



FEP Medical Policy Manual

FEP 6.01.32 Virtual Colonoscopy/Computed Tomography Colonography

Effective Policy Date: January 1, 2021

Related Policies:

Original Policy Date: December 2011

None

Virtual Colonoscopy/Computed Tomography Colonography

Description

Computed tomography colonography (CTC), also known as virtual colonoscopy, is an imaging modality that uses thin-section helical computed tomography 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. 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.

OBJECTIVE

The objective of this evidence review is to determine whether computed tomography colonography improves the net health outcome in individuals who have positive screening results for colorectal cancer. Use in individuals who are asymptomatic being screened for colorectal cancer is not addressed in this policy.

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POLICY STATEMENT

Computed tomography colonography (CTC) 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 (see Policy Guidelines section); CTC may also be considered **medically necessary** for patients 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

CTC 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 have positive colorectal cancer screening (CRC) screening tests or signs or symptoms of CRC who receive computed tomography colonography (CTC), the evidence includes systematic reviews with meta-analysis, a randomized controlled trial (RCT), and cohort studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and treatment-related morbidity. Using CTC on patients with the 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 (FOBT) 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 RCT found that significantly more

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patients required additional evaluation after CTC than after conventional colonoscopy. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position 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

In 2018, the American Cancer Society (ACS) updated its guidelines on CRC screening (Table 1).²⁴ 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."

CTC 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. 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

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Computer tomography colonography every 5 y
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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.²⁵ 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 2. 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"> 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	<ul style="list-style-type: none"> Capsule colonoscopy every 5 y
Available tests not currently recommended	<ul style="list-style-type: none"> Septin 9

American College of Radiology

In 2018, the American College of Radiology updated its 2014 appropriateness criteria on imaging tests for CRC screening.^{26,27} 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.

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).

U.S. Preventive Services Task Force Recommendations

In 2016, the USPSTF updated its recommendations on CRC screening.²⁸ The recommendations included the following:

Adults 50 to 75 years old:

"The USPSTF recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years." (Grade A)

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Adults 76 to 85 years old:

"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.

- Adults in this age group who have never been screened for colorectal cancer are more likely to benefit.
- Screening would be most appropriate among adults who 1) are healthy enough to undergo treatment if colorectal cancer is detected and 2) do not have comorbid conditions that would significantly limit their life expectancy." (Grade C)

In a section on clinical considerations, USPSTF stated that evidence on CTC is limited to studies on test characteristics and that CTC can result in incidental extracolonic findings. The USPSTF also noted indirect harms resulting from standard colonoscopy performed for positive CTC findings.

The USPSTF (2016) recommendations did not include a specific statement on screening with CTC.

The USPSTF is currently in the process of updating these recommendations.

Medicare National Coverage

In 2009, the Centers for Medicare & Medicaid Services published a noncovered national decision memo on CTC screening.²⁹

REFERENCES

1. Lin JS, Piper MA, Perdue LA, et al. Screening for Colorectal Cancer: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. *JAMA*. Jun 21 2016; 315(23): 2576-94. PMID 27305422
2. Martin-Lopez JE, Beltran-Calvo C, Rodriguez-Lopez R, et al. Comparison of the accuracy of CT colonography and colonoscopy in the diagnosis of colorectal cancer. *Colorectal Dis*. Mar 2014; 16(3): O82-9. PMID 24299052
3. Regge D, Iussich G, Segnan N, et al. Comparing CT colonography and flexible sigmoidoscopy: a randomised trial within a population-based screening programme. *Gut*. Aug 2017; 66(8): 1434-1440. PMID 27196588
4. IJspeert JE, Tutein Nolthenius CJ, Kuipers EJ, et al. CT-Colonography vs. Colonoscopy for Detection of High-Risk Sessile Serrated Polyps. *Am J Gastroenterol*. Apr 2016; 111(4): 516-22. PMID 27021193
5. Sali L, Mascacchi M, Falchini M, et al. Reduced and Full-Preparation CT Colonography, Fecal Immunochemical Test, and Colonoscopy for Population Screening of Colorectal Cancer: A Randomized Trial. *J Natl Cancer Inst*. Feb 2016; 108(2). PMID 26719225
6. Weinberg DS, Pickhardt PJ, Bruining DH, et al. Computed Tomography Colonography vs Colonoscopy for Colorectal Cancer Surveillance After Surgery. *Gastroenterology*. Mar 2018; 154(4): 927-934.e4. PMID 29174927
7. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Special Report: Critical appraisal of CT colonography cost-effectiveness analyses. *TEC Assessments*. 2009;Volume 24:Tab 2.
8. Scherer R, Knudsen AB, Pearson SD. Health Technology Assessment: Computed Tomographic Colonography (CTC). Olympia, WA: Health Technology Assessment Program, Washington State Health Authority; 2008.
9. Zauber A, Knudsen AB, Rutter C, et al. Cost-effectiveness of CT colonography to screen for colorectal cancer. Rockville, MD: Agency for Healthcare Research and Quality; 2009.
10. Heitman SJ, Hilsden RJ, Au F, et al. Colorectal cancer screening for average-risk North Americans: an economic evaluation. *PLoS Med*. Nov 23 2010; 7(11): e1000370. PMID 21124887
11. Lansdorp-Vogelaar I, Knudsen AB, Brenner H. Cost-effectiveness of colorectal cancer screening. *Epidemiol Rev*. 2011; 33: 88-100. PMID 21633092
12. Hassan C, Pickhardt PJ, Pickhardt P, et al. Computed tomographic colonography to screen for colorectal cancer, extracolonic cancer, and aortic aneurysm: model simulation with cost-effectiveness analysis. *Arch Intern Med*. Apr 14 2008; 168(7): 696-705. PMID 18413551
13. Hanly P, Skally M, Fenlon H, et al. Cost-effectiveness of computed tomography colonography in colorectal cancer screening: a systematic review. *Int J Technol Assess Health Care*. Oct 2012; 28(4): 415-23. PMID 23006522
14. Steele CB, Rim SH, Joseph DA, et al. Colorectal cancer incidence and screening - United States, 2008 and 2010.. *MMWR*. Nov 22 2013; 62(3): 53-60. PMID 24264490

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15. Stoop EM, de Haan MC, de Wijkerslooth TR, et al. Participation and yield of colonoscopy versus non-cathartic CT colonography in population-based screening for colorectal cancer: a randomised controlled trial. *Lancet Oncol.* Jan 2012; 13(1): 55-64. PMID 22088831
16. Zhu H, Li F, Tao K, et al. Comparison of the participation rate between CT colonography and colonoscopy in screening population: a systematic review and meta-analysis of randomized controlled trials. *Br J Radiol.* Jan 2020; 93(1105): 20190240. PMID 31651188
17. Plumb AA, Halligan S, Pendse DA, et al. Sensitivity and specificity of CT colonography for the detection of colonic neoplasia after positive faecal occult blood testing: systematic review and meta-analysis. *Eur Radiol.* May 2014; 24(5): 1049-58. PMID 24519111
18. Bai W, Yu D, Zhu B, et al. Diagnostic accuracy of computed tomography colonography in patients at high risk for colorectal cancer: a meta-analysis. *Colorectal Dis.* Apr 11 2020. PMID 32277562
19. Simons PC, Van Steenberghe LN, De Witte MT, et al. Miss rate of colorectal cancer at CT colonography in average-risk symptomatic patients. *Eur Radiol.* Apr 2013; 23(4): 908-13. PMID 23085864
20. Plumb AA, Halligan S, Nickerson C, et al. Use of CT colonography in the English Bowel Cancer Screening Programme. *Gut.* Jun 2014; 63(6): 964-73. PMID 23955527
21. Sha J, Chen J, Lv X, et al. Computed tomography colonography versus colonoscopy for detection of colorectal cancer: a diagnostic performance study. *BMC Med Imaging.* May 18 2020; 20(1): 51. PMID 32423413
22. Atkin W, Dadswell E, Wooldrage K, et al. Computed tomographic colonography versus colonoscopy for investigation of patients with symptoms suggestive of colorectal cancer (SIGGAR): a multicentre randomised trial. *Lancet.* Apr 06 2013; 381(9873): 1194-202. PMID 23414650
23. Qaseem A, Crandall CJ, Mustafa RA, et al. Screening for Colorectal Cancer in Asymptomatic Average-Risk Adults: A Guidance Statement From the American College of Physicians. *Ann Intern Med.* Nov 05 2019; 171(9): 643-654. PMID 31683290
24. 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.* Jul 2018; 68(4): 250-281. PMID 29846947
25. Rex DK, Boland CR, Dominitz JA, et al. Colorectal Cancer Screening: Recommendations for Physicians and Patients From the U.S. Multi-Society Task Force on Colorectal Cancer. *Gastroenterology.* Jul 2017; 153(1): 307-323. PMID 28600072
26. Yee J, Kim DH, Rosen MP, et al. ACR Appropriateness Criteria colorectal cancer screening. *J Am Coll Radiol.* Jun 2014; 11(6): 543-51. PMID 24793959
27. Moreno C, Kim DH, Bartel TB, et al. ACR Appropriateness Criteria (R) Colorectal Cancer Screening. *J Am Coll Radiol.* May 2018; 15(5S): S56-S68. PMID 29724427
28. U.S. Preventive Services Task Force. Final Recommendation Statement. Colorectal Cancer: Screening. June 15, 2016; <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening>. Accessed July 27, 2020.
29. Centers for Medicare & Medicaid Services. Decision memo for screening computed tomography colonography (CTC) for colorectal cancer (CAG-00396N). May 12, 2009; [https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=220&TAId=58&NcaName=Screening+Computed+Tomography+Colonography+\(CTC\)+for+Colorectal+Cancer](https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=220&TAId=58&NcaName=Screening+Computed+Tomography+Colonography+(CTC)+for+Colorectal+Cancer). Accessed July 27, 2020.

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.

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Date	Action	Description
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.

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