



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject** Computed Tomographic  
Colonography/Virtual  
Colonoscopy

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## Hyperlink to Related Coverage Policies

Colorectal Cancer Screening and  
Surveillance  
Genetic Testing for Susceptibility to  
Colorectal Cancer  
Tumor Markers for Diagnosis and  
Management of Cancer

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

## Coverage Policy

Coverage of colorectal cancer screening is generally subject to the terms, conditions and limitations of a preventive services benefit as described in the applicable benefit plan's schedule of copayments. Please refer to the applicable benefit plan document and schedules to determine benefit availability and the terms, conditions and limitations of coverage.

If coverage for colorectal cancer screening is available, CIGNA covers computed tomographic colonography (CTC)/virtual colonoscopy for colorectal cancer screening as medically necessary every five years in average-risk individuals age 50 years and older.

CIGNA covers CTC as medically necessary for diagnostic testing or for colorectal cancer surveillance or monitoring in increased- or high-risk individuals when EITHER of the following criteria is met:

- conventional colonoscopy cannot be completed due to a known colonic lesion, structural abnormality or technical difficulty is encountered that prevents adequate visualization of the entire colon.
- criteria for conventional colonoscopy have been met and conventional colonoscopy is medically contraindicated.

Please refer to the CIGNA Coverage Policy on Colorectal Cancer Screening and Surveillance for additional information on colorectal cancer screening, surveillance and monitoring.

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## General Background

Computed tomographic colonography (CTC), also referred to as virtual colonoscopy, is a diagnostic technique that uses data from computed tomography (CT) to generate two- and three-dimensional images of the colon and rectum. Internal images of the colon and rectum can be stored, viewed on a monitor, or printed on film. These high-resolution images are used to create a three-dimensional model of the colonic lumen that can be navigated in an interactive fashion, resembling the view seen through a colonoscope.

CTC is a minimally-invasive imaging technique that does not require intravenous administration of sedatives or analgesics. The day before the CTC, bowel cleansing is performed, similar to the requirements for a colonoscopy. At the time of the CTC, a thin tube is inserted into the rectum and air or carbon dioxide is introduced into the colon to distend the bowel, allowing polyps to be differentiated from the normal surface. Adenomatous polyps, which are the precursors to colon cancer, may be identified using this technique. Colonic perforation is extremely low with this test since it is minimally invasive (Levin, et al., 2008). Patients who are suspected of having inflammatory bowel disease may not be good candidates due to the potential risk of bowel perforation (Torres, 2007).

CTC permits visualization of the entire colon, even in the presence of obstructive/stenosing lesions (Torres, 2007). CTC can also be used in high-risk patients as a “one-stop” test to detect not only the primary tumor but synchronous colon lesions, and to provide additional information regarding regional and distant metastatic disease, depth of wall invasion and precise localization of the lesion within the colon prior to surgery (Harford, 2006; O’Hare, 2006). Inadequate colonic inflation or excess fluid retained within the colon may lead to false-positive reports due to the misinterpretation of findings. However, advances in imaging techniques using fecal tagging and fluid subtraction have enhanced the clarity of the images that are documented (Harford, 2006; O’Hare, 2006). A traditional colonoscopy is still needed in order to biopsy or remove any lesion/polyp that is found (Torres, 2007; Itzkowitz, 2006).

### Colorectal Cancer Screening, Surveillance and Monitoring

**Please refer to the CIGNA HealthCare Coverage Policy on Colorectal Cancer Screening and Surveillance for additional background information on colorectal cancer.**

The population has been stratified into risk categories for the potential development of CRC. These groups include: average risk, increased risk with a personal history, increased risk with a family history and increased/high risk due to hereditary conditions.

Screening is defined by the 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.

Guidelines for colorectal screening, surveillance and monitoring have been developed based on these categories. The NCCN and ACS definitions of these groups include (NCCN, 2009; ACS, 2008b):

Risk	NCCN	ACS
average risk	those individuals 50 years or older with no history of adenoma and inflammatory bowel disease and negative family history	individual with no first-degree relatives having a history of CRC or adenomatous polyps and has not experienced these problems personally
increased risk	individuals with personal history of adenomas, CRC, or inflammatory bowel disease as well as those with a positive family history of: <ul style="list-style-type: none"><li>• first-degree relative with CRC or adenoma</li><li>• two second degree relatives with CRC</li></ul>	individuals those who have a personal history of CRC or adenomas, a family history of CRC or adenomas diagnosed in any first-degree relative before age 50, or in two or more first-degree relatives diagnosed at any age (if not a hereditary syndrome). According to the ACS, individuals who have a personal history of CRC or adenomatous polyp require regular surveillance, not screening.

	<ul style="list-style-type: none"> <li>multiple cases of CRC or HNPCC/Lynch syndrome in the family</li> </ul>	
hereditary/ high risk	individuals who have had CRC before the age of 50 years; those with family history of multiple cases of CRC or HNPCC related cancers; personal or family history of polyposis; or individuals with HNPCC/Lynch syndrome	individuals those who have a personal history of CRC or adenomas, a family history of CRC or adenomas diagnosed in any first-degree relative before age 50, or in two or more first-degree relatives diagnosed at any age (if not a hereditary syndrome). According to the ACS, individuals who have a personal history of CRC or adenomatous polyp require regular surveillance, not screening.

### **Computed Tomographic Colonography (CTC) for Screening in Average-Risk Individuals**

CTC has been included in the 2008 joint guidelines for screening and surveillance for the early detection of CRC and polyps from the ACS, the US Multi-Society Task Force (USMTF) on Colorectal Cancer and the American College of Radiology (ACR). Beginning at age 50, CTC every 5 years is included as one of the recommended tests for average-risk individuals (Levin, et al., 2008). The consensus guidelines note that, "In terms of detection of colon cancer and advanced neoplasia, which is the primary goal of screening for CRC and adenomatous polyps, recent data suggest CTC is comparable to OC (optical colonoscopy) for the detection of cancer and polyps of significant size when state-of-the-art techniques are applied. In previous assessments of the performance of CTC, the ACS concluded that data were insufficient to recommend screening with CTC for average-risk individuals. Based on the accumulation of evidence since that time, the expert panel concludes that there are sufficient data to include CTC as an acceptable option for CRC screening."

### **Computed Tomographic Colonography (CTC) for Diagnostic Testing and Colorectal Cancer Surveillance and Monitoring in Increased- or High-Risk Individuals**

CTC has been proposed as an alternative to colonoscopy for diagnostic purposes in symptomatic patients. The test may also be indicated when a conventional colonoscopy cannot be completed due to a colonic lesion, structural abnormality or technical difficulty occurs during the colonoscopy. It has been recommended for patients with contraindications to conventional colonoscopy which includes risks of sedation or strong anticoagulant therapy.

Colonoscopy has been the standard method used for examining the colon. In most patients it allows for examination of the entire colon. Biopsy of suspicious lesions and polypectomy may be performed during the colonoscopy. However, there are situations when colonoscopy is incomplete, or cannot be performed. These include redundant or tortuous colon, marked diverticular disease, obstructing mass and strictures, and adhesions due to prior surgery. There are contraindications to colonoscopy which would include patients unable to tolerate sedation due to cardiac or pulmonary disease and patients receiving anticoagulants.

There are guidelines published by organizations including ACS, USMTF and NCCN for patients considered increased risk with a personal history, increased risk with a family history and increased/high risk due to hereditary conditions. For these patients considered increased risk, or increased/high risk, colonoscopy is part of the recommended standard surveillance and monitoring. For these patients CTC may be used in similar situations as for diagnostic CTC—when a conventional colonoscopy cannot be completed due to a known colonic lesion, structural abnormality or technical difficulty is encountered that prevents adequate visualization of the entire colon or colonoscopy is medically contraindicated.

### **Literature Review for Computed Tomographic Colonography (CTC) for Colorectal Cancer (CRC) Screening**

**Studies:** Johnson, et al. reported on a multicenter, study that examined the accuracy of CTC as a screening tool in asymptomatic adults (ACRIN study). The study included 2600 asymptomatic participants, 50 years of age or older, at 15 study centers. CTC images were acquired with the use of standard bowel preparation, stool and fluid tagging, mechanical insufflation, and multidetector-row CT scanners (with 16 or more rows). Radiologists trained in CTC reported all lesions that measured 5 mm or more in diameter. Optical colonoscopy and histologic review were performed according to established clinical protocols at each center and served as the reference standard. The primary end point was detection by CTC of histologically confirmed large adenomas and adenocarcinomas (10 mm in diameter or larger) that had been detected by colonoscopy. Evaluation of the detection of smaller colorectal lesions (6 to 9 mm in diameter) was also performed. Complete data was available

for 2531 participants (97%). For large adenomas and cancers, the mean ( $\pm$ SE) per-patient estimates of the sensitivity, specificity, positive and negative predictive values, and area under the receiver-operating-characteristic curve for CTC were:  $0.90\pm 0.03$ ,  $0.86\pm 0.02$ ,  $0.23\pm 0.02$ ,  $0.99\pm <0.01$ , and  $0.89\pm 0.02$ , respectively. The sensitivity of 0.90 (i.e., 90%) indicates that CTC failed to detect a lesion measuring 10 mm or more in diameter in 10% of patients. The per-polyp sensitivity for large adenomas or cancers was  $0.84\pm 0.04$ . The per-patient sensitivity for detecting adenomas that were 6 mm or more in diameter was 0.78. In this study, CT colonographic screening identified 90% of subjects with adenomas or cancers measuring 10 mm or more in diameter.

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 report found that due to this, many of the older studies reviewed may no longer represent currently possible diagnostic performance of the test. A large study published in 2003 showed diagnostic test performance of CTC for polyps to be equivalent to that of optical colonoscopy. Other studies published previously and after that study showed variable performance, with two large studies showing much lower sensitivity than optical colonoscopy. Results from the largest study of a screening population, the ACRIN trial, were recently published. This study used 16–64 row detector CT scanners, stool tagging techniques, and minimum training standards for interpreters of the test. 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.

Selcuk et al. (2006) conducted a study to determine the sensitivity and specificity of CTC for colorectal polyp detection by using colonoscopy as the reference standard. The study included 48 patients with a high risk for CRC who had a CTC followed by a conventional colonoscopy. CTC identified 19 of 22 polyps (sensitivity, 86%) that were also detected by colonoscopy. four of the polyps that were greater than 10 mm in size were detected by CTC (100%). Six of the seven polyps that were 6–9 mm in size were detected (85%) and nine of 11 of the polyps 5 mm in size or smaller (81%) were found. CTC was noted to have an overall sensitivity of 86% and specificity of 98%. The authors concluded the results of the study support that CTC is a sensitive and specific method for detecting colorectal polyps.

Patients with colonic symptoms who are unfit for or too frail to complete a conventional colonoscopy or barium enema were the target population of a longitudinal study conducted by Duff and colleagues (2006). The researchers wanted to determine if CTC was sufficient in excluding CRC in this population and used a one-year follow-up timeframe for comparison. One hundred and twelve patients underwent CTC (age range 39–95), and seven colorectal cancers were detected, with three false-positives and one false-negative, giving a sensitivity of 87.5% and specificity of 97.1% at that time. At the one-year follow-up, 112 patients were available for review. The primary reasons for undergoing a CTC were inability to complete or likely to have an incomplete barium enema or endoscopic examination. At this time, CTC revealed 29 normal colons; CRC was suspected in ten cases and confirmed by additional endoscopic exams in seven patients. Other findings included diverticular disease, colorectal polyps, gallstones, hiatus hernia, abdominal aneurysms and a renal cell carcinoma. The researchers reported that in this population, CTC had a sensitivity of 87.5% and specificity of 97.1% for the diagnosis of CRC. In the unfit, symptomatic population, the clinical question to be addressed is not the detection of premalignant polyps but whether the presenting symptoms represent underlying large bowel malignancy. The researchers concluded that these results justify use of CTC in this select patient population; however, additional studies are needed before this exam is used in the general asymptomatic population.

In a prospective case series of 240 consecutive asymptomatic average-risk adults undergoing primary CTC screening, Pickhardt (2006) studied the effectiveness of CTC visualization of the entire colonic surface. During this study, colonoscopy was used as the comparative gold standard, with the main objective of this study being the detection of colorectal polyps that are of potential clinical significance (i.e., lesions measuring more than 5 mm in size). Polyps were detected in 223 patients, with 26 patients having polyps that measured 6 mm or greater, with the overall colon surface coverage ranging from 93–99%. Polyps were confirmed with a colonoscopy exam on the same day in 17 of the 26 patients. One polyp measuring 6 mm detected on CTC was not found during colonoscopy. Eight other individuals opted to have CTC short-term surveillance for their polyps in lieu of a colonoscopy. The researchers concluded that the use of both supine and prone datasets provides

significant redundancy for polyp detection, and that the addition of this technique could hasten the acceptance of using CTC as a promising screening tool.

The results of a prospective cohort study of 614 patients was conducted by Rockey and colleagues (2005) that assessed the sensitivity of three imaging tests (i.e., air contrast barium enema [ACBE], CTC, and colonoscopy) to detect colon polyps and cancer. The study participants had positive fecal occult blood tests, hematochezia, iron-deficiency anemia, or family history of CRC. All 614 patients completed the three imaging tests (i.e., ACBE, CTC, colonoscopy, respectively), and the outcomes of these tests were then compared. The study participants and the investigators were all blinded to the findings of each imaging study. Analysis on a per-patient basis for lesions 10 mm or larger in size (n=63) were found to be: sensitivity of ACBE was 48% (95% CI 35–61), of CTC 59% (46–71, p=0.1083, for CTC vs ACBE), and colonoscopy 98% (91–100, p<0.0001 for colonoscopy vs CTC). Analysis for lesions 6–9 mm in size (n=116), the findings were: sensitivity 35% for ACBE (27–45), 51% for CTC (41–60, p=0.0080 for CTC vs ACBE); and 99% for colonoscopy (95–100, p<0.0001 for colonoscopy vs CTC). For lesions of 10 mm or larger in size, the findings were: specificity was greater for colonoscopy (0–996) than for either ACBE (0–90) or CTC (0–96) and decreased for ACBE and CTC when smaller lesions were considered. The researchers concluded that all tests were very specific when large lesions were present. The specificity of ACBE and CTC for lesions of 10 mm or larger was high; for colonoscopy it was greater than that of the other tests. During this study, an older version of software was used to conduct the CTC (i.e., 2-D reads with 3-D problem-solving) and therefore conclusions cannot be drawn whether this enhanced software would provide significant outcome variances.

Pickhardt et al. (2003) conducted an evaluation of 1233 asymptomatic adults for the detection of CRC. Each individual underwent same-day CTC and optical colonoscopy (OC). At the time of initial examination of each colonic segment, the physician was unaware of the findings of the virtual colonoscopy, which was revealed to them before any subsequent reexamination. Sensitivity and specificity of CTC was measured along with sensitivity for colonoscopy. The CTC sensitivity for adenomatous polyps was found to be 93.8% for polyps at least 10 mm in diameter, 93.9% for polyps at least 8 mm in diameter, and 88.7% for polyps at least 6 mm in diameter. The sensitivity of colonoscopy for adenomatous polyps was found to be: 87.5%, 91.5%, and 92.3% for the three sizes of polyps, respectively. The specificity of CTC for adenomatous polyps was noted to be: 96.0% for polyps at least 10 mm in diameter, 92.2% for polyps at least 8 mm in diameter, and 79.6% for polyps at least 6 mm in diameter. Two polyps were malignant—both were detected on CTC, and one of them was not found on colonoscopy before the results on CTC were revealed. The authors concluded that 3-D enhanced CTC is an accurate screening method for the detection of colorectal neoplasia in asymptomatic average-risk adults and is comparable to colonoscopy in detecting clinically relevant lesions. The authors also concluded that a number of open issues remain, such as the ability to produce these findings on a larger scale, polyp size threshold and technical standardization (i.e., the use of stool tagging, electronic fluid cleansing, and the use of only multidetector helical CT scanners).

**Meta-analysis/systematic reviews:** Chaparro et al. (2009) reported on a systematic review and meta-analysis of the diagnostic accuracy of CTC for the detection of polyps and colorectal tumors. The study included forty-seven prospective studies with 10,546 patients that compared CTC to the reference standard of conventional colonoscopy (44 studies) or surgery (three studies). Meta-analyses combining sensitivities, specificities and likelihood ratios (LRs) for the diagnosis of polyps and colorectal tumors was performed. The overall per-polyp sensitivity of CTC was found to be 66% (64-68%); for polyps 6-9 mm in size it was 59% (56-61%); and for polyps larger than 9 mm it was 76% (73-79%). The overall per-patient sensitivity was 69% (66-72%); for polyps 6-9 mm 60% (56-65%); and 83% (70-85%) for lesions larger than 9 mm. The overall CTC specificity was 83% (81-84%). Positive and negative LRs were 2.9 (1.8-4) and 0.38 (0.27-0.53), respectively; for polyps 6-9 mm in size, they were 3.8 (2.5-5.7) and 0.4 (0.27-0.59), and 12.3 (7.7-19.4) and 0.19 (0.12-0.3) for polyps larger than 9 mm. Factors that accounted for the wide range of sensitivities included: scanners that used thinner collimation had higher sensitivity; the mode of imaging (e.g., 2D or 3D images); and, bowel preparation.

Rosman and Korsten (2007) conducted a meta-analysis of thirty studies to determine the accuracy of CTC versus endoscopic colonoscopy in the detection of polyps. Inclusion criteria included studies where all subjects undergoing CTC also underwent endoscopic colonoscopy (as a reference standard) and the studies reported the per-patient sensitivities and specificities for polyp detection. Endoscopic colonoscopy was found to have a higher diagnostic accuracy than CTC when sensitivities from the studies were pooled. The authors noted that CTC had a reasonable sensitivity and specificity at detecting large polyps (i.e.,  $\geq 10$  millimeters [mm]) but had a decreased accuracy for the detection or diagnosis of polyps that were smaller in size (i.e.,  $\leq 5$  mm). Based on

these findings, the authors concluded that CTC should not be considered as a first-line screening test in patients with a strong family history of CRC. If it is used for CRC screening in situations without a strong family history, it should be repeated more frequently than the recommended surveillance schedules for colonoscopy.

A systematic review and meta-analysis were conducted on CTC by Mulhall, et al. (2005). After applying inclusion criteria, 33 prospective studies of 6393 adults undergoing CTC after full bowel preparation, with colonoscopy or surgery as the gold standard, were selected. The overall pooled sensitivity for CTC was 70%. The sensitivity of CTC improved as polyp size increased (48% for detection of polyps < 6 mm, 70% for polyps 6–9 mm, and 85% for polyps > 9 mm). Specificity was 92% for detection of polyps < 6 mm, 93% for polyps 6–9 mm, and 97% for polyps > 9 mm. A potential source of bias was differences in disease severity or prevalence among studies. Clinical review bias may have been present in studies because the baseline risk of the study participants may have been apparent to the investigators. A limitation is that some studies used colonoscopy as the gold standard, yet colonoscopy may miss more than 10% of small polyps, up to 10% of large polyps, and up to 5% of CRC. The researchers concluded that although CTC is highly specific, its range of reported sensitivities is wide. Collimation, type of scanner, and mode of imaging explain some of the discrepancies. The researchers state that issues such as consistency of performance and technical variability must be resolved before CTC can be advocated for use in generalized screening for CRC.

Halligan et al. (2005) conducted a meta-analysis to assess the methodological quality of available data in published reports of CTC. Most were single center studies, with one multi-center study. Twenty-four studies met inclusion criteria with 4181 patients with abnormality of 15%–72%. The meta-analysis of 2610 patients, of which 206 had large polyps, demonstrated high per-patient average sensitivity (93%; 95% confidence interval [CI]: 73%, 98%) and specificity (97%; 95% CI: 95%, 99%) for CTC. When the threshold was lowered to include medium polyps, the sensitivity and specificity decreased to 86% (95% CI: 75%, 93%) and 86% (95% CI: 76%, 93%), respectively. When polyps of all sizes were considered, the studies were too heterogeneous in sensitivity (range, 45%–97%) and specificity (range, 26%–97%) to allow significant meta-analysis. There was a relatively high detection of cancer: with 150 cases of cancers, 144 were detected (sensitivity, 95.9%; 95% CI: 91.4%, 98.5%). The data reporting in these studies was found to be frequently incomplete, with no generally accepted format.

#### **Literature Review for Computed Tomographic Colonography (CTC) for Diagnostic Purposes and Surveillance or Monitoring of Increased/High Risk Patient**

White, et al. (2008) reported on a prospective, blinded trial that aimed to evaluate the ability of CTC to assess the large bowel, compared to conventional colonoscopy in patients at high-risk of CRC. The study involved 150 patients (73 males, mean age 60.9 years). Following bowel preparation, VC was undertaken using colonic insufflation and 2D-spiral CT acquisition. Two radiologists reported the images and reached a consensual agreement. A direct comparison was made with colonoscopy that was performed later the same day. Interobserver agreement was calculated using the Kappa method. Patient preference was evaluated with a postal questionnaire. CTC visualized the cecum in all cases. Five (3.33%) CTCs were classified as inadequate owing to poor distension/fecal residue. Colonoscopy completion rate was 86%. Results included: 44 patients had normal findings; 44 had diverticular disease; 11 had inflammatory bowel disease; 18 had cancers; and 33 patients had 42 polyps. CTC identified 19 cancers—a sensitivity and specificity of 100% and 99.2% respectively. Regarding the detection of polyps >10mm, CTC had a sensitivity and specificity (per patient) of 91% and 99.2% respectively. CTC identified four polyps proximal to stenosing carcinomas and extracolonic malignancies in nine patients (6%). There were no procedural complications with either investigation. A Kappa score achieved for interobserver agreement was 0.777.

Roberts-Thomson, et al. (2008) reported on a prospective study that compared the results from CTC with conventional colonoscopy in symptomatic patients. The study included 227 adults, mean age 60 years, with appropriate indications for colonoscopy. CTC and colonoscopy were performed on the same day. Colonoscopists were initially blinded to the results of CTC, but there was segmental unblinding during the procedure. The primary outcome measures were the sensitivity and specificity of CTC for the identification of polyps seen at colonoscopy (i.e. analysis by polyp). Secondary outcome measures included an analysis by patient, extracolonic findings at CTC, adverse events with both procedures and patient acceptance and preference. Twenty-five patients (11%) were excluded from the analysis because of incomplete colonoscopy or poor bowel preparation that affected CTC, colonoscopy or both procedures. Polyps and masses (usually cancers) were detected at colonoscopy and CTC in 35% and 42% of the patients, respectively. Of nine patients with a final diagnosis of cancer, eight (89%) were identified by CTC as masses (5) or polyps (3). For polyps

analyzed according to polyp, the overall sensitivity of CTC was 50% (95% CI, 39%-61%) but this increased to 71% (95% CI, 52%-85%) for polyps  $\geq$  6 mm in size. Similarly, specificity for all polyps was 48% (95% CI, 39%-58%) increasing to 67% (95% CI, 56%-76%) for polyps  $\geq$ 6mm. Adverse events were infrequent but did include one colonic perforation at colonoscopy. Patient acceptance was high for both procedures but preference favored CTC procedure.

Yucel et al. (2008) conducted a study to assess the performance of CTC in patient older than 60 years who were referred because colonoscopy was contraindicated or incomplete. Sixty-one patients were studied over a two year period. Forty-two were 60 years or older (range 60-87; mean age 71 years). The indication for colonic evaluation at time of referral were varied and included: rectal bleeding, anemia, abdominal pain, history of polyps, screening, history of diverticular disease, change in bowel habits, history of colon carcinoma and history of lymphoma and increased uptake e in area of cecum on PET. Contraindications to colonoscopy among these patients include: anticoagulation (n=8), increased anesthesia risk (n=3), and poor tolerance for colonoscopy preparation (n=1). Reasons for incomplete colonoscopy in the remaining 30 patients (71%) included: diverticular disease (n=10), colonic redundancy (n=10), adhesions (n=3), residual colonic content (n=3), sigmoid stricture (n=1), ventral hernia (n=1), and unknown causes (n=2). There were no complications observed during or after the CTC. Optimal distension of the entire colon was achieved in 38 patients (90%). Thirty-nine (93%) of the 42 patients had abnormal finding that included: diverticular disease (n=25), one or more polyps (n=22), a mass lesion (n=1), a lipoma (n=1), and inflammatory stricture (n=1). In 26 patients (62%), extracolonic findings potentially requiring further evaluation or treatment were observed. The authors concluded that CTC using CO<sub>2</sub> insufflation was well tolerated and successful in imaging the entire colon in most of the 42 patients, despite the presence of sigmoid diverticular disease or colonic redundancy.

Arnesen et al. (2007) reported on a study to evaluate the diagnostic performance of CTC as compared with conventional colonoscopy. The study included 231 consecutive CTCs that were performed prior to a same-day scheduled colonoscopy. The radiologist and physicians performing the colonoscopy were blinded to each other's findings. The findings included that for patients with polyps >5mm and >10mm, the sensitivity was 69% (95% CI 58–80%) and 81% (68–94%), and the specificity was 91% (84–98%) and 98% (93–100%), respectively. In regards to the detection of polyps >5mm and >10mm, the sensitivity was 66% (57–75%) and 77% (65–89%). Additionally, a flat, elevated low-grade carcinoma was missed by CTC. One cancer relapse was missed by colonoscopy, and a cecal cancer was missed by an incomplete colonoscopy and follow-up double-contrast barium enema. The authors concluded that colonoscopy is superior to CTC and should remain the first choice for the diagnosis of colorectal polyps; however, for the diagnosis of lesions >10 mm, both CTC and colonoscopy should be considered as complementary methods.

Eighty patients who were suspected of having recurrent CRC agreed to undergo a conventional colonoscopy and CTC as part of their follow-up examination (You, et al., 2006). Patients with a contraindication to contrast dye and those with an end or diverting colostomy were excluded. The endoscopist was blinded to the radiological CTC results. Local recurrence was found in 51 patients, and five patients were found to have external luminal wall masses. The colonoscopic exams of the five patients with luminal masses showed lumen stenosis, while on physical exam three palpable masses could be felt, and two colonic obstructions were seen radiographically. Colonoscopy findings within the 51 patients with local recurrence showed a tumor or stricture with friable mucosa at the anastomosis, prompting a biopsy for recurrent adenocarcinoma. All 51 patients had positive findings on CTC and on colonoscopy, and all 51 had positive surgical findings as well. One metachronous cancer was not found on CTC, was noted by colonoscopy and confirmed surgically. The researchers concluded that contrast-enhanced CTC had a sensitivity of 100%, a specificity of 83%, and an overall accuracy of 94% in detecting local recurrent CRC, and would be helpful in detecting extraluminal local recurrence, peritoneal carcinomatosis and distant metastasis.

### **Literature Review for Computed Tomographic Colonography (CTC) for Mixed Purposes (Diagnostic and Screening)**

ECRI Institute published an evidence report regarding CTC for CRC screening and diagnosis (ECRI, 2009). Findings regarding diagnostic performance of CTC for detecting clinically important polyps and cancer when used for CRC screening included:

- For screening of asymptomatic, average-risk individuals:
  - CTC has a sensitivity of 91% (95% CI: 86–95%) (stability of evidence: moderate). Specificity cannot be accurately summarized due to differences among study findings.

- An estimated 0.4% (95% CI: 0.3%–0.7) with a negative test actually have significant polyps or cancer. The proportion with a positive result who have significant findings cannot be accurately estimated due to differences among study findings.
- For screening asymptomatic, high-risk individuals:
  - The sensitivity and specificity of screening with CTC cannot be estimated due to differences in findings between the studies. Neither study had a sensitivity of greater than 85%.
  - Predictive values cannot be determined due to unexplained differences between the studies' findings.
- For diagnosing symptomatic individuals:
  - CTC had a sensitivity of 89% (95%CI: 76%–95%) and specificity of 99% (95% CI: 96%–100%).(stability of evidence: moderate)
  - 92% (95% CI: 73%–98%) with a positive result have significant polyps or cancer, and 1% (95% CI: 1%–3%) with a negative result have significant polyps or cancer.

The ECRI report also noted the following:

- Adverse effects were infrequently reported and were generally minor
- The quantity of evidence was insufficient to determine the impact of CTC on compliance with screening recommendations
- Few conclusions about the diagnostic performance of CTC are currently possible. Based on the currently available evidence CTC appears most promising for screening asymptomatic average-risk patients. In asymptomatic high-risk patients the sensitivity may be too low to be sufficiently useful.

Yun et al. (2007) investigated the diagnostic value of CTC for the detection of colorectal polyps. Asymptomatic patients, symptomatic patients (e.g., anal bleeding, hematochezia, bowel habit change, etc.), and high-risk patients for developing a colorectal neoplasm were all recruited for undertaking CTC. Of these 2,343 patients, 399 underwent follow-up conventional colonoscopy. We retrospectively reviewed the results of the 399 patients' CTC and compared the findings with the follow-up conventional colonoscopy results. Cases of advanced CRC were excluded. CTC findings were retrospectively analyzed along with the follow-up colonoscopy findings of 113 patients who had polyps more than 6 mm in diameter. 3D and 2D computer generated displays interpreted the CTC images were used by the radiologists. The physicians performing the colonoscopy were aware of the CTC findings before the procedure. The CTC detected 132 polyps in 107 of the 113 patients, while the colonoscopy detected 114 colorectal polyps more than 6 mm in diameter in 87 of the 113 patients. The sensitivity of CTC was analyzed per polyp and found to be 91% (41/45) for polyps more than 10 mm in diameter and 89% (101/114) for polyps more than 6 mm in diameter. There were 13 polyps were missed by CTC, but detected on the follow-up colonoscopy. The authors concluded that CTC is a sensitive diagnostic tool for the detection of colorectal polyps and adequate bowel preparation, optimal bowel distention and clinical experience are needed to reduce the rate of missing appropriate lesions.

The Medical Services Advisory Committee (MSAC, 2006), an independent committee that provides reports to government in Australia, published a meta-analysis of the studies regarding CTC. The report was an evaluation of CTC for the diagnosis or exclusion of colorectal neoplasia and other colorectal disease in symptomatic patients or in asymptomatic patients with a high risk of colorectal neoplasia. In this role it may be considered as a replacement for double contrast barium enema (DCBE) or colonoscopy. The report included the following findings:

- In regards to safety:
  - CTC is a relatively safe procedure compared to DCBE and as least as safe as, or safer than, diagnostic colonoscopy.
  - Both CTC and DCBE expose patients to ionizing radiation and are associated with a very small risk of colonic perforation.
- In regards to effectiveness:
  - There was evidence found regarding CTC accuracy for the detection of cancers and polyps  $\geq$  10 mm. CTC compared favorably with DCBE in this aspect, but not with colonoscopy.
  - There appears to be little evidence about accuracy of CTC compared to DCBE accuracy in patients following an incomplete colonoscopy.
  - There appear to be advantages of CTC over DCBE that include:
    - The ability to successfully visualize the entire colon following an incomplete colonoscopy and the proximal colon in patients with a distal obstruction

- the ability to be performed immediately after a failed colonoscopy
- CTC may be preferred and better tolerated by patients.

The conclusion noted that on the basis of strength of the evidence pertaining to effectiveness, CTC should be supported for the exclusion of colorectal neoplasia in symptomatic or high-risk patients who are either ineligible for colonoscopy due to patient contraindications or where there is an inability to perform or complete a colonoscopy.

A prospective study included 51 consecutive patients at high risk for CRC who had a history of altered bowel habits, anemia of unknown cause, abdominal pain, positive fecal occult blood results, and hematochezia (Chung, et al., 2005). They underwent CTC following a standard colonoscopy. The diagnostic accuracies of CTC for TNM (T = tumor size, N = node involvement, M = metastasis status) staging were 95%, 85%, and 100% for tumor, node, and metastasis, respectively. The combined sensitivity of both CTC and initial colonoscopy for cancer detection was 100%. The overall sensitivities of CTC and initial colonoscopy for polyp detection were 90% and 78%, respectively (p=0.001). The sensitivity of CTC for detecting polyps of 5 mm or smaller was 84%, 6–9 mm was 94%, and of 10 mm or larger it was 100%. Study limitations include the imaging criteria for TNM staging, and the criteria for determining lymphadenopathy are unclear. The number of patients with positive lymph nodes and metastasis was insufficient to determine the accuracy of CTC, as only one patient had metastases. Another limitation is that no objective criteria were used for bowel distention. However, authors concluded that for patients with clinical suspicion of CRC, CTC is valuable in staging the tumor and in detecting additional polyps or cancers in areas not evaluated by conventional colonoscopy.

During a nonrandomized, multicenter, evaluator-blinded study, 600 patients underwent same-day CTC and colonoscopies (Cotton, et al., 2004). Participants included individuals aged 50 years or older who were scheduled for a clinically indicated elective conventional colonoscopy. The study did not include a screening population and excluded participants who had undergone colonoscopy within 3 years. There were a total of 827 lesions detected in 308 of the 600 participants who had both procedures performed. One hundred and four participants were noted to have lesions sized at least 6 mm. The sensitivity of CTC for detecting participants with 1 or more lesions sized at least 6 mm was 39.0% (95% confidence interval [CI], 29.6%–48.4%) and for lesions sized at least 10 mm, it was 55.0% (95% CI, 39.9%–70.0%). The results were significantly lower than those found with colonoscopy—sensitivities of 99.0% (95% CI, 97.1%–99.9%) and 100%, respectively. There were 496 participants that were without any lesion sized at least 6mm. The specificity of CTC and colonoscopy for detecting participants without any lesion sized at least 6 mm was 90.5% (95% CI, 87.9%–93.1%) and 100%, respectively, and without lesions sized at least 10 mm, 96.0% (95% CI, 94.3%–97.6%) and 100%, respectively. CTC missed two of eight cancers. The accuracy of CTC appeared to differ considerably between the nine centers and did not improve as the study progressed. There was no clear preference expressed by the participants for either technique.

#### **U.S. Food and Drug Administration (FDA) for Computed Tomographic Colonography (CTC):**

Software programs that allow the visualization of 2-D and 3-D medical imaging of the colon for the detection of polyps, masses, cancers, and other lesions have received 510(k) approval as class II medical device by the FDA. Examples of these devices include but are not limited to: Viatronix V3D-Colon<sup>®</sup> virtual colonoscopy system (Viatronix, Inc. Stonybrook, NY), the CT Colonography/Navigator2 (General Electric Medical Systems, Milwaukee, WI) and the CT Colonography option (General Electric Medical Systems, Milwaukee, WI) (FDA, 2004).

#### **Professional Societies/Organizations**

**American Cancer Society (ACS)/American College of Radiology (ACR)/US Multi-Society Task Force on Colorectal Cancer (USMSTF):** Joint guidelines from these organizations were published in 2008 screening and surveillance for the early detection of CRC and adenomatous polyps in asymptomatic average-risk adults. The guidelines include CTC as a screening option. They make the following statement, “In terms of detection of colon cancer and advanced neoplasia, which is the primary goal of screening for CRC and adenomatous polyps, recent data suggest CTC is comparable to OC (optical colonoscopy) for the detection of cancer and polyps of significant size when state-of-the-art techniques are applied. In previous assessments of the performance of CTC, the ACS concluded that data were insufficient to recommend screening with CTC for average-risk individuals. Based on the accumulation of evidence since that time, the expert panel concludes that there are sufficient data to include CTC as an acceptable option for CRC screening.”

**American Cancer Society (ACS)/US Multi-Society Task Force on Colorectal Cancer (USMSTF):** These two organizations published joint consensus guidelines for colonoscopy surveillance after cancer resection (Rex, et al., 2006). Regarding the use of CTC, they note:

- CTC is not established as a surveillance modality.
- In the case of obstructing colon cancers, CTC may be used.

**American Cancer Society (ACS)/US Multi-Society Task Force on Colorectal Cancer (USMSTF):** These two organizations published joint consensus guidelines for colonoscopy surveillance after polypectomy (Winawer, et al., 2006). Regarding the use of CTC, they note it is an evolving technology and is not yet established as a surveillance modality.

**American College of Radiology (ACR):** The ACR published practice guidelines for the performance of CTC in adults. The guidelines include the following indications for the use of CTC examinations (ACR, 2006):

- as screening examination in individuals who are at average or elevated risk for CRC or who have a first-degree relative with a history of CRC
- as surveillance in patients with a history of previous colonic neoplasm, either benign or malignant
- as a diagnostic examination in patients with known or prior colorectal carcinoma and in symptomatic patients including, but not limited to, those with abdominal pain, diarrhea, constipation, gastrointestinal bleeding, anemia, intestinal obstruction, and weight loss
- following an incomplete screening, surveillance, or diagnostic colonoscopy
- in patients who require a colonoscopy while on anticoagulant therapy

**Institute for Clinical Systems Improvement (ICSI):** In their Health Care Guideline for CRC screening, ICSI includes the use of CTC every five years as one method for screening of average-risk individuals. (ICSI, 2008).

**National Comprehensive Cancer Network (NCCN):** The NCCN published within their CRC screening guidelines the following statements concerning the use of CTC (NCCN, 2009):

- CTC is being assessed as a colon cancer screening modality. Although presently it is not recommended as a primary screening test, it can be utilized for patients who do not wish to have the other recommended tests, and for those in whom colonoscopy cannot be completed because of technical difficulties.
- Regarding the published literature it is noted:
  - various studies have demonstrated that CTC is very specific, especially in detecting polyps larger than 9 mm in individuals at average risk of developing colorectal CRC
  - a wide range of sensitivity for CTC (55-94%) was observed

**National Institute for Health and Clinical Excellence (NICE):** NICE (2005) conducted a review of the literature and published recommended indications for use of CTC. The authors stated that conventional colonoscopy and double-contrast barium enema are the main methods currently used for examining the colon. They also indicate that CTC may be used:

- for the examination of the colon and rectum to detect abnormalities such as polyps and cancer
- in asymptomatic patients with a high risk of developing CRC.
- as an alternative procedure to barium enema in frail and elderly patients as a diagnostic tool to detect tumors.

**U.S. Preventive Services Task Force (USPSTF):** The USPSTF published evidenced-based recommendations for screening for colorectal cancer (USPTF, 2008, Whitlock, et al., 2008). Regarding CTC, the recommendations included the following findings:

- Up to 16% of people having their first CTC are found to have extracolonic abnormalities that require further testing. Evidence is inadequate to assess the clinical consequences of identifying these abnormalities, but there is potential for both benefit and harm.
- Potential harms may arise from additional diagnostic testing and procedures for lesions found incidentally, which may have no clinical significance. This additional testing also has the potential to burden the patient and adversely impact the health system.
- The risks for perforation associated with screening CTC in research settings are estimated to be 0 to 6 per 10,000 CTC studies. However, these estimates may be higher than what can be expected in screened populations because the studies included symptomatic populations.

- The lifetime cumulative radiation risk from the use of CTC to screen for colorectal cancer should be considered in the context of the growing cumulative radiation exposure from the use of other diagnostic and screening tests that involve radiation exposure. Improvements in CTC technology and practice are lowering this radiation dose.

The recommendations made the following conclusion regarding CTC: “the evidence is insufficient to assess the benefits and harms of computed tomographic colonography and fecal DNA testing as screening modalities for colorectal cancer. “

### Summary

Researchers have proposed the use of computed tomographic colonography (CTC)/virtual colonoscopy as an alternative to colonoscopy either for screening for colorectal cancer (CRC), or for diagnostic purposes in symptomatic patients. CTC is included in the joint guidelines for screening and surveillance for the early detection of CRC and polyps from the American Cancer Society (ACS), the US Multi-Society Task Force (USMTF) on Colorectal Cancer and the American College of Radiology (ACR). Beginning at age 50, CTC every 5 years is included as one of the recommended tests for average-risk individuals.

Evidence within the peer-reviewed literature suggests that CTC may be useful for diagnostic purposes in symptomatic patients with a known colonic obstruction, for those patients who are unable to complete a colonoscopy due to a stenosing colonic lesion or newly found obstruction, or patients, that due to existing medical conditions, cannot safely tolerate a conventional colonoscopy.

### Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Covered when medically necessary:**

CPT <sup>®</sup> * Codes	Description
74261	Computed tomographic (CT) colonography, diagnostic, including image postprocessing; without contrast material
74262	Computed tomographic (CT) colonography, diagnostic, including image postprocessing; with contrast material(s) including non-contrast images, if performed
74263	Computed tomographic (CT) colonography, screening, including image postprocessing
0066T	CT colonography (i.e., virtual colonoscopy); screening (code deleted 12/31/2009)
0067T	CT colonography (i.e., virtual colonoscopy); diagnostic (code deleted 12/31/2009)

ICD-9-CM Diagnosis Codes	Description
153.0-153.9	Malignant neoplasm of colon
154.0	Malignant neoplasm of rectosigmoid junction
154.1	Malignant neoplasm of rectum
154.8	Malignant neoplasm of rectum, contiguous or overlapping point of origin unknown
230.3	Carcinoma in situ of colon
230.4	Carcinoma in situ of rectum
V10.00	Personal history of malignant neoplasm of unspecified site in gastrointestinal tract
V10.05	Personal history of malignant neoplasm of large intestine
V10.06	Personal history of malignant neoplasm of rectum, rectosigmoid junction, and anus
V12.72	Personal history of colonic polyps

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## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	6/15/2008	0083	Computed Tomographic Colonography/Virtual Colonoscopy
Great-West Healthcare	2/1/2008	01.214.04	Virtual Colonoscopy (Computed Tomography Colonography)

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