Virtual Colonoscopy/Computed Tomography Colonography

Description
Computed tomography colonography (CTC), also known as virtual colonoscopy, is an imaging modality of the colon 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.

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.

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

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
Based on the currently available evidence, a colon cancer screening strategy using computed tomography colonography is likely to produce outcomes similar to those with optical colonoscopy. Therefore, the “least costly alternative” provision of the medically necessary definition may apply (see Benefit Application section).

Computed tomography colonography outcomes described in the literature represent outcomes under ideal conditions. This generally involves a comprehensive colon cancer screening program that includes rapid access to optical colonoscopy when necessary and systematic follow-up and surveillance of patients who generally have a more complicated follow-up schedule than do patients undergoing optical colonoscopy. Therefore, to achieve outcomes described in the literature that are similar to optical colonoscopy, CTC needs to be offered as part of a comprehensive colon cancer screening program that optimizes follow-up of patients undergoing this procedure.
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BENEFIT APPLICATION

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

RATIONALE

Summary of Evidence

For individuals who are asymptomatic and undergoing CRC screening who receive 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 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 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, 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; the randomized controlled trial 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

In 2012, the American College of Physicians (ACP) updated its guidelines for colorectal cancer (CRC) screening.21 ACP made the following recommendations on colon cancer screening:

“ACP recommends using a stool based test, flexible sigmoidoscopy, or optical colonoscopy as a screening test in patients who are at average risk. ACP recommends using optical colonoscopy as a screening test in patients who are at high risk. Clinicians should select the test based on the benefits and harms of the screening test, availability of the screening test, and patient preferences.”

The guidelines further noted that computed tomography colonography (CTC) is an option for screening average-risk patients older than 50 years.

American Cancer Society et al

In 2008, the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology (ACR) released joint guidelines on CRC screening.22 These guidelines

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recognized 2 types of screening tests: colon cancer prevention and cancer detection. Colon cancer prevention tests detect both early cancer and adenomatous polyps. The cancer prevention options recommended were flexible sigmoidoscopy every 5 years, colonoscopy every 10 years, double-contrast barium enema every 5 years, or CTC every 5 years. For cancer detection, 3 types of fecal screening tests were supported: annual guaiac-based tests, annual fecal immunochemical tests, and stool DNA tests. The guidelines endorsed colon cancer prevention as the “primary goal of [colorectal cancer] screening” where resources and patient acceptance permit.22

A 2006 statement by the American Cancer Society and the U.S. Multi-Society Task Force on Colorectal Cancer on colonoscopy surveillance after cancer resection recommended that, in patients with obstructing colon cancers, CTC with intravenous contrast may be used to detect neoplasms in the proximal colon.23

**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.24 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 1. 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 1. Colorectal Cancer Screening Tier Strategy**

<table>
<thead>
<tr>
<th>Tier</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1</td>
<td>• Colonoscopy every 10 y</td>
</tr>
<tr>
<td></td>
<td>• Annual fecal immunochemical test</td>
</tr>
<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>

In 2012, the American College of Gastroenterology, along with the American Gastroenterological Association Institute and the American Society for Gastrointestinal Endoscopy, updated their 2006 guidelines on colonoscopy surveillance after polypectomy.25 The guidelines made the following statement on CTC and other newer colonic imaging technologies: “The role of new endoscopic technologies has not been studied in surveillance cohorts, although there are ongoing studies of CT colonography.... At this point, these technologies technology do not have an impact on surveillance intervals.”

In 2009, the American College of Gastroenterology issued guidelines for CRC screening. It recommended colonoscopy every 10 years, beginning at age 50, as the preferred screening strategy for the general population.26 Patients who declined colonoscopy or for whom colonoscopy would not be feasible should be offered other screenings such as flexible sigmoidoscopy every 5 to 10 years, CTC every 5 years, and an annual fecal immunochemical test.

**European Society of Gastrointestinal Endoscopy et al**

In 2014, the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastrointestinal and Abdominal Radiology (ESGAR) issued guidelines on the use of CTC.27 These guidelines recommended CTC as outlined in Table 2.
Table 2. Guidelines on Use of CTC

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>SOR</th>
<th>QOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESGE/ESGAR recommend CTC as the radiologic examination of choice for the diagnosis of colorectal neoplasia</td>
<td>Strong</td>
<td>High</td>
</tr>
<tr>
<td>ESGE/ESGAR do not recommend barium enema in this setting</td>
<td>Strong</td>
<td>High</td>
</tr>
<tr>
<td>ESGE/ESGAR recommend CTC, preferably the same or next day, if colonoscopy is incomplete. Delay of CTC should be considered following endoscopic resection. In the case of obstructing colorectal cancer, preoperative contrast-enhanced CTC may also allow location or staging of malignant lesions. When endoscopy is contraindicated or not possible, ESGE/ESGAR recommend as an acceptable and equally sensitive alternative for patients with symptoms suggestive of colorectal cancer</td>
<td>Strong</td>
<td>High</td>
</tr>
<tr>
<td>ESGE/ESGAR do not recommend CTC as a primary test for population screening or in individuals with a positive first-degree family history of CRC. However, it may be proposed as a CRC screening test on an individual basis providing the screenee is adequately informed about test characteristics, benefits, and risks.</td>
<td>Weak</td>
<td>Moderate</td>
</tr>
</tbody>
</table>


American College of Radiology

In 2014, ACR updated its appropriateness criteria on imaging tests for CRC screening, which included the guidelines related to CTC listed in Table 3.28

Table 3. Appropriateness Criteria for Colorectal Cancer Screening

<table>
<thead>
<tr>
<th>Variant</th>
<th>Procedure</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average-risk individual: age ≥50 y</td>
<td>CTC every 5 y after negative screen</td>
<td>9</td>
</tr>
<tr>
<td>Average-risk individual after positive fecal occult blood test, indicating a relative elevation in risk</td>
<td>CTC</td>
<td>9</td>
</tr>
<tr>
<td>Average-, moderate-, or high-risk individual after incomplete colonoscopy</td>
<td>CTC</td>
<td>9</td>
</tr>
<tr>
<td>Moderate-risk individual: personal history of adenoma or carcinoma or first-degree family history of cancer or adenoma</td>
<td>CTC every 5 y after negative screen</td>
<td>9</td>
</tr>
<tr>
<td>High-risk individual: hereditary nonpolyposis colorectal cancer</td>
<td>CTC</td>
<td>3&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>High-risk individual: ulcerative colitis or Crohn colitis</td>
<td>CTC</td>
<td>3&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

American College of Radiology rating scale: 1-3: usually not appropriate; 4-6: may be appropriate; 7-9: usually appropriate.

CTC: computed tomography colonography.
<sup>a</sup> Colonoscopy is the preferred procedure.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES


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**POLICY HISTORY**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2013</td>
<td>Update 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>
</tr>
<tr>
<td>September 2014</td>
<td>Update 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 &quot;equivalent&quot; was changed to &quot;similar in the Policy Guidelines and Benefit Application sections.</td>
</tr>
<tr>
<td>December 2017</td>
<td>Update Policy</td>
<td>Policy updated with literature review through July 20, 2017; no references added; note 24 updated. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

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