BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 6.01.32 Virtual Colonoscopy/Computed Tomography Colonography

Annual Effective Policy Date: January 1, 2024

Original Policy Date: December 2011

Related Policies:

None

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Description

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Computed tomography colonography (CTC), also known as virtual colonoscopy, is an imaging modality that has been investigated as an alternative to conventional endoscopic ("optical") colonoscopy. It has been most widely studied as an alternative screening technique for colon cancer, and for the diagnosis of colorectal cancer (CRC) in people with related symptoms and for other colorectal conditions.

OBJECTIVE

The objective of this evidence review is to determine whether computed tomography colonography improves the net health outcome in individuals who are asymptomatic being screened for colorectal cancer or have positive screening results for colorectal cancer.

POLICY STATEMENT

Computed tomography colonography (CTC) may be considered **medically necessary** for the purposes of colon cancer screening.

Computed tomography colonography may be considered **medically necessary** in individuals for whom a conventional colonoscopy is indicated but who are unable to undergo conventional colonoscopy for medical reasons (see Policy Guidelines section); CTC may also be considered **medically necessary** for individuals with an incomplete conventional colonoscopy because of colonic stenosis or obstruction.

Except for the indications outlined in the policy statements above, CTC is considered **investigational**.

POLICY GUIDELINES

Computed tomography colonography should be performed with a minimum 16-row detector computed tomography scanner.

Having adequate training was an important component of CTC clinical trials.

Contraindications to conventional colonoscopy may include continuous anticoagulation therapy or high anesthesia risk.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Multiple computed tomography devices, including multiple CTC devices, have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA product code: JAK.

RATIONALE

Summary of Evidence

For individuals who are asymptomatic and undergoing colorectal cancer (CRC) screening who receive Computed tomography colonography (CTC), the evidence includes systematic reviews with meta-analysis, randomized and nonrandomized controlled trials, and modeling studies. Relevant outcomes are overall survival (OS), 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 or slightly below 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 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 strategies. Participation in screening may be higher with CTC, which has reduced or no cathartic preparation, than with optical colonoscopy, and this may ameliorate or offset some improved outcomes associated with optical colonoscopy. The evidence is sufficient to determine that the technology results in an 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 systematic reviews with meta-analysis, a randomized controlled trial, and cohort 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; the randomized controlled trial found that significantly more patients required additional evaluation after CTC than after conventional colonoscopy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Physicians

In 2023 , the American College of Physicians updated its guidelines for colorectal cancer (CRC) screening. [24,] The American College of Physicians recommends 1 of the following 3 strategies for screening in asymptomatic average-risk adults aged 50 to 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 that are potentially important and required follow-up in 3.4% to 26.9% of screening examinations. Positive findings on CTC require follow-up with colonoscopy, which limits the utility of CTC as a direct visualization test.

American Cancer Society

In 2018, the American Cancer Society (ACS) updated its guidelines on CRC screening (Table 1).[25,] The 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."

Computed tomography colonography was listed as an option for CRC screening (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 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 1. American Cancer Society Guidelines on Colorectal Cancer Screening Options

Colorectal Cancer Screening Guidelines
Stool-based test
Fecal immunochemical test every 1 y
High-sensitivity, guaiac-based fecal occult blood test every 1 y
Multitarget stool DNA test every 3 y
Structural test
Colonoscopy every 10 y
Computer tomography colonography every 5 y

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.[26,] The panel recommended CRC screening beginning at age 50 years 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 2. American College of Gastroenterology Colorectal Cancer Screening Tier Strategy

Tier	Recommendation
Tier 1	• Colonoscopy every 10 y • Annual fecal immunochemical test
Tier 2	• Computed tomography colonography every 5 y • Fecal immunochemical test-fecal DNA every 3 y • Flexible sigmoidoscopy every 10 y (or every 5 y)
Tier 3	• Capsule colonoscopy every 5 y
Available tests not currently recommended	• Septin 9

In 2021, the American College of Gastroenterology released updated CRC screening guidelines.[27,] 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

In 2018, the American College of Radiology updated its 2014 appropriateness criteria on imaging tests for CRC screening.[28,29,] While CTC was not recommended for screening of patients at high-risk for CRC, it 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.

Computed tomography colonography 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) guideline on colorectal cancer screening (v1.2023), 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. These findings require further investigations and have a potential for both benefit and harm. At the present time, data to determine the clinical impact of these incidental findings are insufficient."

U.S. Preventive Services Task Force Recommendations

In 2021, the U.S. Preventive Services Task Force (USPSTF) updated its recommendations on CRC screening.[31,] The recommendations included the following:

Adults 50 to 75 years old:

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

Adults 45 to 49 years old:

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

Adults 76 to 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."

- (Grade C)

Regarding evidence of efficacy for CTC, 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."

Medicare National Coverage

In 2009, the Centers for Medicare & Medicaid Services published a noncovered national decision memo on CTC screening.[32,]

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
March 2013	Replace policy	Policy and references updated with literature search. Policy statement revised.
September 2014	Replace policy	Policy updated with literature review. Multiple references added.Rationale section extensively reorganized. Policy statement added to state that CT colonography may be considered medically necessary for colon cancer screening.
December 2016	Replace policy	Policy updated with literature review through July 24, 2016; references 2, 6-7, and 28 added. The parenthetical referring to contractual impact and language regarding equivalence were removed from the second policy statement. Policy statements are otherwise unchanged. The term "equivalent, was changed to "similar in the Policy Guidelines and Benefit Application sections.
December 2017	Replace policy	Policy updated with literature review through July 20, 2017; no references added; note 24 updated. Policy statements unchanged.
December 2018	Replace policy	Policy updated with literature review through July 26, 2018; reference 21 added. CTC for colorectal screening information removed due to benefit considerations (Colorectal cancer screening is addressed in the Preventative Section of the brochure) otherwise policy statement unchanged.
December 2019	Replace policy	Policy updated with literature review through July 8, 2019; no references added. Policy statement unchanged.
December 2020	Replace policy	Policy updated with literature review through August 5, 2020; references added. Policy statement unchanged.
December 2021	Replace policy	Policy updated with literature review through July 26, 2021; references added. Policy statement unchanged.
December 2022	Replace policy	Policy updated with literature review through August 5, 2022; no references added. Change: CTC for colorectal screening added as medical necessary to Policy statement.Minor editorial refinements to policy statements; intent unchanged.
December 2023	Replace policy	Policy updated with literature review through July 28, 2023; references added. Policy statement unchanged.