Virtual Colonoscopy/Computed Tomography Colonography

Description

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.

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.
POLICY STATEMENT

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.

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 through the 510(k) process. Food and Drug Administration product code: JAK.

RATIONALE

Summary of Evidence

For individuals who have positive colorectal cancer (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. The 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 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

The American College of Physicians (2015) updated its guidelines for colorectal cancer (CRC) screening. The American College of Physicians recommends 1 of the following 4 strategies for adults aged 50-75 years:

- High-sensitivity fecal occult blood test or fecal immunochemical test every year.

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- Sigmoidoscopy every five years.
- Combined high-sensitivity fecal occult blood test or fecal immunochemical test every three years plus sigmoidoscopy every five years.
- Optical colonoscopy every ten years.

The guidelines did not mention virtual colonoscopy or computed tomography colonography (CTC).

**American Cancer Society et al**

The ACS (2018) updated its guidelines on CRC screening (see Table 1). 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 (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 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**

<table>
<thead>
<tr>
<th>Colorectal Cancer Screening Guidelines</th>
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<tbody>
<tr>
<td>Stool-based test</td>
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<tr>
<td>Fecal immunochemical test every 1 y</td>
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<tr>
<td>High-sensitivity, guaiac-based fecal occult blood test every 1 y</td>
</tr>
<tr>
<td>Multitarget stool DNA test every 3 y</td>
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<tr>
<td>Structural test</td>
</tr>
<tr>
<td>Colonoscopy every 10 y</td>
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<tr>
<td>Computer tomography colonography every 5 y</td>
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</table>

**American College of Gastroenterology**

The American College of Gastroenterology (2017) 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. The panel recommended CRC screening beginning at age 50.

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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

<table>
<thead>
<tr>
<th>Tier</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>Tier 1</td>
<td>• Colonoscopy every 10 y</td>
</tr>
<tr>
<td></td>
<td>• Annual fecal immunochemical test</td>
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<tr>
<td>Tier 2</td>
<td>• Computed tomography colonography every 5 y</td>
</tr>
<tr>
<td></td>
<td>• Fecal immunochemical test-fecal DNA every 3 y</td>
</tr>
<tr>
<td></td>
<td>• Flexible sigmoidoscopy every 10 y (or every 5 y)</td>
</tr>
<tr>
<td>Tier 3</td>
<td>• Capsule colonoscopy every 5 y</td>
</tr>
<tr>
<td>Available tests not currently recommended</td>
<td>• Septin 9</td>
</tr>
</tbody>
</table>

**American College of Radiology**

The American College of Radiology (2018) updated its 2014 appropriateness criteria on imaging tests for CRC screening. 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**

The USPSTF (2016) updated its recommendations on CRC screening. 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)

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**

The Centers for Medicare & Medicaid Services (2009) published a noncovered national decision memo on CTC screening.

**REFERENCES**


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

<table>
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<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>March 2013</td>
<td>Replace policy</td>
<td>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.</td>
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<tr>
<td>September 2014</td>
<td>Replace policy</td>
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<tr>
<td>December 2016</td>
<td>Replace policy</td>
<td>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.”</td>
</tr>
<tr>
<td>December 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 20, 2017; no references added; note 24 updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>December 2018</td>
<td>Replace policy</td>
<td>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.</td>
</tr>
<tr>
<td>December 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 8, 2019; no references added. Policy statement unchanged.</td>
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