COMPUTED TOMOGRAPHIC COLONOGRAPHY

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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COVERAGE RATIONALE

Computed tomographic colonography is proven for the following:
- As a diagnostic tool for symptomatic patients who are unable to undergo a complete colonoscopy (such as individuals with an obstructive tumor and others who may be unable to tolerate the procedure)
- Patients on anticoagulation therapy who cannot safely discontinue treatment and would be at risk of bleeding from a more invasive procedure
- As a screening test for colon cancer

Computed tomographic colonography is unproven as a diagnostic tool for the following:
- Crohn's disease
- Diverticulitis

There is insufficient evidence to support the use of computed tomographic colonography for Crohn's disease and diverticulitis. Widespread use of computed tomographic colonography in Crohn's disease is currently not supported due to the potential of false-negative findings.
Computed tomographic colonography was compared to conventional colonoscopy in patients with symptomatic diverticular disease. While use of CTC for diverticulitis is more promising, there was only one study available for review involving 50 patients. Further studies are needed to determine the safety and efficacy of computed tomographic colonography as a follow-up diagnostic tool for Crohn's disease or diverticulitis.

**BACKGROUND**

Colonoscopy is the "gold standard" screening test; however, it is invasive and frequently requires sedation or anesthesia, so screening rates are low.

Computed tomography colonography (CTC), also referred to as virtual colonoscopy, is perceived by some persons to be a less invasive method of colon cancer screening than optical colonoscopy. It has been developed to obtain detailed 2-dimensional (2D) and 3-dimensional (3D) colonoscopic images of the colon and rectum using helical computed tomography (CT). These images are then reconstructed to produce computer-generated 3D images suitable for interpretation by a gastrointestinal radiologist. If suspicious lesions are detected, the patient usually undergoes further testing, including possible biopsy, by conventional colonoscopy. Since CTC is believed by some to be less invasive than conventional colonoscopy and does not require sedation, it may be more acceptable to patients and thereby improve compliance with colorectal cancer screening recommendations.

Computed tomographic colonography may not detect lesions ≤6mm in size which could result in delay in treatment and/or conversion to colonoscopy.

**CLINICAL EVIDENCE**

**Surveillance and Monitoring for Colorectal Cancer.**

Screening is defined by the American Cancer Society (ACS) as the search for disease, such as cancer, in people without symptoms. Surveillance is considered to be the screening of individuals known to be at an increased risk. Monitoring is the follow-up after a diagnosis or treatment.

Stoop et al. (2012) reported on a population-based randomized trial that compared the participation and diagnostic yield of colonoscopy and non-cathartic CTC in average-risk individuals (n=2258) in a population-based program of colorectal cancer screening. Subjects were randomly allocated (2:1) to primary screening for colorectal cancer by colonoscopy or by CTC. Based on the study results, the authors concluded that participation in colorectal cancer screening with CTC was significantly better than with colonoscopy, but colonoscopy identified significantly more advanced neoplasia per 100 participants than CTC. The diagnostic yield for advanced neoplasia per 100 subjects was similar for both strategies, which appears to indicate that both techniques can be used for population-based screening for colorectal cancer. The authors also noted that cost-effectiveness and perceived burden should be taken into account.

Pickhardt et al. (2011) performed a systematic review and meta-analysis of studies assessing the sensitivity of computed tomographic (CT) colonography and optical colonoscopy (OC) for detecting colorectal cancer. Forty-nine studies provided data on 11,151 patients. The sensitivity of CT colonography for colorectal cancer was 96.1%. The sensitivity of OC for colorectal cancer, derived from a subset of 25 studies including 9223 patients, was 94.7%. No heterogeneity (bias across studies) was observed with CTC, whereas a moderate degree of heterogeneity was found with OC. The authors concluded that CT colonography is highly sensitive for colorectal cancer, especially when both cathartic and tagging agents are combined in the bowel preparation.

Blue Cross Blue Shield Association (BCBSA) Technology Evaluation Center (TEC) published a technology assessment of CTC for colon cancer screening (2009). The objective was to determine whether there is adequate evidence to demonstrate that CTC screening is effective in reducing mortality from colon cancer. Diagnostic performance of CTC is highly dependent on the
technology and techniques used. The results of this study show 90% sensitivity of CTC for polyps 10 mm or larger and 86% specificity; positive and negative predictive values were 23% and 99%, respectively. After a review of the available evidence, the assessment concluded that CTC for the purpose of colon cancer screening meets the TEC criteria.

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.

- 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.

A 2008 systematic review found that CTC is as likely as colonoscopy to detect lesions 10 mm or greater but may be less sensitive for smaller adenomas. Potential radiation-related harms, the effect of extra-colonic findings, and the accuracy of test performance of CTC in community settings remain uncertain. (Whitlock, 2008)

A prospective study by Graser et al. (2008) compared the performance characteristics of 5 different screening tests for the detection of advanced colon cancer. The tests included CT colonography (CTC), colonoscopy, flexible sigmoidoscopy, fecal immunochemical stool testing (n= 285) and fecal occult blood testing (n=276). Three hundred and seven participants completed the study. Each participant collected stool samples for fecal occult blood testing and fecal immunochemical stool testing prior to endoscopy. After CTC, patients had a colonoscopy and flexible sigmoidoscopy. Lesions were rated as positive if they were detected by both CTC and colonoscopy. Lesions were also considered positive if the lesion was within the same size category or if there was a deviation of no more than one size category. Only polyps detected in the rectum and sigmoid colon were included for analysis of flexible sigmoidoscopy. A total of 221 adenomas were detected in patients receiving CTC and colonoscopy. The sensitivities for adenomas of all sizes was much higher for colonoscopy, with 212 of 221 (95.9%) lesions detected compared with 155 adenomas (70.1%) detected by CTC. In contrast, CTC detected 31 of 33 (93.9%) lesions in the large adenoma group and 43 of 46 (93.5%) lesions in the advanced colon cancer group. Compared with colonoscopy, the sensitivity was 100% and 97.8% respectively. In contrast, for adenomas >10 mm, sigmoidoscopy identified 68%, fecal immunochemical stool testing identified 33.3% and fecal occult blood testing identified 23.8%. The authors concluded that CTC performs equally as well as colonoscopy in detecting advanced adenomas.

Twelve studies published between the years 2003 to 2005 met the criteria for detailed review. These included nine prospective, evaluator-blinded studies and three meta-analyses. All but one of the prospective studies compared computed tomographic colonography (CTC) with conventional colonoscopy alone. One study assessed the comparative accuracy of three screening tests: CTC, colonoscopy, and air-contrast barium enema (ACBE) (Rockey, 2005). Many of the studies used conventional colonoscopy as the reference standard; several of the studies used segmental unblinding to create an enhanced reference standard; one study used a combination of the initial findings of conventional colonoscopy, any additional findings after segmental unblinding to CTC reports, and the results of additional diagnostic tests performed at a later time.

Kim et al. (2007) compared primary CTC in 3120 consecutive adults with primary optical colonoscopy (OC) screening in 3163 consecutive adults. The main outcome measures included detection of advanced neoplasia (advanced adenomas and carcinomas) and total number of
harvested polyps. Primary CTC and OC screening resulted in similar detection rates for advanced neoplasia (3.2% for CTC and 3.4% for OC), although the numbers of polypectomies (561 CTC vs. 2434 OC) and complications were considerably smaller (7 colonic perforations in the OC group vs. none in the CTC group) in the CTC group. The authors therefore concluded that these findings support the use of CTC as a primary screening test before therapeutic OC.

Some studies were conducted in low-prevalence populations consisting of asymptomatic adults at average risk for colorectal cancer, as well as in asymptomatic patients with increased risk for colorectal cancer. Those at average risk generally were referred for routine, clinically indicated colonoscopy. Other studies were conducted in symptomatic patients (e.g., as a follow-up to an abnormal screening test, such as hemoccult testing, sigmoidoscopy, or barium enema, or to evaluate iron deficiency anemia or minor gastrointestinal symptoms), and/or in individuals with a personal or family history of colorectal polyps or cancer. Sample sizes for the prospective studies ranged from moderate (n=150 to n=250, 4 studies), to large (n=600 to n=703, 3 studies), to very large (n=1233, 1 study).

A meta-analysis by Chaparro et al. (2009) evaluated the diagnostic accuracy of CTC for the detection of polyps and colorectal tumors in 47 studies (10,546 patients) that compared CTC to the reference standard of conventional colonoscopy. Overall per-polyp sensitivity of CTC was 59% (56–61%), for polyps 6–9 mm in size and 76% (73–79%) for polyps larger than 9 mm. Overall CTC specificity was 83%. The authors concluded that CTC is highly specific for the detection of colorectal polyps and tumors larger than 10 mm in size. However, growths of this size would require conventional colonoscopy or surgery for removal.

One meta-analysis analyzed data from 1324 participants in 14 prospective studies (Sosna, 2003); 1 included data from 4181 patients from 24 studies (Halligan, 2005), and the third meta-analysis included 33 prospective studies involving 6393 patients (Mulhall, 2005). Inclusion criteria for the meta-analyses were similar: prospective, blinded studies of adults undergoing CTC after full bowel preparation, with colonoscopy (or surgery for the Mulhall et al. analysis) as the reference standard; use of state-of-the art technology, including at least a single-detector CT scanner with supine and prone positioning, and both 2-dimensional and 3-dimensional views during scan interpretation. The Sosna et al. analysis included 7 studies with < 50 patients (50%) and 4 studies with 50 to 100 patients (28.6%). The Halligan et al. (2005) analysis included 4 studies with < 50 patients (16.7%) and 10 studies with 50 to 100 patients (41.7%). The Mulhall et al. (2005) analysis included 3 studies with < 50 patients (9.1%) and 12 studies with 50 to 100 patients (36.4%).

Regge et al. (2009) conducted a multicenter, cross-sectional study to assess the accuracy of CTC in detecting advanced colorectal cancer. There were 937 asymptomatic patients who were at increased risk of colorectal cancer. Each patient underwent both CTC followed by colonoscopy on the same day. Sensitivity and specificity of CT colonography in detecting advanced neoplasia (for example, advanced adenoma or CRC) 6 mm or larger was the main outcome measurement. CTC identified 151 of 177 participants with advanced neoplasia 6 mm or larger (sensitivity 85.3%). CTC correctly classified results as negative for 667 of 760 participants without these lesions (specificity 87.8%). The positive and negative predictive values were 61.9% and 96.3% respectively. The authors concluded that CT colonography had a negative predictive value of 96.3% compared with colonoscopy and is potentially as effective as colonoscopy for screening persons at increased risk.

As in the earlier studies, the principal outcome measures were sensitivity and specificity of CTC on a per-patient and per-lesion basis. Some investigators noted that the per-patient data provided the most important perspective for a screening test since this analysis assessed the ability of CTC to identify patients with colorectal lesions who are in need of a colonoscopy, excluding those without clinically relevant lesions who do not need to undergo colonoscopy. Per-polyp data emphasized the ability of CTC to find colonic lesions, i.e. this type of analysis assessed the performance of the technology rather than its utility as a screening tool (Halligan, 2005; Mulhall,
Some studies provided results for all types of polyps combined (neoplastic and non-neoplastic), whereas other studies distinguished between neoplastic polyps (adenomas or adenomatous polyps) and non-neoplastic polyps (hyperplastic polyps) that do not have the potential to become cancerous. Some studies used the term lesions rather than polyps to include carcinomas as well as adenomas.

Findings from these studies suggest that the sensitivity of CTC on a per-polyp basis is dependent on lesion size, with sensitivity increasing with increasing size of the lesion. In the individual studies, sensitivity for lesions 10 mm in diameter or larger ranged from 51% to 100%, with a median of 76%. The Sosna et al. meta-analysis reported pooled per-polyp sensitivities of 81% for polyps greater than or equal to 10 mm and 43% for polyps less than or equal to 5 mm, with a significant increase in sensitivity for detection of polyps increasing as the polyp size increased. In two of the smaller studies that investigated overall sensitivity (for any size lesion), values were reported to be 70% and 64% for polyps, and 72% for neoplastic polyps. (Iannaccone, 2003; Iannaccone, 2004)

Overall, per-patient specificity was not quite as dependent on polyp size with some studies showing an increase in specificity with increasing size of lesion, while others did not. Specificity for lesions greater than or equal to 10 mm in diameter ranged from 92% to 97%, with a median of 95.5%. The Sosna et al. (2003) meta-analysis reported a 95% pooled overall specificity for detecting polyps > 10 mm, Halligan et al. (2003) reported a per-patient mean specificity of 97% for lesions greater than or equal to 10 mm and an 86% specificity for lesions 6-9 mm in diameter and Mulhall et al. (2005) reported a per-patient specificity of 97% for polyps > 9 mm and 91% for polyps < 6 mm. In three studies that reported per-patient specificity for lesions greater than or equal to 6 mm, values were 70%, 80%, and 83%, respectively. Finally, in five studies that reported overall (for any size lesion) specificity, the values were 31%, 62%, 71%, 92%, and 97%, respectively. In the study that reported the lowest overall specificity, 83% of polyps were <6mm, which may account for this low value. (Van Gelder, 2004)

The Pickhardt et al. (2003) study, conducted in a low prevalence, asymptomatic, average-risk screening population (n=1233), reported that CTC was an accurate screening method and compared favorably with optical colonoscopy in terms of detection of clinically relevant lesions. CTC had a high sensitivity (89% per-patient, 86% per-polyp) and an acceptable specificity (80% per-patient) for adenomas that were greater than or equal to 6 mm in diameter. For polyps greater than or equal to 10 mm, the per-patient sensitivity was 94% (compared with 88% for colonoscopy). There were some notable differences between the two studies.

The meta-analyses also arrived at different conclusions. The earlier and smaller of the three reports by Sosna et al. (2003) concluded that the collective evidence suggests that CTC is an accurate tool for detecting clinically important colorectal polyps (i.e., those that are greater than or equal to 10 mm in diameter). The sensitivity and specificity of CTC, pooled across the 14 studies, were high for polyps greater than or equal to 10 mm. However, this analysis had several limitations: small numbers of patients enrolled in each study, inherent publication bias, possible verification bias, and heterogeneity of studies (which was not accounted for in the analysis). Halligan et al. also concluded that CTC was sufficiently sensitive and specific for the detection of large (greater than or equal to 10 mm) and medium-sized (6-9 mm) polyps, and especially sensitive in the detection of symptomatic cancer.

Rockey et al. (2005) was a large study assessed the comparative accuracy of three imaging tests (ACBE, CTC, and colonoscopy), and reported negative results. The study reported that colonoscopy was significantly more sensitive than either ACBE or CTC in 614 patients at high risk for colon neoplasmia. While the specificity of ACBE and CTC for lesions greater than or equal to 10 mm were high, it was significantly higher for colonoscopy than either of the other two tests. The remainder of the individual studies reported positive results.

Summers et al. (2005) compared the sensitivity of CTC to optical colonoscopy for detection of
adenomatous colonic polyps in 1186 screening patients at 3 medical centers. The data were randomized into separate training (n=394) and test (n=792) sets for analysis by a computer-aided polyp detection (CAD) program. For the test set, per-polyp and per-patient sensitivities for CAD were both 89.3% for detecting retrospectively identifiable adenomatous polyps at least 1 cm in size. The false-positive rate was 2.1 false polyps per patient. Both carcinomas were detected by CAD at a false-positive rate of 0.7 per patient; only 1 of 2 was detected by optical colonoscopy before segmental unblinding. At both 8-mm and 10-mm adenoma size thresholds, the per-patient sensitivities of CAD were not significantly different from those of optical colonoscopy before segmental unblinding. The investigators concluded the per-patient sensitivity of CAD in an asymptomatic screening population is comparable to that of optical colonoscopy for adenomas greater than or equal to 8 mm and is generalizable to new CTC data.

**Crohn's Disease**
The clinical evidence was reviewed on September 9, 2013 with no additional information identified that would change the unproven conclusion for use of computed tomographic colonography as a diagnostic tool for Crohn's disease.

In a comparative study of 16 patients by Biancone et al. (2003), the findings from virtual colonoscopy (VC) were compared to conventional colonoscopy (CC) for assessing postoperative recurrence of Crohn's disease. Conventional colonoscopy showed perianastomotic recurrence in 15 of 16 patients while virtual colonoscopy detected 11 of the 15 patients. Conventional colonoscopy identified stenosis in 8 of the 16 while virtual colonoscopy detected stenosis in 7 of the 16 patients; therefore, there was a false-negative reading in 1 of the 16 patients. The authors therefore concluded that although the widespread use of virtual colonoscopy in Crohn's disease is currently not indicated because of possible false-negative findings, this technique may represent an alternative to conventional colonoscopy in noncompliant postsurgical patients with a rigid stenosis not allowing passage of the endoscope.

**Diverticulitis**
In a prospective study by Hjern et al. (2007), 50 patients diagnosed with diverticulitis were assessed to determine whether computed tomography colonography (CTC) is a viable alternative to colonoscopy. All 50 patients underwent CTC immediately followed by conventional colonoscopy. The results were blinded to the examiners. Diverticular disease was found in 48 of the 50 (96%) patients utilizing CTC and in 45 of 50 (90%) patients with conventional colonoscopy. These results indicate that CTC can provide at least the same level of accuracy as conventional colonoscopy. The authors conclude that CTC appears to have a better diagnostic potential for imaging of diverticular disease-specific findings when compared with colonoscopy, and is a reasonable alternative in follow-up of patients with symptomatic diverticular disease. The study design, however, did require that the CTC be completed prior to conventional colonoscopy which may have introduced a biased response favoring CTC. In addition, residual gas from CTC may have contributed to greater discomfort during the subsequent colonoscopy. Further studies are needed to determine the efficacy of computed tomographic colonography as a follow-up diagnostic tool for diverticulitis.

A study conducted by Obana et al. (2013), enrolled a total of 52 patients with the aim of evaluating the ability of contrast-enhanced computed tomography (CE-CT) in the detection of colonic diverticular bleeding (CDB). Patient were enrolled based on their ability to undergo both a CE-CT and a total colonoscopy. The patient were also known to have hematochezia and were clinically suspected of CDB. The detection rate for contrast-enhanced computed tomography was only 15.4%. The detection rate for the total colonoscopy was 38.5%. Based on the results this study concluded that though the CE-CT may play a complementary role to colonoscopy in patients with suspected colonic diverticular bleeding it is not recommended for all cases due to the low detection rate demonstrated during the course of the study. Optical colonoscopy still remains the primary recommended screening tool.

Although CTC involves exposure to x-rays and may cause minor complications such as
discomfort, bloating, cramping or nausea, it is considered a reasonably safe procedure. The studies selected for detailed review did not report any major adverse events as a consequence of CTC. Definitive patient selection criteria have not been established for CTC as a screening test for colorectal cancer. However, there is sufficient evidence to support the use of CTC as a diagnostic tool for symptomatic patients who are unable to undergo a complete colonoscopy, such as the elderly, individuals with an obstructive tumor, and others who may have a contraindication to the procedure.

The use of CT in the U.S. has been increasing exponentially over the past decade. The greatest increases in CT use have been in pediatric diagnosis and adult screening. The risks and benefits of these tests should be carefully analyzed and radiation exposure risk assessment should be conducted as part of the selection of diagnostic and screening tests. (Johnson et al., 2009)

In 2008, the United States Preventive Services Task Force (USPSTF) concluded that the evidence is insufficient to assess the benefits and harms of computed tomographic colonography as a screening modality for colorectal cancer.

**Professional Societies**

**American College of Radiology (ACR):** A 2009 Practice Guideline for the Performance of Computed Tomography (CT) Colonography in Adults lists the following indications for a CTC examination which include, but are not limited to:

1. Screening examination in individuals who are at average or moderate risk for developing colorectal carcinoma
2. Screening examinations in individuals who are at moderate risk for colorectal cancer based on family history (with no personal history of colon polyps or colon cancer) should be managed individually based on clinical context or local practice patterns.
3. Surveillance examination in patients with a history of previous colonic neoplasm, depending on the appropriate clinical context.
4. Diagnostic examination in symptomatic patients, particularly in the setting of incomplete colonoscopy, including, but not limited to, those with:
   - Abdominal pain
   - Diarrhea
   - Constipation
   - Gastrointestinal bleeding
   - Anemia
   - Intestinal obstruction
   - Weight loss
5. Following incomplete screening, surveillance, or diagnostic colonoscopy and for characterization of colorectal lesions indeterminate on optical colonoscopy.
6. Patients who may be at increased risk for complications during optical colonoscopy (e.g., advanced age, anticoagulant therapy, sedation risk, prior incomplete colonoscopy).

The relative contraindications or conditions that require caution in performing a CTC examination include, but are not limited to:

- Symptomatic acute colitis
- Acute diarrhea
- Recent acute diverticulitis
- Recent colorectal surgery
- Symptomatic colon-containing abdominal wall hernia
- Recent deep endoscopic biopsy or polypectomy/mucosectomy
- Known or suspected colonic perforation
- Symptomatic or high-grade small bowel obstruction

CTC is not indicated for:

- Routine follow-up of inflammatory bowel disease
b. Hereditary polyposis or nonpolyposis cancer syndromes

c. Evaluation of anal canal disease

d. The pregnant or potentially pregnant patient

American Cancer Society (ACS): In 2008, ACS worked jointly with both the US Multi-Society Task Force and the American College of Radiology to publish colorectal cancer guidelines (Levin, 2008). Based on their review, the task force concluded that screening of average-risk adults with CTC should begin at age 50 years with repeat exams every 5 years if the initial CTC is negative for significant polyps. However, if current studies detect polyps 6 mm or greater, colonoscopy should be offered. Additionally, CTC surveillance could be offered to those patients who would benefit from screening but either decline colonoscopy or who are not good candidates for colonoscopy for one or more reasons. If colonoscopy is contraindicated because the patient is not likely to benefit from screening due to life-limiting comorbidity, then neither CTC nor any other CRC screening test would be appropriate.

American Gastroenterological Association (AGA): AGA recommends that the test be performed once every 5 years for average-risk individuals and who do not have any signs or symptoms. It is recommended that patients at higher risk for colorectal cancer, including those with a family history or a personal history of polyps or colon cancer should talk to their gastroenterologist about scheduling a colonoscopy since patients with these features are more likely have colon polyps that will require a colonoscopy to remove them. (AGA, 2008)

American Society for Gastrointestinal Endoscopy (ASGE): A 2009 technology status report on CTC found that the accuracy for detection of polyps improves with increasing polyp size and is comparable with colonoscopy for polyps 10 mm or larger. However, the detection of polyps smaller than 10 mm and flat polyps is inferior to colonoscopy, and this should be considered by providers and patients when considering screening options. CTC is preferred to a barium enema for evaluation of the colon proximal to an obstructing lesion and in patients with an incomplete colonoscopy.

National Comprehensive Cancer Network (NCCN): The NCCN published within their CRC screening guidelines the following statements regarding the use of CTC (NCCN, 2012):

- Regarding CTC, it is noted that currently there is not consensus on the use of CTC as a primary screening modality and it is evolving with regards to recommended/programmatic frequency, polyp size leading to referral for colonoscopy, and protocol for evaluating extracolonic lesions. The available data suggests, that if CTC is negative with no polyps, then CTC should be repeated in five years and if positive/polyps, colonoscopy should be performed.

National Institute for Health and Clinical Excellence (NICE) (United Kingdom): NICE (2011 published recommendations for colonoscopic surveillance for prevention of colorectal cancer in people with ulcerative colitis, Crohn's disease or adenomas. The guidelines include the following regarding CTC:

- consider CTC as a single examination if colonoscopy is not clinically appropriate (e.g., because of comorbidity or because colonoscopy cannot be tolerated)
- consider double contrast barium enema as a single examination if CTC is not available or not appropriate.
- consider CTC or double contrast barium enema for ongoing surveillance if colonoscopy remains clinically inappropriate, with a discussion of the risks and benefits

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Helical CT scanners are regulated by the FDA as Class II devices, and numerous systems have met all requirements of the 510(k) approval process. The complete list of commercially available helical CT scanners is too extensive for inclusion here; however, major manufacturers of devices used in the studies selected for detailed review include Siemens Medical Solutions, General Electric Medical Systems, and Philips Medical Systems.
In 2010, the U.S. Food and Drug Administration announced an initiative to reduce unnecessary radiation exposure from three types of medical imaging procedures: computed tomography (CT), nuclear medicine studies, and fluoroscopy. These types of imaging exams expose patients to ionizing radiation, a type of radiation that can increase a person’s lifetime cancer risk.

Additional information:  
Accessed September 6, 2013

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not cover screening computed tomographic colonography (CTC). See the National Coverage Determination (NCD) for Colorectal Cancer Screening Tests (210.3)

Local Coverage Determinations (LCDs) exist for Colorectal Cancer Screening and Computed Tomographic Colonography and Radiology: Computed Tomographic (CT) Colonography and compliance with these policies is required where applicable. Accessed September 6, 2013

APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

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<tr>
<td>74262</td>
<td>Computed tomographic (CT) colonography, diagnostic, including image postprocessing; with contrast material(s) including non-contrast images, if performed</td>
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REFERENCES


Institute for Clinical Systems Improvement (ICSI). Colorectal cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2010 May. 27 p. [57 references]


**POLICY HISTORY/REVISION INFORMATION**

<table>
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<th>Date</th>
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| 11/01/2013 | • Updated description of services to reflect most current clinical evidence, FDA information and references; no change to coverage rationale or lists of applicable codes  
|            | • Archived previous policy version 2012T0521L                                      |