**Medical Policy**

**Title:** Virtual Colonoscopy / CT Colonography

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<tr>
<td>Individuals: • Who are asymptomatic and undergoing colorectal cancer screening</td>
<td>Interventions of interest are: • Computed tomography colonography</td>
<td>Comparators of interest are: • Optical colonoscopy • Sigmoidoscopy • Fecal occult blood test</td>
<td>Relevant outcomes include: • Overall survival • Disease-specific survival • Test accuracy • Test validity • Treatment-related morbidity</td>
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<tr>
<td>Individuals: • With positive colorectal cancer screening tests or signs or symptoms of colorectal cancer</td>
<td>Interventions of interest are: • Computed tomography colonography</td>
<td>Comparators of interest are: • Optical colonoscopy • Standard care without colonoscopy</td>
<td>Relevant outcomes include: • Overall survival • Disease-specific survival • Test accuracy • Test validity • Treatment-related morbidity</td>
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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.

OBJECTIVE
The objective of this policy is to determine whether computed tomography colonography improves the net health outcome in individuals who are asymptomatic being screened for colorectal cancer or have positive screening results for colorectal cancer.

BACKGROUND
Computed tomography colonography uses thin-section helical CT 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.

Indications
Diseases of the colon and rectum for which CTC may be considered as a diagnostic or screening tool include CRC and precancerous conditions, diverticulosis and diverticulitis, and inflammatory bowel disease. The most widely studied use of CTC is as an alternative screening technique for colon cancer.

REGULATORY STATUS
Multiple CT devices, including multiple CTC devices, have been cleared by for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA product code: JAK.

POLICY
A. Virtual colonoscopy / CT colonography may be considered medically necessary as a screening technique for colorectal cancer in average risk, asymptomatic individuals between the ages of 50 and 75 years when no other colorectal cancer screening has been performed during the recommended screening interval:

1. Guaiac-based fecal occult blood test in the past year, OR
2. Fecal immunochemical test in the past year, OR
3. Multitargeted stool DNA test in the past 3 years, OR
4. Colonoscopy in the past 10 years, OR
5. CT colonography in the past 5 years, OR
6. Flexible sigmoidoscopy in the past 5 years.

Policy Guidelines
1. Average risk of developing colorectal cancer include those individuals who have no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's disease and ulcerative colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer.
2. Asymptomatic individuals include those who have no signs or symptoms of colorectal disease including, but not limited to, lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test or fecal immunochemical test.

RATIONALE
The most recent literature review covers the period through July 20, 2017.

Computed Tomography Colonography for Colon Cancer Screening
Colon cancer screening prevents morbidity from colon cancer by the detection of early colon cancers and the detection and removal of cancer precursors such as polyps. The detection of cancer and removal of polyps initially or ultimately require an optical colonoscopy. CTC (virtual colonoscopy) is an imaging procedure that can identify cancers or polyps. The effectiveness and efficiency of virtual colonoscopy is dependent on its capability to accurately identify cancer or polyps, so that all or most patients who have such lesions are appropriately referred for colonoscopy for ultimate diagnosis and treatment and that polyps or cancer are not falsely identified.

Clinical Validity
Systematic Reviews
The diagnostic characteristics of CTC as a colon cancer screening test have been investigated in many studies in which patients referred for optical colonoscopy agree to first undergo a CTC. Using a second-look unblinded colonoscopy aided by the results of the CTC as the reference standard, the diagnostic characteristics of CTC and the blinded colonoscopy can be calculated and compared. The sensitivity of CTC is a function of the size of the polyp; sensitivity is poorer for smaller polyps. A 2004 TEC Assessment found variable sensitivity and specificity of CTC at that time, with many studies showing poor sensitivity.¹

Several subsequent systematic reviews of studies on CTC in a colorectal cancer (CRC) screening setting have been published. Most recently, in 2016, Lin et al published a systematic review and meta-analysis of literature on CRC screening, conducted for the U.S. Preventive Services Task Force (USPSTF).² The investigators identified 9 prospective diagnostic accuracy studies on CTC (total N=6497 patients). Seven studies involved CTC with bowel preparation and 2 involved CTC without bowel preparation. Five studies, including both without bowel preparation, were rated by
USPSTF as good quality and the remaining 4 were considered fair quality. In 4 studies of CTC with bowel preparation, the sensitivity to detect adenomas 6 mm or larger ranged from 73% to 98%, and the specificity ranged from 89% to 91%. The sensitivity of CTC to detect adenomas 10 mm or larger (7 studies) ranged from 67% to 94% and the specificity ranged from 96% to 98%. Four (n=481) of the 9 studies also provided data on colonoscopy. The sensitivity for adenomas 6 mm or larger ranged from 75% to 93%, and the sensitivity to detect adenomas 10 mm and larger ranged from 89% to 98%.

In addition, the Lin systematic review evaluated evidence on harms and extracolonic findings associated with CTC. Eleven fair or good quality prospective studies (total N=10,272 patients) suggested little or no risk of serious adverse effects such as perforation. In contrast, Lin et al estimated that, with optical colonoscopy, the risk of perforation was 4 in 10,000 procedures (95% confidence interval [CI], 2 to 5 in 10,000) and the risk of major bleeding was 8 in 10,000 procedures (95% CI, 5 to 14 in 10,000). Radiation exposure is a potential harm of CTC, and many of the studies did not report the extent of radiation exposure. Using data from 4 studies, Lin estimated that the radiation dose of a full-screening CTC examination was about 4.5 to 7 mSv. However, in more recent studies (ie, published in 2004 to 2008), the estimated radiation dose was lower, about 1 to 5 mSv. Among studies reporting this outcome, extracolonic findings occurred in 27% to 69% of CTC examinations. Approximately 1% to 11% underwent diagnostic evaluation and 3% required treatment. Extracolonic cancers occurred in about 0.5% of individuals undergoing CTC examinations.

in 2014, Martin-Lopez et al published a meta-analysis that included 9 studies of CRC screening. Studies conducted for the diagnosis of CRC or in elderly, high-risk, or symptomatic patients were excluded. The overall per patient pooled sensitivity and specificity of CTC were 66.8% (95% CI, 62.7% to 70.8%) and 80.3% (95% CI, 77.7% to 82.8%), respectively. For colonoscopy, the pooled sensitivity was 92.5% (95% CI, 89.0% to 95%) and pooled specificity was 73.2% (95% CI, 67.7% to 78.1%). In the subgroup with larger lesions, the diagnostic accuracy of the 2 approaches was more similar. For lesions 10 mm or larger, CTC had a pooled sensitivity of 91.2% (95% CI, 86.5% to 94.6%) and a specificity of 87.3% (95% CI, 86.2% to 88.3%). The pooled sensitivity of colonoscopy for lesions 10 mm or larger was 92.9% (95% CI, 86.0% to 97.1%) and the specificity was 91.3% (95% CI, 89.9% to 92.5%).

**Randomized Controlled Trials**

One of the largest studies of a screening population, the American College of Radiology Imaging Network (ACRIN) trial, was published by Johnson et al in 2008. Patients underwent CTC prior to standard colonoscopy. The study used 16- to 64-row detector computed tomography scanners, stool-tagging techniques, and minimum training standards for interpreters of the test. A total of 2600 individuals were enrolled, and data were available for 2531 (97%) of them. The results of this trial showed 90% sensitivity of CTC for polyps 10 mm or larger and 86% specificity; positive and negative predictive values were 23% and 99%, respectively. In a follow-up analysis of the ACRIN trial, Fidler et al demonstrated that CTC had similar sensitivity and specificity in the detection of nonpolypoid adenomas.

More recently, several large RCTs have compared the diagnostic accuracy of CTC to a different method of CRC screening. In the IJspeert et al (2016) study, 8844 individuals were invited to be screened and 2258 (26%) agreed to participate. This included 982 (34%) of 2920 randomized to CTC and 1276 (22%) of 5924 randomized to standard colonoscopy. The analysis focused on detection of high-risk sessile serrated polyps (SSPs). SSPs were detected significantly more often
in colonoscopy examinations (n=55 [4.3%]) than in CTC examinations (n=8 [0.8%]). For the outcome of all SSPs (high and low risk), significantly more were detected with colonoscopy (n=83 [6.5%]) than with CTC (n=21 [2.1%]; p<0.001). Adverse events were not discussed.

Regge et al (2016) reported on an RCT in which 5412 individuals were randomized to CTC (n=2674) or flexible sigmoidoscopy (n=2738). The detection rate for advanced adenomas did not differ significantly between groups (p=0.52). Detection rates were 133 (5.1%) in the CTC group and 127 (4.7%) in the flexible sigmoidoscopy group. Ten CRCs were identified in the CTC group and 9 in the flexible sigmoidoscopy group. No serious adverse events were reported.

**Clinical Utility**

There is no direct evidence that evaluates the impact of CTC on health outcomes compared with optical colonoscopy. Modeling studies, generally done as part of cost-effectiveness analyses, can provide insights into the health outcome benefits of CTC and provide relevant data on cost-effectiveness.

A 2009 TEC Special Report provided a critical appraisal of cost-effectiveness analyses of CTC that informs this review. Seven published studies were selected. Two studies completely simulated assumptions that are consistent with the current diagnostic capability of CTC and recommended practice guidelines. In the study by Zauber et al, colonoscopy was slightly more effective and was less expensive than CTC. This was based on a model using 1000 individuals who were 65 years old. Despite a somewhat lower per procedure cost, the strategy using CTC was more expensive because CTC was performed every 5 years (vs every 10 years for optical colonography), and patients with polyps 6 mm or larger were referred for optical colonoscopy for polyp removal. In this model, the payment for colonoscopy without polypectomy was $500 and for CTC was $488. In the study by Scherer et al, the model was based on 1000 individuals aged 50 years. In this analysis, the only model for CTC that was more effective than every 10-year optical colonoscopy was CTC every 5 years for removal of polyps 6 mm or larger. Using these assumptions, this CTC approach saved 118.5 lives compared with 116.8 for every 10-year optical colonoscopy; the costs of the 2 approaches were $2.95 million and $1.86 million, respectively. In this analysis, the costs of each procedure were comparable—$523 for CTC compared with $522 for optical colonoscopy without polypectomy. Thus, outcomes using CTC were comparable to those for optical colonoscopy, yet the CTC strategy was more costly. In this study, a sensitivity analysis showed that when the cost of CTC was 0.36 than that of colonoscopy, CTC became less expensive.

Another cost-effectiveness analysis of several colon cancer screening techniques by Heitman et al compared several colon cancer screening techniques. This analysis indicated that CTC was similar in effectiveness to several other established screening techniques but was more expensive and was, therefore, a dominated or unpreferred strategy.

Lansdorp-Vogelaar et al conducted a systematic review of cost-effectiveness studies of colon cancer screening techniques and found 55 publications relating to 32 unique cost-effectiveness models. CTC was evaluated in 8 models. Although CTC was deemed cost-effective compared with no screening, it was dominated (ie, both more expensive and less effective) by established screening strategies in 5 of the analyses. They found 1 study in which CTC would be the recommended screening strategy at a cost per life-year gained of less than $50,000.
In general, in these cost-effectiveness analyses, colonoscopy was the more effective screening test. CTC was a dominant option (more effective and less costly) only in the 1 study that added CTC’s benefit of detection of aortic aneurysm and extracolonic cancers. This study also incorporated long-term radiation effects. This benefit of detecting extracolonic disease was calculated to account for up to 20% of the total health benefit achieved. Most of the benefit was estimated to be from early detection of aortic aneurysms. Screening for aneurysm using ultrasound has been demonstrated to be effective in older (ie, age ≥65 years) men and has been recommended for older male smokers. Screening for the other cancers assumed to be detected has not been shown to be effective. Further research is needed to bolster the data supporting considerable benefit of CTC regarding aortic aneurysm, especially in older people, and extracolonic cancer detection, as well as the costs and potential health risks of false-positive findings.

Hanly et al published a systematic review of cost-effectiveness studies of CTC in 2012. They concluded that CTC is cost-effective compared with no screening. They could not reach a conclusion for their comparison with colonoscopy, due to differences in study parameters and assumptions. They noted that in early studies, colonoscopy dominated CTC; that is, it was both more effective and less expensive. More recent studies have had variable results, dependent on the threshold for colonoscopy referral and whether the costs and effects of acting on extracolonic findings seen on CTC are taken into account.

Due to differing assumptions, current studies and practice guidelines vary in their evaluation of the comparative costs and effects of CTC and colonoscopy. Overall benefit without consideration of costs appears to be similar between the 2 tests regarding colon cancer prevention. Most studies did not consider the potential benefits of aortic aneurysm detection and extracolonic cancer detection. CTC was generally more expensive and, in many studies, less effective as a screening strategy than colonoscopy, and in other studies only slightly more effective.

Impact of CTC on Colon Cancer Screening Adherence
Compliance with recommendations for optical colonoscopy is suboptimal, with the most recent data suggesting a screening rate of about 60% (in the prior 10 years) among people ages 50 to 75. CTC has been proposed as an alternative colon cancer screening technique that may improve patient compliance compared with optical colonoscopy. A literature survey of studies that attempted to determine whether the availability of CTC would improve population screening rates found survey studies, patient satisfaction studies, and focus group studies. It is unclear how such studies provide a sufficient base of evidence to demonstrate that population adherence to colon cancer screening would improve through CTC.

Stoop et al published an RCT in 2012 that evaluated the impact of CTC on colon cancer screening rates. This trial was performed in the Netherlands, and members of the general population ages 50 to 75 years were randomized to an invitation for CTC or optical colonoscopy. The CTC protocol included a noncathartic preparation, consisting of iodinated contrast agent given the day before the exam and 1.5 hours before the exam, in conjunction with a low fiber diet. The participation rate in the CTC group was 34% (982/2920) compared with a rate of 22% (1276/5924) in the optical colonoscopy group (p<0.001). The diagnostic yield per patient of advanced polyps was higher in the optical colonoscopy group, at 8.7 of 100 participants compared with 6.1 of 100 participants for CTC (p=0.02). However, the diagnostic yield of advanced neoplasia per invitee were similar, at 2.1 of 100 invitees for CTC and 1.9 of 100 invitees for optical colonoscopy (p=0.56). These data indicated that the increased participation rates with CTC offset the
advantages of optical colonoscopy and that overall outcomes are likely to be similar between the 2 strategies. It is not known whether the same participation rates would be achieved if CTC employed a cathartic preparation or whether the different preparation regimens affect participation rates.

Section Summary: Computed Tomography Colonography for Colon Cancer Screening
There is some variability in the diagnostic accuracy of CTC in the literature; this is likely due to the improvement in technical performance over time. The most recent studies have reported that the diagnostic accuracy for CTC is high and in the same range as optical colonoscopy for polyps greater than 10 mm.

There are no long-term comparative studies that directly report on outcomes of CTC versus optical colonoscopy. The determination of comparative outcomes of CTC and optical colonoscopy is complex, due to the differing patterns of follow-up associated with each strategy. Studies of cost-effectiveness have modeled outcomes of the 2 procedures and generally concluded that outcomes are similar, or that optical colonoscopy results in better outcomes. These analyses assumed equal participation rates between strategies.

At least 1 well-done RCT has reported reports that CRC screening participation rates are improved with CTC compared with optical colonoscopy. The improved screening rate may offset, or even outweigh, any benefit of optical colonoscopy on outcomes. However, the available study used a noncathartic preparation, and it is not certain that similar screening rates would be achieved with a cathartic preparation.

CTC for Colon Cancer Diagnosis
CTC has not been generally employed as a test to identify disease in persons with positive cancer screening tests or symptoms, because compared to screening settings, the expected probability of disease is much higher. Findings on CTC require confirmation with colonoscopy; thus it is not rational to use a noninvasive test if the probability of needing a confirmatory invasive test is high.

However, several studies have evaluated the role of CTC in the diagnosis of colon cancer in patients who have had symptoms or positive findings on other screening modalities (eg, fecal occult blood testing [FOBT]). In 2014, Plumb et al published a systematic review and meta-analysis of studies evaluating the performance of CTC for the diagnosis of colon cancer among subjects with positive FOBT.17 FOBT is a recommended screening technique for CRC; positive tests are typically followed up with colonoscopy. In this meta-analysis, the reviewers included only studies that used CTC in the evaluation of patients who had a positive FOBT and compared colonography results with a reference test, conventional colonoscopy, segmental unblinded colonoscopy, or surgery with subsequent histopathology. Five articles were included in the analysis, representing 4 studies with 622 patients. Pooled per-patient sensitivity and specificity for adenomas 6 mm or larger or CRC were 88.8% (95% CI, 83.6% to 92.5%) and 75.4% (95% CI, 58.6% to 86.8%), respectively. The reviewers commented that the data on CTC for patients with a positive FOBT are limited (only 4 studies) and that, based on the available evidence, CTC has a reasonably high sensitivity for detecting adenomas 6 mm or larger but a relative low specificity.

Also in 2014, Plumb et al published findings of a retrospective study comparing results from CTC and optical colonoscopy in patients evaluated at a single center who were indicated for CRC diagnostic assessment because of a positive FOBT.18 This study was not included in the Plumb
2014 systematic review (described above). Based on the institutional protocol, optical colonoscopy was preferred for individuals with positive FOBT, but CTC substituted if the subject was unable to safely complete colonoscopic bowel preparation, was too frail or immobile to undergo colonoscopy (although potentially fit for necessary treatment), had another contraindication to colonoscopy, or had an incomplete colonoscopy. The study analyzed 2731 FOBT-positive patients screened with CTC as their first screening test. Of these, 1027 (37.6%) had CRC or polyps suspected (95% CI, 33.8% to 41.4%), and 911 underwent confirmatory testing. One hundred twenty-four (4.5%) were found to have CRC and 533 (19.5%) were found to have polyps, for an overall CRC- or polyp-detection rate of 24.1% (95% CI, 21.5% to 24.1%). The positive predictive value for CRC or polyps was 72.1% (95% CI, 66.6% to 77.6%).

Colonoscopy data were available for 72,817 FOBT-positive patients who underwent colonoscopy as an initial screening test, among whom 9.0% had CRC and 50.6% had polyps. The authors attributed the difference in CRC and polyp rates between the groups to underlying differences in risk between those referred for CTC and potential biases in the interpretation of screening guidelines.

Several studies have evaluated the role of CTC for patients with symptoms suggestive of CRC. In 2013, Atkin et al reported results from an unblinded RCT comparing colonoscopy and CTC in the evaluation of patients with symptoms suggestive of CRC.\textsuperscript{19} Given the challenges of conducting a trial that would be adequately powered to detect small differences between CTC and colonoscopy in CRC and large polyp detection, the authors used rates of the need for additional evaluation after CTC as a primary outcome, on the assumption that such rates would strongly affect the evaluation of the benefits and costs of the procedure. The study randomly allocated patients ages 55 or older with symptoms suggestive of CRC in a 2:1 fashion to colonoscopy or CTC. Both colonoscopy and CTC procedures were conducted with a full bowel preparation. The trial’s primary outcome was the proportion of patients who had additional colonic investigation, defined as any subsequent examination of the colon until diagnosis (usually histologic confirmation of a cancer or polyp) or until a patient was referred back to his or her physician. Additional diagnostic evaluation of the colon was required in 160 (30.0%) of 533 of those assigned to CTC compared with 86 (8.2%) of 1047 of those assigned to colonoscopy (p<0.001). The overall detection rate for CRC or large polyps did not differ between the groups (relative risk, 0.95; 95% CI, 0.70 to 1.27; p=0.69).

Simons et al evaluated the false-negative rate and sensitivity of CTC for CRC among patients who presented with symptoms of CRC.\textsuperscript{20} The authors included 1855 consecutive patients who underwent CTC at a single center. These data were linked to a comprehensive population-based cancer registry to determine if patients were diagnosed with CRC in the 2 years after their CTC. Fifty-three patients were diagnosed with CRC, of whom 40 patients had had suspected CRC, 5 diagnosed with large polyps that appeared malignant on histology, and 5 diagnosed with an indeterminate mass on CTC. Two patients who developed cancer had not been diagnosed on CTC, and 1 patient who developed cancer had had an incomplete colonography. The overall sensitivity of CTC was 94.3% (95% CI, 88% to 100%).

\textit{Section Summary: CTC for Colon Cancer Diagnosis}

There are a relatively small number of studies of CTC for diagnosis of CRC in patients with a positive screening test or with symptoms of CRC. A systematic review of CTC studies in patients with a positive FOBT identified only 4 studies and found a reasonably high sensitivity for detecting adenomas 6 mm or larger but a relative low specificity. An RCT comparing CTC with colonoscopy in symptomatic patients found a significantly greater need for additional evaluation
after CTC compared with colonoscopy. Because the prevalence of disease is much higher in patients with positive screening tests or symptoms of CRC, going directly to colonoscopy is usually the preferred clinical strategy. Additional studies are needed to determine with certainty the diagnostic accuracy of CTC for diagnosis of CRC; however, for patients unable to undergo a colonoscopy, based on the available evidence, CTC may be a reasonable option.

**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 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.

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.

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

**American College of Physicians**

In 2012, the American College of Physicians (ACP) released updated guidelines for colorectal cancer screening. ACP’s guideline development process involves the assessment of existing guidelines via the Appraisal of Guidelines for Research and Evaluation II instrument. ACP makes the following recommendations regarding 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 note that CTC is an option for screening in average-risk patients older than 50 years and is supported by some guidelines.
American Cancer Society and the U.S. Multi-Society Task Force on Colorectal Cancer
The 2008 edition of colorectal cancer screening guidelines released jointly by the American Cancer Society (ACS), the American College of Radiology, and the U.S. Multi-Society Task Force on Colorectal Cancer recognizes 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 ACS endorses 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.

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. 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>
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<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>
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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. 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. 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 and European Society of Gastrointestinal and Abdominal Radiology

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

**Table 2. Guidelines on Use of CTC**

<table>
<thead>
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<th>Recommendation</th>
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<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.</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>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>
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American College of Radiology

In 2014, ACR published updated appropriateness criteria for imaging tests for CRC screening, which includes the guidelines related to CTC in Table 3.

**Table 3. Appropriateness Criteria for Colorectal Cancer Screening**

<table>
<thead>
<tr>
<th>Variant</th>
<th>Procedure</th>
<th>Rating</th>
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<tr>
<td>Average-risk individual: age ≥50 years</td>
<td>CT colonography every 5 years 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>CT colonography</td>
<td>9</td>
</tr>
<tr>
<td>Average-risk, moderate-, or high-risk individual after incomplete colonoscopy</td>
<td>CT colonography</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>CT colonography every 5 years after negative screen</td>
<td>9</td>
</tr>
<tr>
<td>High-risk individual: hereditary nonpolyposis colorectal cancer</td>
<td>CT colonography</td>
<td>3a</td>
</tr>
<tr>
<td>High-risk individual: ulcerative colitis or Crohn colitis</td>
<td>CT colonography</td>
<td>3a</td>
</tr>
</tbody>
</table>

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

**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.

**ONGOING AND UNPUBLISHED CLINICAL TRIALS**

Some currently unpublished trials that might influence this policy are listed in Table 4.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT01651624</td>
<td>Comparison Between Faecal Occult Blood Test (FOBT), Computed Tomographic Colonography (CTC) With Computer Aided Diagnosis (CAD) and Colonoscopy as a Primary Screening Test for Colorectal Cancer</td>
<td>14,000</td>
<td>Dec 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

**CODING**

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

**CPT/HCPCS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>74261</td>
<td>Computed tomographic (CT) colonography, diagnostic, including image postprocessing; without contrast material</td>
</tr>
<tr>
<td>74262</td>
<td>Computed tomographic (CT) colonography, diagnostic, including image postprocessing; with contrast material(s) including non-contrast images, if performed</td>
</tr>
<tr>
<td>74263</td>
<td>Computed tomographic (CT) colonography, screening, including image postprocessing</td>
</tr>
</tbody>
</table>

**ICD-9 Diagnoses**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>153.0</td>
<td>Malignant neoplasm of colon, Hepatic flexure</td>
</tr>
<tr>
<td>153.1</td>
<td>Malignant neoplasm of colon, Transverse colon</td>
</tr>
<tr>
<td>153.2</td>
<td>Malignant neoplasm of colon, Descending colon</td>
</tr>
<tr>
<td>153.3</td>
<td>Malignant neoplasm of colon, Sigmoid colon</td>
</tr>
<tr>
<td>153.4</td>
<td>Malignant neoplasm of colon, Cecum</td>
</tr>
<tr>
<td>153.5</td>
<td>Malignant neoplasm of colon, Appendix</td>
</tr>
<tr>
<td>153.6</td>
<td>Malignant neoplasm of colon, Ascending colon</td>
</tr>
<tr>
<td>153.7</td>
<td>Malignant neoplasm of colon, Splenic flexure</td>
</tr>
<tr>
<td>153.8</td>
<td>Malignant neoplasm of colon, Other specified sites of large intestine</td>
</tr>
<tr>
<td>153.9</td>
<td>Malignant neoplasm of colon, Colon, unspecified</td>
</tr>
<tr>
<td>154.0</td>
<td>Malignant neoplasm of rectosigmoid junction</td>
</tr>
</tbody>
</table>
197.5 Secondary malignant neoplasm of large intestine and rectum
211.3 Benign neoplasm of colon
211.4 Benign neoplasm of rectum and anal canal
230.3 Carcinoma in situ of colon
230.4 Carcinoma in situ of rectum
230.5 Carcinoma in situ of anal canal
230.6 Carcinoma in situ of anus, unspecified
235.2 Neoplasm of uncertain behavior of stomach, intestines, and rectum
555.1 Regional enteritis of large intestine
556.0 Ulcerative colitis
556.1 Ulcerative (chronic) ileocolitis
556.2 Ulcerative (chronic) proctitis
556.3 Ulcerative (chronic) proctosigmoiditis
556.4 Pseudopolyposis of colon
556.5 Left-sided ulcerative (chronic) colitis
556.6 Universal ulcerative (chronic) colitis
556.8 Other ulcerative colitis
556.9 Ulcerative colitis, unspecified
558.1 Other and unspecified noninfectious gastroenteritis and colitis, Gastroenteritis and colitis due to radiation
558.2 Other and unspecified noninfectious gastroenteritis and colitis, Toxic gastroenteritis and colitis
558.3 Other and unspecified noninfectious gastroenteritis and colitis, Allergic gastroenteritis and colitis
558.9 Other and unspecified noninfectious gastroenteritis and colitis,
562.10 Diverticulosis of colon (without mention of hemorrhage)
562.11 Diverticulitis of colon without mention of hemorrhage
562.12 Diverticulosis of colon with hemorrhage
562.13 Diverticulitis of colon with hemorrhage
564.1 Irritable bowel syndrome
564.7 Megacolon, other than Hirschsprung's
569.0 Anal and rectal polyp
569.1 Rectal prolapse
569.3 Hemorrhage of rectum and anus
V12.72 Diseases of digestive system, Colonic polyps
V18 Family history of certain other specific conditions, Colonic polyps
V76.51 Special screening for malignant neoplasm of colon

ICD-10 Diagnoses
C18.0 Malignant neoplasm of cecum
C18.1 Malignant neoplasm of appendix
C18.2 Malignant neoplasm of ascending colon
C18.3 Malignant neoplasm of hepatic flexure
C18.4 Malignant neoplasm of transverse colon
C18.5 Malignant neoplasm of splenic flexure
C18.6 Malignant neoplasm of descending colon
C18.7 Malignant neoplasm of sigmoid colon
C18.8 Malignant neoplasm of overlapping sites of colon
C19 Malignant neoplasm of rectosigmoid junction
C78.5  Secondary malignant neoplasm of large intestine and rectum
D01.0  Carcinoma in situ of colon
D01.2  Carcinoma in situ of rectum
D12.0  Benign neoplasm of cecum
D12.1  Benign neoplasm of appendix
D12.2  Benign neoplasm of ascending colon
D12.3  Benign neoplasm of transverse colon
D12.4  Benign neoplasm of descending colon
D12.5  Benign neoplasm of sigmoid colon
D12.7  Benign neoplasm of rectosigmoid junction
D12.8  Benign neoplasm of rectum
D12.9  Benign neoplasm of anus and anal canal
D37.1  Neoplasm of uncertain behavior of stomach
D37.2  Neoplasm of uncertain behavior of small intestine
D37.3  Neoplasm of uncertain behavior of appendix
D37.4  Neoplasm of uncertain behavior of colon
D37.5  Neoplasm of uncertain behavior of rectum
K50.10 Crohn's disease of large intestine without complications
K50.111 Crohn's disease of large intestine with rectal bleeding
K50.112 Crohn's disease of large intestine with intestinal obstruction
K50.113 Crohn's disease of large intestine with fistula
K50.114 Crohn's disease of large intestine with abscess
K50.118 Crohn's disease of large intestine with other complication
K51.00 Ulcerative (chronic) pancolitis without complications
K51.011 Ulcerative (chronic) pancolitis with rectal bleeding
K51.012 Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013 Ulcerative (chronic) pancolitis with fistula
K51.014 Ulcerative (chronic) pancolitis with abscess
K51.018 Ulcerative (chronic) pancolitis with other complication
K51.20 Ulcerative (chronic) proctitis without complications
K51.211 Ulcerative (chronic) proctitis with rectal bleeding
K51.212 Ulcerative (chronic) proctitis with intestinal obstruction
K51.213 Ulcerative (chronic) proctitis with fistula
K51.214 Ulcerative (chronic) proctitis with abscess
K51.218 Ulcerative (chronic) proctitis with other complication
K51.30 Ulcerative (chronic) rectosigmoiditis without complications
K51.311 Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312 Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313 Ulcerative (chronic) rectosigmoiditis with fistula
K51.314 Ulcerative (chronic) rectosigmoiditis with abscess
K51.318 Ulcerative (chronic) rectosigmoiditis with other complication
K51.40 Inflammatory polyps of colon without complications
K51.411 Inflammatory polyps of colon with rectal bleeding
K51.412 Inflammatory polyps of colon with intestinal obstruction
K51.413 Inflammatory polyps of colon with fistula
K51.414 Inflammatory polyps of colon with abscess
K51.418 Inflammatory polyps of colon with other complication
K51.50 Left sided colitis without complications
K51.511 Left sided colitis with rectal bleeding
K51.512  Left sided colitis with intestinal obstruction
K51.513  Left sided colitis with fistula
K51.514  Left sided colitis with abscess
K51.518  Left sided colitis with other complication
K51.80   Other ulcerative colitis without complications
K51.811  Other ulcerative colitis with rectal bleeding
K51.812  Other ulcerative colitis with intestinal obstruction
K51.813  Other ulcerative colitis with fistula
K51.814  Other ulcerative colitis with abscess
K51.818  Other ulcerative colitis with other complication
K51.90   Ulcerative colitis, unspecified, without complications
K51.911  Ulcerative colitis, unspecified with rectal bleeding
K51.912  Ulcerative colitis, unspecified with intestinal obstruction
K51.913  Ulcerative colitis, unspecified with fistula
K51.914  Ulcerative colitis, unspecified with abscess
K51.918  Ulcerative colitis, unspecified with other complication
K52.0    Gastroenteritis and colitis due to radiation
K52.1    Toxic gastroenteritis and colitis
K52.21   Food protein-induced enterocolitis syndrome
K52.22   Food protein-induced enteropathy
K52.29   Other allergic and dietetic gastroenteritis and colitis
K52.3    Indeterminate colitis
K52.83   Microscopic colitis
K52.831  Collagenous colitis
K52.832  Lymphocytic colitis
K52.838  Other microscopic colitis
K52.839  Microscopic colitis, unspecified
K52.89   Other specified noninfective gastroenteritis and colitis
K57.20   Diverticulitis of large intestine with perforation and abscess without bleeding
K57.21   Diverticulitis of large intestine with perforation and abscess with bleeding
K57.30   Diverticulosis of large intestine without perforation or abscess without bleeding
K57.31   Diverticulosis of large intestine without perforation or abscess with bleeding
K57.32   Diverticulitis of large intestine without perforation or abscess without bleeding
K57.33   Diverticulitis of large intestine without perforation or abscess with bleeding
K57.40   Diverticulitis of both small and large intestine with perforation and abscess without bleeding
K57.41   Diverticulitis of both small and large intestine with perforation and abscess with bleeding
K57.50   Diverticulosis of both small and large intestine without perforation or abscess without bleeding
K57.51   Diverticulosis of both small and large intestine without perforation or abscess with bleeding
K57.52   Diverticulitis of both small and large intestine without perforation or abscess without bleeding
K57.53   Diverticulitis of both small and large intestine without perforation or abscess with bleeding
K57.80   Diverticulitis of intestine, part unspecified, with perforation and abscess without bleeding
K57.92 Diverticulitis of intestine, part unspecified, without perforation or abscess without bleeding
K58.0 Irritable bowel syndrome with diarrhea
K58.1 Irritable bowel syndrome with constipation
K58.2 Mixed irritable bowel syndrome
K58.8 Other irritable bowel syndrome
K58.9 Irritable bowel syndrome without diarrhea
K59.31 Toxic megacolon
K59.39 Other megacolon
K62.0 Anal polyp
K62.1 Rectal polyp
K62.2 Anal prolapse
K62.3 Rectal prolapse
K62.5 Hemorrhage of anus and rectum
K63.5 Polyp of colon
Z12.11 Encounter for screening for malignant neoplasm of colon
Z86.010 Personal history of colonic polyps

**REVISIONS**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>12-31-2009</td>
<td>Updated Description section.</td>
</tr>
</tbody>
</table>

In Policy section:
- Removed "Virtual colonoscopy/CT colonography as a screening test for colorectal polyps is considered experimental/investigational.

Virtual colonoscopy/CT colonography screening for colorectal cancer is considered medically necessary as an alternative to colonoscopy when the patient has failed a colonoscopy AND the patient is at higher than average risk for colorectal cancer based on one or more of the following:
- Personal history of resected colorectal cancer; OR
- Prior history of adenomatous polyps; OR
- Older unscreened relatives of an individual with newly diagnosed Familial Adenomatous Polyposis (FAP) but who do not have specific genetic evidence or clinical manifestations of the disease; OR
- Patients with a genetic or clinical diagnosis of Hereditary Non Polyposis Colorectal Cancer (HNPPC), OR
- Inflammatory bowel disease OR
- Family history of colorectal cancer or adenomas as evidenced by ANY ONE of the following:
  - One first degree relative with colorectal cancer or adenoma diagnosed < age 60; OR
  - Multiple (2 or more) first degree relatives with colorectal cancer or adenomas at any age; OR
  - One or more first degree relatives with colorectal cancer or adenoma diagnosed > age 60, or two second degree relatives."
- Added the policy liberalization of, "Virtual colonoscopy / CT colonography as a test for colorectal cancer is considered not medically necessary, except when the patient failed to successfully complete a colonoscopy."

In Coding Section (effective 01/01/2010):
- Added CPT Codes: 74261, 74262, 74263
- Removed CPT Codes: 0066T, 0067T
<table>
<thead>
<tr>
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<th>Updated Policy Language</th>
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<tr>
<td><strong>10-08-2010</strong></td>
<td>Updated Policy Language</td>
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<tr>
<td></td>
<td>In the policy language:</td>
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<tr>
<td></td>
<td>• Removed &quot;screening&quot; to read &quot;Virtual colonoscopy / CT Colonography as a test for colorectal cancer is considered not medically necessary, except when the patient: ...&quot;</td>
</tr>
<tr>
<td></td>
<td>• Inserted &quot;A. Failed to successfully complete a colonoscopy (an inadequate prep does not constitute a failed colonoscopy).&quot;; &quot;B. when a patient is not an appropriate candidate to safely perform a colonoscopy.&quot;</td>
</tr>
<tr>
<td></td>
<td>• Inserted &quot;Examples of conditions where the patient might not be an appropriate candidate to safely perform a colonoscopy are as follows, but not limited to:--Known colonic obstruction or stenosing lesions--Inability to perform colonoscopy because anticoagulant therapy cannot be discontinued--High anesthesia risk for the patient&quot;</td>
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<td><strong>09-17-2013</strong></td>
<td>Updated Description section.</td>
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<tr>
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<td>Updated Rationale section.</td>
</tr>
<tr>
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<td>In Coding section:</td>
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<tr>
<td></td>
<td>• Added ICD-10 Diagnosis codes <em>(Effective October 1, 2014)</em></td>
</tr>
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<td><strong>02-16-2015</strong></td>
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<tr>
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<td>Updated Rationale section.</td>
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<tr>
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<td>In Coding section:</td>
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<td></td>
<td>• Changed ICD-10 Diagnoses Effective date to October 1, 2015.</td>
</tr>
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<td><strong>07-21-2015</strong></td>
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<td><strong>10-01-2016</strong></td>
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<td>In Coding section:</td>
</tr>
<tr>
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<td>• Added ICD-10 codes effective 10-01-2016: K52.21, K52.22, K52.29, K52.3, K52.83, K52.831, K52.832, K52.838, K52.839, K58.1, K58.2, K58.8, K59.31, K59.39</td>
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<td>• Termined ICD-10 codes effective 09-30-2016: K52.2, K59.3</td>
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<tr>
<td><strong>10-25-2017</strong></td>
<td>Updated Description section.</td>
</tr>
<tr>
<td></td>
<td>In Policy section:</td>
</tr>
<tr>
<td></td>
<td>• Previous policy language was removed: A. Virtual colonoscopy / CT colonography as a test for colorectal cancer is considered not medically necessary, except when the patient: 1. Failed to successfully complete a colonoscopy (an inadequate prep does not constitute a failed colonoscopy); OR 2. When a patient is not an appropriate candidate to safely perform a colonoscopy. B. Examples of conditions where the patient might not be an appropriate candidate to safely perform a colonoscopy are as follows, but not limited to: 1. Known colonic obstruction or stenosing lesions 2. Inability to perform colonoscopy because anticoagulant therapy cannot be discontinued 3. High anesthesia risk for the patient</td>
</tr>
<tr>
<td></td>
<td>• The following language was added: A. Virtual colonoscopy / CT colonography may be considered medically necessary as a screening technique for colorectal cancer in average risk, asymptomatic individuals between the ages of 50 and 75 years when no other colorectal cancer screening has been performed during the recommended screening interval: 1. Guaiac-based fecal occult blood test in the past year, OR 2. Fecal immunochemical test in the past year, OR 3. Multitargeted stool DNA test in the past 3 years, OR 4. Colonoscopy in the past 10 years, OR 5. CT colonography in the past 5 years, OR 6. Flexible sigmoidoscopy in the past 5 years.</td>
</tr>
<tr>
<td></td>
<td>• Added Policy Guidelines.</td>
</tr>
</tbody>
</table>
REFERENCES


**Other References**

1. Blue Cross and Blue Shield of Kansas Medical Advisory Committee, April 2007; April 2008; April 2010.
3. Blue Cross and Blue Shield of Kansas Board of Directors, May 2010.