.5%]) than with CTC (n=21 [2.1%]; p<0.001). Adverse events were not discussed.

Nonrandomized Trials

One of the largest studies of a screening population, the American College of Radiology Imaging Network (ACRIN) trial, was published by Johnson et al in 2008.⁵ Patients underwent CTC prior to standard colonoscopy. The study used 16- to 64-row detector computed tomography scanners, stool-tagging techniques, and minimum training standards for interpreters of the test. A total of 2600 individuals were enrolled, and data were available for 2531 (97%) of them. The results of this trial showed 90% sensitivity of CTC for polyps 10 mm or larger and 86% specificity; positive and negative predictive values were 23% and 99%, respectively. In a follow-up analysis of the ACRIN trial, Fidler et al (2014) demonstrated that CTC had similar sensitivity and specificity in the detection of nonpolypoid adenomas.⁶

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No RCTs comparing outcomes for patients undergoing CTC screening with patients who did not undergo CTC screening were identified.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

A chain of evidence involves evaluating: (1) evidence that CTC is accurate and (2) evidence that CTC identifies appropriate patients with CRC who would not otherwise be screened. The

clinical validity of CTC for screening for CRC has been demonstrated in systematic reviews and meta-analysis studies as well as several large RCTs. While modeling studies have reported that optical colonoscopy is likely more beneficial than CTC,^{7,13} higher participation with CTC may ameliorate otherwise lower improvement in net health outcome compared with optical colonoscopy.

Compliance with recommendations for optical colonoscopy is suboptimal. As reported by Steele et al (2013), the screening rate is about 60% (in the prior 10 years) among people ages 50 to 75.¹⁴ CTC has been proposed as an alternative colon cancer screening technique that may improve patient compliance compared with optical colonoscopy. A literature survey of studies that attempted to determine whether the availability of CTC would improve population screening rates found 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 CTC.

Stoop et al (2012) published an RCT that evaluated the impact of CTC on colon cancer screening rates.¹⁵ This trial was performed in the Netherlands, and members of the general population ages 50 to 75 years were randomized to an invitation for CTC or optical colonoscopy. The CTC protocol included a noncathartic 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 CTC group was 34% (982/2920) compared with a rate of 22% (1276/5924) in the optical colonoscopy group ($p < 0.001$). The diagnostic yield per-patient of advanced polyps was higher in the optical colonoscopy group, at 8.7 of 100 participants compared with 6.1 of 100 participants for CTC ($p = 0.02$). However, the diagnostic yield of advanced neoplasia per invitee was similar, at 2.1 of 100 invitees for CTC and 1.9 of 100 invitees for optical colonoscopy ($p = 0.56$). The data would suggest that the increased participation rates with CTC offset the advantages of optical colonoscopy and that overall outcomes would likely be similar between strategies. It is not known whether the different preparation regimens affected participation rates.

Section Summary: Computed Tomography Colonography for Colon Cancer Screening

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

There are no long-term comparative studies that directly report on outcomes of CTC versus optical colonoscopy. The determination of comparative outcomes of CTC 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 2 procedures and generally concluded that outcomes are similar, or that optical colonoscopy results in better outcomes. These analyses assumed equal participation rates between the 2 strategies.

At least 1 well-done RCT has reported reports that CRC screening participation rates are improved with CTC compared with optical colonoscopy. The improved screening rate may offset, or even outweigh, any benefit of optical colonoscopy on outcomes. However, the available study used a noncathartic preparation, and it is not certain that similar screening rates would be achieved with a cathartic preparation.

CTC for Colon Cancer Diagnosis

Clinical Context and Therapy Purpose

The purpose of CTC in patients who have positive CRC screening or signs and symptoms of CRC is to identify disease.

CTC has not generally been employed as a test to identify the disease in persons with positive cancer screening tests or symptoms because, compared with screening settings, the expected probability of disease is much higher. Findings on CTC require confirmation with colonoscopy; thus it would be inappropriate to use a noninvasive test if the probability of needing a confirmatory invasive test is high.

The question addressed in this evidence review is: Does the use of CTC improve the net health outcome in patients who have positive CRC screening tests or signs or symptoms of CRC?

The following **PICOs** were used to select literature to inform this review.

Populations

The relevant populations of interest are individuals with positive CRC screening tests or signs or symptoms of CRC.

Interventions

The test being considered is CTC.

Comparators

The following tests are currently being used to make decisions about patients who have positive CRC screening or signs and symptoms of CRC: optical colonoscopy and standard care without a colonoscopy.

Outcomes

The outcomes of interest are disease-specific morbidity and mortality. Beneficial outcomes relate to true positive testing, which leads to detection of disease that would be otherwise missed. Harmful outcomes result from false-negative testing, which may delay diagnosis and management of CRC.

Study Selection Criteria

The principles followed to select methodologically credible studies for this section are outlined in the first indication above.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Systematic Reviews

Several studies have evaluated the role of CTC in the diagnosis of colon cancer in patients who have had symptoms or positive findings on other screening modalities (e.g., fecal occult blood testing [FOBT]). In 2014, Plumb et al published findings from a systematic review and meta-analysis of studies evaluating the performance of CTC for the diagnosis of colon cancer

among subjects with positive FOBT.¹⁶ FOBT is a recommended screening technique for colorectal cancer; positive tests are typically followed up with colonoscopy. In this meta-analysis, the authors included only studies that used CTC in the evaluation of patients who had had a positive FOBT and compared colonography results with a reference test, either conventional colonoscopy, segmental unblinded colonoscopy, or surgery with subsequent histopathology. Five articles were included in the authors' analysis, representing 4 studies with 622 patients. Pooled per-patient sensitivity and specificity for adenomas 6 mm or larger or colorectal cancer were 88.8% (95% CI, 83.6% to 92.5%) and 75.4% (95% CI, 58.6% to 86.8%), respectively.

Retrospective Studies

Simons et al (2013) evaluated the false-negative rate and sensitivity of CTC for CRC among patients who presented with symptoms of CRC.¹⁷ The authors included 1855 consecutive patients who underwent CTC at a single center. These data were linked to a comprehensive population-based cancer registry to determine if patients were diagnosed with CRC in the 2 years after their CTC. Fifty-three patients were diagnosed with CRC, of whom 40 patients had suspected CRC, 5 diagnosed with large polyps that appeared malignant on histology, and 5 diagnosed with an indeterminate mass on CTC. Two patients who developed cancer had not been diagnosed on CTC, and 1 patient who developed cancer had had an incomplete colonography. The overall sensitivity of CTC was 94.3% (95% CI, 88% to 100%).

Also in 2014, Plumb et al published findings of a retrospective study comparing results from CTC and optical colonoscopy in patients evaluated at a single center who were indicated for CRC diagnostic assessment because of a positive FOBT.¹⁸ This study was not included in the Plumb 2014 systematic review (described above). Based on the institutional protocol, optical colonoscopy was preferred for individuals with positive FOBT, but CTC substituted if the subject was unable to safely complete colonoscopic bowel preparation, was too frail or immobile to undergo colonoscopy (although potentially fit for necessary treatment), had another contraindication to colonoscopy, or had an incomplete colonoscopy. The study analyzed 2731 FOBT-positive patients screened with CTC as their first screening test. Of these, 1027 (37.6%) had CRC or polyps suspected (95% CI, 33.8% to 41.4%), and 911 underwent confirmatory testing. One hundred twenty-four (4.5%) were found to have CRC and 533 (19.5%) were found to have polyps, for an overall CRC- or polyp-detection rate of 24.1% (95% CI, 21.5% to 24.1%). The positive predictive value for CRC or polyps was 72.1% (95% CI, 66.6% to 77.6%). Colonoscopy data were available for 72,817 FOBT-positive patients who underwent colonoscopy as an initial screening test, among whom 9.0% had CRC and 50.6% had polyps. The authors attributed the difference in CRC and polyp rates between the groups to underlying differences in risk between those referred for CTC and potential biases in the interpretation of screening guidelines.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

Several studies have evaluated the role of CTC for patients with symptoms suggestive of CRC. In 2013, Atkin et al reported results from an unblinded RCT comparing colonoscopy and CTC in the evaluation of patients with symptoms suggestive of CRC.¹⁹ Given the challenges of conducting a trial that would be adequately powered to detect small differences between CTC and colonoscopy in CRC and large polyp detection, the authors used rates of the need for additional evaluation after CTC as a primary outcome, on the assumption that such rates would strongly affect the evaluation of the benefits and costs of the procedure. The study randomly allocated patients ages 55 or older with symptoms suggestive of CRC in a 2:1 fashion to colonoscopy or CTC. Both colonoscopy and CTC procedures were conducted with a full bowel preparation. The trial's primary outcome was the proportion of patients who had additional colonic investigation, defined as any subsequent examination of the colon until diagnosis (usually histologic confirmation of a cancer or polyp) or until a patient was referred back to his or her physician. Additional diagnostic evaluation of the colon was required in 160 (30.0%) of 533 of those assigned to CTC compared with 86 (8.2%) of 1047 of those assigned to colonoscopy ($p < 0.001$). The overall detection rate for CRC or large polyps did not differ between the groups (relative risk, 0.95; 95% CI, 0.70 to 1.27; $p = 0.69$).

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of CTC for colon cancer diagnosis has not been established, a chain of evidence supporting the clinical utility of CTC for this population cannot be constructed.

Section Summary: CTC for Colon Cancer Diagnosis

There are a relatively small number of studies of CTC for diagnosis of CRC in patients with a positive screening test or with symptoms of CRC. A systematic review of CTC studies in patients with a positive FOBT identified only 4 studies and found a reasonably high sensitivity for detecting adenomas 6 mm or larger but a relative low specificity. An RCT comparing CTC with colonoscopy in symptomatic patients found a significantly greater need for additional evaluation after CTC compared with colonoscopy. Because the prevalence of disease is much higher in patients with positive screening tests or symptoms of CRC, going directly to colonoscopy is usually the preferred clinical strategy. Additional studies are needed to determine with certainty the diagnostic accuracy of CTC for diagnosis of CRC; however, for patients unable to undergo a colonoscopy, based on the available evidence, CTC may be a reasonable option.

SUMMARY OF EVIDENCE

For individuals who are asymptomatic and undergoing colorectal cancer (CRC) screening who receive computed tomography colonography (CTC), the evidence includes diagnostic accuracy studies, systematic reviews of diagnostic accuracy studies, and modeling studies on clinical utility. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and treatment-related morbidity. The available evidence supports the conclusion that the diagnostic accuracy of CTC is in the same range as optical colonoscopy, with a moderate-

to-high sensitivity and a high specificity for the detection of larger polyps and CRC. As a result, screening with CTC may provide similar diagnostic results to screening using conventional optical colonoscopy. Most modeling studies have reported that the overall health outcome benefits of a strategy that uses optical colonoscopy likely exceed the benefits of a strategy using CTC. However, these analyses assume equal participation rates in screening between the 2 strategies. Participation in screening may be higher with CTC than with optical colonoscopy, and this may ameliorate or offset any improved outcomes associated with optical colonoscopy. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have positive CRC screening tests or signs or symptoms of CRC who receive CTC, the evidence includes a randomized controlled trial (RCT), diagnostic accuracy studies, and a systematic review of diagnostic accuracy studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and treatment-related morbidity. Using CTC on patients with suspected disease might be an inefficient testing strategy because CTC findings need to be confirmed with conventional colonoscopy. There are a small number of studies on CTC for diagnosis of CRC in patients with a positive screening test or with symptoms of CRC, and thus the diagnostic accuracy cannot be determined with certainty. Studies of patients with a positive fecal occult blood test have suggested a reasonably high sensitivity for detection of adenomas 6 mm or larger but a relatively low specificity. There are fewer studies of patients with CRC symptoms; 1 RCT found that significantly more patients required additional evaluation after CTC than after conventional colonoscopy. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

No ongoing clinical trials were identified.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND CONSENSUS STATEMENTS

American College of Physicians

In 2019, the American College of Physicians updated its guidelines for colorectal cancer (CRC) screening.²³ The American College of Physicians recommends 1 of the following 3 strategies for adults aged 50-75 years:

- High-sensitivity guaiac-based fecal occult blood test or fecal immunochemical test every 2 years.
- Fecal immunochemical test every 2 years plus flexible sigmoidoscopy every 10 years.
- Colonoscopy every 10 years.

The guideline stated that computed tomography colonography (CTC) may result in incidental extracolonic findings in 40% to 70% of screening examinations that may lead to additional evaluations and overtreatment. Screening intervals are more frequent for CTC, and positive findings on CTC require follow-up with colonoscopy.

American Cancer Society and the U.S. Multi-Society Task Force on Colorectal Cancer

The American Cancer Society (2018) updated its guidelines on CRC screening (see Table 1).²¹ ACS made the following recommendations on colon cancer screening:

“The ACS recommends that adults aged 45 years and older with an average risk of colorectal cancer undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) examination, depending on patient preference and test availability.... The recommendation to begin screening at age 45 years is a qualified recommendation. The recommendation for regular screening in adults aged 50 years and older is a strong recommendation.”

CTC was listed as an option for CRC screening (see Table 1) and was acknowledged to have comparable sensitivity and specificity to a colonoscopy. Stated limitations associated with CTC included exposure to low-dose radiation as well as complications of a full bowel preparation, including rare cases of bowel perforation. It remains unclear whether incidental detection of extracolonic findings during CTC provides net benefit or harm to patients.

Table 2. Guidelines on Colorectal Cancer Screening Options

Stool-based tests	
	<ul style="list-style-type: none"> • Stool-based test • Fecal immunochemical test every year • High-sensitivity, guaiac-based fecal occult blood test every year • Multitarget stool DNA test every 3 years
Structural examinations	
	<ul style="list-style-type: none"> • Colonoscopy every 10 years • CT colonography every 5 years • Flexible sigmoidoscopy every 5 year

American College of Gastroenterology

In 2017, the American College of Gastroenterology published recommendations of the U.S. Multi-Society Task Force of Colorectal Cancer made up of expert gastroenterologists from the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy.²² The panel recommended CRC screening beginning at age 50 with adjustments based on race and family history using a ranked-tiered CRC screening approach in Table 2. Considerations for recommending the tiered system of current CRC screening tests included performance, cost, patient acceptance, and the lack of randomized trial results that directly compare the effects of different tests on CRC incidence or mortality.

Table 3. Colorectal Cancer Screening Tier Strategy

Tier	Recommendation
Tier 1	<ul style="list-style-type: none"> • Colonoscopy every 10 y • Annual fecal immunochemical test
Tier 2	<ul style="list-style-type: none"> • CTC every 5 y • Fecal immunochemical test-fecal DNA every 3 y • Flexible sigmoidoscopy every 10 y (or every 5 y)
Tier 3	<ul style="list-style-type: none"> • Capsule colonoscopy every 5 y
Available tests not currently recommended	<ul style="list-style-type: none"> • Septin 9

In 2021, the American College of Gastroenterology released updated CRC screening guidelines.²⁵ The guidelines recommend CRC screening in average risk individuals between 50 to 75 years of age (strong recommendation; moderate quality of evidence) and suggest CRC screening in average risk individuals between 45 to 49 years of age (conditional recommendation; very low quality of evidence) to reduce the incidence of advanced adenoma, CRC, and mortality from CRC. The guideline recommends “colonoscopy and fecal immunochemical testing as the primary screening modalities for CRC screening” (strong recommendation; low quality of evidence). Flexible sigmoidoscopy, multitarget stool DNA testing, CTC, or colon capsule are suggested for consideration for individuals unable or unwilling to undergo a colonoscopy or fecal immunochemical testing (conditional recommendation; very low quality of evidence). The guidelines recommend that fecal immunochemical testing should be performed every year and colonoscopy every 10 years (strong recommendation; low quality of evidence) and suggest that a multitarget stool DNA test be performed every 3 years, flexible sigmoidoscopy every 5 to 10 years, CTC every 5 years, and colon capsule every 5 years (conditional recommendation; very low quality of evidence).

American College of Radiology

The American College of Radiology (2018) updated its 2014 appropriateness criteria on imaging tests for CRC screening.^{24, 25} While CTC was not recommended for screening of patients at high risk for CRC, was appropriate for screening in the following populations:

- Average-risk individual, >50 years old
- Moderate-risk individual with a first-degree family history of cancer or adenoma
- Average-, moderate-, or high-risk individual with incomplete colonoscopy.
- CTC was also appropriate for CRC detection in moderate-risk individuals, and in average-risk individuals after positive fecal screening tests (fecal occult blood test or fecal immunochemical test).

National Comprehensive Cancer Network

Per the National Comprehensive Cancer Network (NCCN), colonoscopy is “the most complete screening procedure and is considered the current gold standard for assessing the severity of detecting neoplasia for other screening modalities. The general consensus is that a 10-year interval is appropriate for most average risk individuals who had a high-quality normal colonoscopy...”³⁰ Regarding CTC, the NCCN guideline states that CTC “is evolving as a promising technique for CRC screening. CT colonography has the advantages of being noninvasive and not requiring sedation. The risk of test-related complications is also very low....CT colonography may be cost-effective when compared to colonoscopy. However, a positive finding requires a colonoscopy, and extracolonic findings – which are present in up to 16% of patients – pose a dilemma.”

U.S. Preventive Services Task Force Recommendations

In 2021, the U.S. Preventive Services Task Force (USPSTF) updated its recommendations on CRC screening.²⁸ The recommendations included the following:

Adults 45 to 49 years old:

“The USPSTF recommends screening for CRC in adults aged 45 to 49 years.” (Grade B)

Adults 50 to 75 years old:

“The USPSTF recommends screening for colorectal cancer in all adults aged 50 to 75 years (Grade A)

Adults 76-85 years old:

“The USPSTF recommends that clinicians selectively offer screening for CRC in adults aged 76 to 85 years. Evidence indicates that the net benefit of screening all persons in this age group is small. In determining whether this service is appropriate in individual cases, patients and clinicians should consider the patient’s overall health, prior screening history, and preferences.”

Regarding evidence of efficacy for CT colonography, the USPSTF stated:

- “Evidence available that CT colonography has reasonable accuracy to detect CRC and adenomas;
- No direct evidence evaluating effect of CT colonography on CRC mortality;
- Limited evidence about the potential benefits or harms of possible evaluation and treatment of incidental extracolonic findings, which are common. Extracolonic findings detected in 1.3% to 11.4% of examinations; <3% required medical or surgical treatment.”

The USPSTF also noted that “more studies evaluating the direct effectiveness of screening with CT colonography on CRC mortality are needed, as well as more studies that report on long-term consequences of identifying extracolonic findings on CRC screening.”

Government Regulations

National:

CAG-00396N

On May 12, 2009, the Centers for Medicare and Medicaid Services published a decision memo for CT colonography screening that states “The evidence is inadequate to conclude that CT colonography is an appropriate colorectal cancer screening test under §1861(pp)(1) of the Social Security Act. CT colonography for colorectal cancer screening remains noncovered.”²⁷

Local:

WPS Medicare Legacy Part B, “CT Colonography (Virtual Colonoscopy [VC]) (L30300).”
For services performed on or after 10/01/2015: Retired.

Coverage Indications, Limitations, and/or Medical Necessity

Indications

1. CT colonography also known as “Virtual Colonoscopy” (VC) utilizes helical computed tomography of the abdomen and pelvis to visualize the colon lumen, along with 2D or 3D reconstruction. The test requires colonic preparation similar to that required for flexible colonoscopy, and air insufflation to achieve colonic distention. Both 2D and 3D evaluation of a colon adequately distended and cleansed of stool should be performed using software and hardware designed for 2D and 3D evaluation.
2. CT colonography is indicated in those patients in whom a *diagnostic* (performed for signs/symptoms of disease) optical colonoscopy (OC) of the entire colon is incomplete. Failure to complete the OC may be secondary to conditions such as, but not limited to, an

obstructing neoplasm, stricture, tortuosity, spasm, redundant colon, diverticulitis, extrinsic compression or aberrant anatomy/scarring from prior surgery.

3. CT colonography is indicated when utilized in pre-operative cancer staging and the determination of colonic wall invasion.
4. If during the course of a screening OC a condition is found, or a complication is encountered which results in the conversion of the screening OC into a diagnostic OC, and the diagnostic OC cannot be completed because of complicating conditions (see #2 above), VC would be covered.
5. CT colonography is also indicated for the evaluation of a submucosal abnormality detected on colonoscopy or other imaging study.
6. CT colonography is indicated in patients with serious coagulopathies and anticoagulated patients in whom it would be hazardous to discontinue anticoagulation therapy.
7. In patients with a history of previous incomplete OC and/or serious complication during OC, the reason for such incomplete and/or complicated OC being a condition which is unlikely to improve (extreme tortuosity, abdominal adhesions, etc.), CT colonography is covered as an alternative to *diagnostic* (not screening) OC.
8. In patients with previously documented, usually by barium enema, conditions which make OC unsafe (extreme tortuosity, etc.), CT colonography is covered as an alternative to *diagnostic* (not screening) OC.

Limitations

1. The screening colonoscopy benefit being under national (CMS) authority and, therefore, not under Carrier discretion, CT colonography is never covered, under the auspices of this LCD, when screening (in the absence of signs or symptoms of disease) OC is incomplete due to any of the above reasons.
2. CT colonography is never covered when used for screening (in the absence of signs or symptoms of disease) regardless of family history or other risk factors for the development of colonic disease.
3. CT colonography is never covered when used as an *elective alternative* to OC, for screening (in the *absence of signs or symptoms* of disease).
4. Since any CT colonography showing abnormal or suspicious findings would require a subsequent OC for diagnosis (e.g., biopsy) or for treatment (e.g., polypectomy), CT colonography is never covered when used as an *elective alternative* to OC, even though performed for signs or symptoms *of disease* (*diagnostic* OC). (38)

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January 2022, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
6/16/03	6/16/03	6/20/03	Joint medical policy established
9/5/04	9/5/04	9/31/04	Routine maintenance
9/7/05	9/7/05	8/26/05	Routine maintenance
11/1/06	9/14/06	9/18/06	Change medical policy statement to “established” for specific patient populations.
11/1/07	8/21/07	10/31/07	Routine maintenance
7/1/09	4/21/09	4/21/09	Routine maintenance; CMS criteria updated.
7/1/10	4/20/10	4/20/10	Code update; deleted 0066T and 0067T, replaced with 74261, 74262 and 74263
9/1/12	6/12/12	6/19/12	Reformatted policy to BCBSA mirror BCBSA policy.
9/1/13	6/19/13	6/26/13	Routine maintenance; title changed from “Virtual Colonoscopy (Computed Tomography Colonoscopy – CTC)” to “Virtual Colonoscopy/CT Colonography.”
5/1/15	2/17/15	2/27/15	Routine maintenance References 9, 11, 26-29, 31, and 36 added. Rationale section extensively reorganized.
7/1/16	4/19/16	4/19/16	Routine maintenance with updates in references and rationale.
5/1/17	2/21/17	2/21/17	Rationale section reorganized and updated along with references (added 2, 6, 7, removed 31, 32, and 34). No policy status change.
5/1/18	2/20/18	2/20/18	Routine policy maintenance, no change in policy status.
5/1/19	2/19/19		Routine policy maintenance, no change in policy status.
5/1/20	2/18/20		Routine policy maintenance. No change in policy status.

5/1/21	2/16/21		Routine policy maintenance. No change in policy status.
5/1/22	2/15/22		Routine policy maintenance, no change in policy status.

Next Review Date: 1st Qtr. 2023

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: VIRTUAL COLONOSCOPY/CT COLONOGRAPHY

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Diagnostic CTC-Covered; criteria apply. Screening-Not covered.
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.