6.01.32 Virtual Colonoscopy/Computed Tomography Colonography

Summary

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

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) or in patients with an incomplete conventional colonoscopy because of colonic stenosis or obstruction.

CTC may be considered medically necessary for the purposes of colon cancer screening. Except for the indications outlined in the policy statements above, CTC is considered investigational.

POLICY GUIDELINES (IF NEEDED)

Based on the currently available evidence, a colon cancer screening strategy using computed tomography colonography (CTC) 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).

CTC 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...
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offered as part of a comprehensive colon cancer screening program that optimizes follow-up of patients undergoing this procedure.

**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 colorectal cancer (CRC) screening who receive computed tomography colonography (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 2 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 qualitatively 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 (RCT), 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; 1 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 Cancer Society and the U.S. Multi-Society Task Force on Colorectal Cancer**

In 2008, the American Cancer Society (ACS) and the U.S. Multisociety Task Force on Colorectal Cancer, along with the American College of Radiology (ACR), released guidelines on CRC screening. These guidelines 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.
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The guideline endorsed colon cancer prevention as the “primary goal of [colorectal cancer] screening” where resources and patient acceptance permit.

A 2006 statement by ACS 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.

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (USPSTF) published updated recommendations on CRC screening in 2016. The recommendations are:

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. USPSTF also noted indirect harms resulting from standard colonoscopy performed for positive CTC findings.

Previously, in the 2008 version of USPSTF recommendation on CRC screening, the evidence for CTC was judged to be insufficient to evaluate the benefits and harms (ie, I rating). The conclusion was based on concerns about potential harms of radiation exposure and potential for harm due to evaluation of extracolonic findings. The 2016 USPSTF recommendation does not have a specific statement on screening with CTC.

Medicare National Coverage

On May 12, 2009, Centers for Medicare and Medicaid Services published a decision memo for CTC screening that stated: “The evidence is inadequate to conclude that CT colonography is an appropriate colorectal cancer screening test under §1861(pp)(1) of the Social Security Act. CT colonography for colorectal cancer screening remains noncovered.”

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>
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<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 “equivalent” was changed to “similar in the Policy Guidelines and Benefit Application sections.</td>
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<tr>
<td>December 2016</td>
<td>Update policy</td>
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Signature on File

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