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Medical Policy Manual

Topic: Virtual Colonoscopy/CT Colonography

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Section: Radiology

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Computed tomography colonography (CTC), also known as "virtual colonoscopy," is an imaging technique that uses thin-section helical CT to generate high-resolution 2-dimensional images of the colon. From these images, three-dimensional pictures may then be reconstructed which resemble the images obtained with conventional endoscopic ("optical") colonoscopy.

CTC has been investigated as an alternative screening technique to colonoscopy for colorectal cancer (CRC). While CTC requires a full bowel preparation, similar to conventional colonoscopy, no sedation is required. However, the technique involves gas insufflation of the intestine, which may be uncomfortable to the patient.

MEDICAL POLICY CRITERIA

I. Computed tomography (CT) colonography may be considered **medically necessary** for patients who meet one of the following criteria:

   A. A conventional colonoscopy is indicated but the patient is unable to undergo conventional colonoscopy for medical reasons (eg, continuous anticoagulation therapy or high anesthesia

risk); or

B. Conventional colonoscopy was incomplete because of colonic stenosis, obstruction, or significant anatomical abnormality.

II. Except as noted in the criteria above, CT colonography is considered **not medically necessary**.

SCIENTIFIC EVIDENCE[1]

Conventional endoscopic colonoscopy is the standard of care for colon cancer screening. Suspicious lesions of any size can be removed immediately and evaluated for the presence of colorectal cancer (CRC) or dysplasia.[2-6]

In order to demonstrate its efficacy, computed tomography colonography (CTC) needs to be compared to the standard of care, conventional colonoscopy, in randomized controlled trials.

Literature Appraisal

Technology Assessments, Systematic Reviews, and Meta-Analyses

- A 2009 BlueCross and BlueShield Association (BCBSA) Technology Evaluation Center (TEC) Assessment evaluated the scientific literature comparing the effectiveness of CTC to that of conventional colonoscopy.[6] This assessment concluded:
  - Based primarily on the results from 2 large trials in asymptomatic patient populations,[7,8] CTC sensitivity for the detection of lesions 10 mm or larger approaches the sensitivity of conventional colonoscopy.
  - However, the diagnostic performance of CTC was highly dependent on the technology and techniques used. If these practices (eg, use of the most current CT scanners, stool tagging techniques, and highly trained radiologists) can be replicated in the community, then it is likely that improved health outcomes can be achieved outside the investigational setting.

- The 2008 Agency for Healthcare Research and Quality (AHRQ) systematic review of tests used for colorectal cancer screening concluded the following with regard to CTC technology:[9]
  - The published reports on CTC screening suggested at least comparable sensitivity to colonoscopy for CRC and large adenomas (10mm or larger).
  - For smaller polyps (6mm or larger), published data were inconsistent, with some studies suggesting either reduced sensitivity or sensitivity that may be dependent upon the CT technology used and the expertise of the individual reader.
  - Published specificity estimates for CTC were consistently high for large polyps (≥96%), but appeared lower and more variable (80-94%) for smaller polyps (6mm or larger).
  - Approximately 40% of patients had extracolonic findings; however, the net impact of these findings was uncertain in terms of added benefits or harms.

- The Centers for Medicare and Medicaid Services published an evidence-based decision memo that stated, "The evidence is inadequate to conclude that CT colonography is an appropriate colorectal cancer screening test…"[2] This review noted the following uncertainties:

- "CT colonography using at least 8 to 16 slice CT scanners has sensitivity and specificity that are comparable to optical colonoscopy for polyps ≥ 10mm,… For polyps 6-9mm, the evidence is suggestive but less convincing given the lower sensitivity and specificity. CT colonography does not appear to have the ability to reliably detect small polyps < 6mm."
- "Since CT colonography cannot reliably detect polyps < 6mm, the impact of these polyps in the intervening screening interval is important but unknown at this point…Further research on the natural history of polyps < 6mm and nonpolypoid lesions and their health outcomes is needed."
- "The value of an intermediate screening test such as CT colonography that does not have therapeutic options may well be reduced or negated if there is a high rate of referral to optical colonoscopy leading to duplicative tests."
- "Since extracolonic findings are common, evidence based standards and guidelines on reporting, monitoring and subsequent evaluation of these findings are needed…Since individuals undergoing screening are asymptomatic by definition, the potential impact of extracolonic findings on health outcomes needs to be determined prior to general use of this modality."

- A large meta-analysis of CTC diagnostic performance included 33 prospective studies in 6,393 adult patients.[10] Heterogeneity was addressed through statistical analysis and by performing stratified analyses of confounding variables.

  This study reported that the sensitivity of CTC varied, but improved as polyp size increased:

  - Sensitivities ranged from 48% for detection of polyps smaller than 6 mm, to 70% for polyps 6 to 9 mm, to 85% for polyps larger than 9 mm.
  - In contrast, specificity was more consistent (92% for polyps smaller than 6 mm, 93% for polyps 6 to 9 mm, and 97% for polyps larger than 9 mm).
  - In a subanalysis, characteristics of the CT scanner technology explained only some of the variation between studies.

Another large meta-analysis of five studies with a total of 4,086 participants also reported that CT colonography has a high sensitivity for adenomas ≥10mm, but lower sensitivity for adenomas ≥6mm.[11]

Cost-effectiveness

- A 2009 BCSBA TEC Special Report evaluated 7 studies appraising the cost-effectiveness of CTC compared with conventional colonoscopy. This report determined that in general, conventional colonoscopy was the more effective screening test. CTC was generally more expensive and in many analyses less effective as a screening strategy than colonoscopy.[12]
- Subsequent to the BCBSA TEC Report, several cost-effectiveness analyses of colon cancer screening techniques also reported that CT colonography is not cost-effective compared with the established screening options.[13,14]
- In 2012, Hanly and colleagues published a systematic review of cost-effectiveness studies of CT colonography and concluded that CT colonography is cost-effective compared to no screening.[15] They could not reach a conclusion regarding a comparison to colonoscopy, due to differences in study parameters and assumptions. It was noted that early studies demonstrated that colonoscopy was both more effective and less expensive than CTC; however, 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 addressed.

Other Case Series, Retrospective Reviews, and Non-randomized Comparative Studies

The diagnostic accuracy of CT colonography compared to colonoscopy was recently assessed in a study by Zalis et al. in 2012. A laxative-free bowel preparation technique for CT colonography[16] was used in 605 patients aged 50 to 85 years with average to moderate colon cancer risk. Sensitivity and specificity were calculated on a per-patient basis and authors reported that for adenomas 10mm 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.

The remaining evidence on CTC diagnostic performance is not reliable for one or more of the following reasons:

- High-risk subjects were included (eg, symptomatic patients, patients referred for additional testing, or those with a family history of cancer). These subjects are not representative of a screening population and may create selection bias.[6,17-20]
- Study populations sizes were too small, which limits the ability to rule out the role of chance as an explanation of findings and does not permit conclusions for a test that is intended to be used in a large screening population.[6,17]
- Estimates of sensitivity were based on a per polyp (rather than per patient) basis. These estimates may result in misleading calculations of sensitivity, and they do not reflect how the test would be used in the clinical setting.[6,17]
- Older CTC machinery or screening techniques were used, which is not reflective of the current technology. These studies may not accurately reflect the best diagnostic performance of CTC.[6] In addition, variability in performance of older scanners or imaging techniques limits comparisons between studies and may introduce performance bias.
- CTC and conventional colonoscopy were compared in separate patient populations. These studies do not allow calculation of sensitivity and specificity between the two tests in the same patient population and only give an estimate of the diagnostic yield of each test.[6,21]

Clinical Practice Guidelines

Much of the evidence supporting colorectal cancer screening is indirect, and consensus groups reviewing the same evidence have come to differing conclusions regarding the evidence on CTC for colon cancer screening.[6,22]

Evidence-based Guidelines

The U.S. Preventive Services Task Force (USPSTF) clinical guideline on colorectal cancer screening determined the evidence was insufficient to evaluate the benefits and harms of CT colonography as a screening tool.[23]

Consensus-based Guidelines

While these guidelines report outcomes of numerous studies, the authors did not provide a critical analysis of the quality of the studies, and/or did not rate the strength of the evidence supporting their recommendations:

- The 2009 American College of Gastroenterology Guidelines for Colorectal Cancer Screening recommend colonoscopy every 10 years, beginning at age 50, as the preferred CRC screening strategy. However, these guidelines note that not all eligible persons are willing to undergo colonoscopy for screening purposes and recommend, in these cases, patients be offered an

alternative CRC prevention test such as flexible sigmoidoscopy every 5 to 10 years, CTC every 5 years, or a cancer detection test such as fecal immunochemical test for blood.[5]

- A 2008 joint position statement issued by the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology states colon cancer prevention is the primary goal of colorectal cancer screening and endorses CT colonography every 5 years as one screening option.[24]
- A 2006 American Gastroenterological Association (AGA) position paper states peer-reviewed published data suggest that CT colonography is only indicated as a diagnostic tool for patients who have undergone incomplete colonoscopies for limited indications.[25] A 2008 letter clarifying their position states, "The AGA does not endorse CT colonography as a first-line colon cancer screening test. While AGA supports CT colonography as a screening option, colonoscopy is the definitive test for colorectal cancer screening and prevention..."[3]
- The 2007 AGA Standards for Gastroenterologists Performing and Interpreting Diagnostic CTC states, "Based on currently available data, CT colonography is not endorsed as a primary screening modality for CRC in asymptomatic adults."[26]
- The 2006 American Society for Gastrointestinal Endoscopy states, "Virtual colonoscopy is an evolving technique and is not currently recommended as the primary method of screening for CRC."[4]

Safety

A number of questions remain unanswered in the published scientific literature with respect to the safety of CTC:

- The lifetime cumulative radiation risk from use of CTC in addition to other medical diagnostic or screening tests is uncertain and needs further evaluation.[2,3,6,9,23]
- The best interval for repeat CTC after negative CT colonography is unknown and needs to be established.[2,5,8] Insufficient follow-up may lead to under treatment and too frequent follow-up may lead to unnecessary radiation exposure.
- The natural history of smaller adenomas, particularly those of different sizes (e.g. < 10mm) is unknown. It is not clear that leaving small polyps is safe; there are no long-term, adequately controlled studies on the subject.[2,6,8,9,17]
- How to interpret and manage additional CT findings outside the colon (extracolonic findings) is not well defined.[2,6,7,9,17] False positive findings may lead to unnecessary procedures. Interdisciplinary algorithms for management of these findings are needed.[7]

Summary

Computed tomography colonography (CTC) has not been shown to be superior to colonoscopy. Evidence suggests CTC is as sensitive as conventional colonoscopy for detecting lesions 10mm or larger. However, for lesions less than 10mm, the evidence is inconsistent and suggests CTC is less sensitive. If suspicious lesions are found on CTC, they cannot be immediately removed and evaluated. Patients must be referred for conventional colonoscopy for lesion removal. In addition, CTC is frequently more costly than colonoscopy as a screening tool for colorectal cancer. Therefore, except in a select group of patients (those unable to undergo conventional colonoscopy for medical reasons or for whom conventional colonoscopy was incomplete because of colonic stenosis, obstruction, or significant anatomical abnormality), CT colonography is considered not medically necessary.

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CROSS REFERENCES

Whole Body CT Screening, Radiology, Policy No. 40

CODES	NUMBER	DESCRIPTION
CPT	74261	Computed tomographic (CT) colonography, diagnostic including image post-processing without contrast material
	74262	Computed tomographic (CT) colonography, diagnostic including image post-processing with contrast materials
	74263	Computed tomographic (CT) colonography, screening, including image post-processing
HCPCS	None	