



# CIGNA HEALTHCARE COVERAGE POSITION

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Subject **Virtual Colonoscopy**

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## Hyperlink to Related Coverage Positions

- Colorectal Cancer Screening and Surveillance
- Genetic Testing for Susceptibility to Colorectal Cancer
- Stool-Based DNA Testing for Colorectal Cancer
- Tumor Markers for Diagnosis and Management of Cancer

### INSTRUCTIONS FOR USE

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## Coverage Position

**CIGNA HealthCare covers virtual colonoscopy as medically necessary in individuals with a colonic mass, for colorectal cancer (CRC) diagnosis or for colorectal cancer surveillance when EITHER of the following criteria is met:**

- 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.
- When criteria for conventional colonoscopy have been met and conventional colonoscopy is medically contraindicated.

**CIGNA HealthCare does not cover virtual colonoscopy for any other indication, including routine colorectal cancer screening, because such use is experimental, investigational or unproven.**

## General Background

Colorectal cancer (CRC) is the third most common malignant neoplasm worldwide and the second leading cause of death in the United States. CRC primarily affects men and women ages 50 years or older. For men, CRC is the third most common cancer after prostate and lung cancer. For women, CRC is the third most common cancer after breast and lung cancer. The National Cancer Institute (NCI) has

estimated that 112,340 new cases of colon cancer and 41,420 new cases of rectal cancer will be diagnosed in the U.S. during 2007.

Although numerous medical societies and specialty associations support guidelines for colorectal screening, diagnosis, and surveillance for the early detection of precancerous changes, many individuals do not undergo these tests, as they are invasive, require bowel preparation, can cause discomfort and have poor patient acceptance (American Cancer Society [ACS], 2007; NCI, 2007; Torres, 2007; Bresalier, 2006; Itzkowitz, 2006). In an attempt to develop a minimally invasive procedure that may increase patients' acceptance, a virtual colonoscopy that includes the use of computerized images has been developed.

### **Virtual Colonoscopy**

Virtual colonoscopy uses data from computed tomography (CT) to generate two- and three-dimensional images of the colon and rectum. Due to the inclusion of CT imaging, this procedure has also been referred to as computed tomographic colonography (CTC). 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, which involves inserting a fiber optic camera into the colon for a visual inspection.

Virtual colonoscopy is a minimally-invasive procedure that requires no intravenous administration of sedatives or analgesics. The day before the CT scan, bowel cleansing is performed. At the time of the CT scan, 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 has been reported due to over inflation of the colon. Patients who are suspected of having inflammatory bowel disease may not be good candidates due to the potential risk of bowel perforation (Torres, 2007).

Researchers have proposed the use of this minimally-invasive procedure as an alternative to existing screening tests (i.e., colonoscopy) for CRC, and as a means of diagnosing patients with contraindications that would make the use of conventional colonoscopy unsafe: fulminant colitis, acute diverticulitis, perforated viscus, or a recent myocardial infarction. Other relative contraindications include chronic, stable irritable bowel syndrome, chronic abdominal pain, acute diarrhea, upper gastro-intestinal tract bleeding or melana with a demonstrated upper gastrointestinal tract source, metastatic adenocarcinoma or unknown primary site in the absence of colonic signs, or symptoms when the colonoscopy would not influence patient management (Beers, 2007).

Virtual colonoscopy does permit visualization of the entire colon, even in the presence of stenosing lesions (Torres, 2007). CT 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). Another drawback of this diagnostic procedure is that a traditional colonoscopy is still needed in order to biopsy or remove any lesion/polyp that is found (Torres, 2007; Feldman, 2006).

### **Literature Review**

Rosman and Korsten (2007) conducted a meta-analysis of thirty studies to determine the accuracy of CT colonography versus endoscopic colonoscopy (considered the gold standard) in the detection of polyps or CRC. Endoscopic colonoscopy was found to have a higher diagnostic accuracy than CT colonography when sensitivities from the studies were pooled. The authors noted that CT colonography 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 CT colonography 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.

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 CTCs' use in this select patient population; however, additional studies are needed before this exam is used in the general asymptomatic population.

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.

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 an optical 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.

A HAYES literature review (2006) was published of studies that focused on the use of CTC as a screening tool for the detection of colorectal lesions. These studies were conducted between 1966 and December 2005. The authors of this review concluded that there is inconsistent evidence to support the use of CTC as an effective screening tool for detecting colorectal lesions, or in using CTC as a means to determine which patient should have a follow-up colonoscopy based on the CTC findings. The sensitivities noted within these studies varied but did correlate with lesion size. Preliminary evidence also suggests that CTC can detect colorectal polyps and tumors in sections of the colon that cannot be evaluated by conventional colonoscopy due to poor bowel preparation, difficult colon configuration, an obstructing neoplasm, poor patient tolerance, and can also detect extra-colonic abdominal disorders that conventional colonoscopy cannot. While definitive patient selection criteria have not been established for

CTC as a screening test for the detection of CRC, 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 [anticoagulation]).

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). 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. During the colonoscopy phase of the study, if discrepancies between the previous tests and colonic findings were present, then discrepant findings were reconciled by a specific re-examination of that segment of the bowel. This review was conducted by an independent committee who were blinded to the outcomes of the tests that had been performed. If a lesion was detected by the ACBE or CTC but could not be detected during the colonoscopy, all three tests were repeated. This study also included representatives from the National Cancer Institute (NCI) as ex-officio members of the data safety and monitoring board. 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.

A systematic review and meta-analysis were conducted on CTC, starting with a literature review through February 2005 (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 colorectal cancers. 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 CT colonography can be advocated for use in generalized screening for colorectal cancer.

A prospective study included 51 consecutive patients at high risk for colorectal cancer 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 CT colonography 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. 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 colorectal cancer, 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 conventional colonoscopies (CC) (Cotton, et al., 2004). A total of 827 lesions were detected in 308 participants, and 104 participants had lesions sized at least 6 mm; the sensitivity of CTC was 39.0%, compared with 99% sensitivity for detection with CC. The sensitivity of CTC for detecting lesions sized at

least 10 mm was 55%, compared with 100% for CC. Both examinations failed to detect two large lesions. Conventional colonoscopy also missed one 7 mm lesion in the sigmoid colon and 19 lesions of 1–5 mm. The authors stated “the main result of this study was surprising and disappointing,” and that “an obvious question is whether the radiologists in our study were sufficiently experienced.” The authors concluded CTC is not yet ready for widespread clinical application.

An evaluation of 1233 asymptomatic adults for the detection of colorectal cancer was conducted by Pickhardt and colleagues (2003). Thirty-two individuals had an above-average risk of neoplasia due to family history. Each individual underwent same-day virtual colonoscopy (VC) and optical colonoscopy (OC). Optical colonoscopies were done blinded (before viewing virtual images) and unblinded (after viewing virtual images). Results showed no significant difference in the prevalence of adenomas between the patients with average risk and those with above-average risk. In the 3-D analysis according to the polyp type, the sensitivity of VC for all advanced neoplasms was 91.5%, and the sensitivity of the initial OC was 88.1%. The sensitivity of VC was slightly higher than that of OC for adenomatous polyps of 8 mm or larger, but the differences were not statistically significant. The authors concluded that 3-D enhanced CT virtual colonoscopy is an accurate screening method for the detection of colorectal neoplasia in asymptomatic average-risk adults and is comparable to optical 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).

In a meta-analysis conducted by the Institute for Clinical Systems Improvement (ICSI, 2006b) the authors concluded that due to the high number of extracolonic findings that required additional evaluation, additional studies are needed to determine if CTC can be an alternative to colonoscopy for colorectal cancer screening. They also concluded that CTC may be indicated in settings where the proximal colon cannot be examined by conventional colonoscopy or in patients where colonoscopy is relatively contraindicated (e.g., anticoagulation). These conclusions are also reflected in their guidance for colorectal cancer screening (ICSI, 2006a).

The Medical Services Advisory Committee (MSAC, 2006) published a meta-analysis of the studies regarding CTC and concluded that:

- CTC is a relatively safe procedure. CTC, double-contrast barium enema (DCBE) and colonoscopy are associated with a small risk of complications.
- Evidence in relation to the comparison of CTC with colonoscopy indicates that CTC is less effective and should not be proposed as a substitute for colonoscopy.
- 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.

The National Institute for Health and Clinical Excellence (NICE, 2005) conducted a review of the literature and published recommended indications for use of VC. 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 VC 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 colorectal cancer.
- as an alternative procedure to barium enema in frail and elderly patients as a diagnostic tool to detect tumors.

In a 2004 Blue Cross and Blue Shield Technology (BCBS TEC) assessment of CT colonography, the authors concluded that, based on the available evidence, CT colonography as an alternative to colonoscopy for the purpose of colon cancer screening does not meet the TEC criteria.

### **U.S. Food and Drug Administration (FDA)**

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 by the FDA.

Examples of these programs include: 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). This list may not be all-inclusive (FDA, 2007).

### **Professional Societies/Organizations**

**American Cancer Society (ACS, 2003):** The ACS does not recommend the use of virtual colonoscopy for the screening of colorectal cancer. The ACS has concluded that virtual colonoscopy “is a compelling, emerging technology that shows considerable promise, but it has not yet been studied in a typical screening population.” Therefore, it is not included at this time as one of the recommended colorectal cancer screening methods. Virtual colonoscopy is also being used for screening by some doctors, but this isn't recommended by the American Cancer Society except in clinical trials or if colonoscopy can't be done (for example, because of certain medical problems that would make the sedative used with colonoscopy unsafe for that patient).

**American College of Radiology (ACR):** In October 2005, the ACR published their indications for the use of CT colonography examinations:

- 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

**American Society of Clinical Oncology (ASCO, updated 2005):** ASCO recognizes several currently available methods of screening for the detection and diagnosis of CRC (i.e., fecal occult blood, flexible sigmoidoscopy, colonoscopy, and double contrast barium enema). They also indicate that computed tomographic colonography (virtual colonoscopy) and stool-based molecular screening are under development.

**American Society of Gastroenterology (ASGE, 2006):** ASGE published their guidance for the screening and surveillance of CRC. Studies that have been conducted to evaluate virtual colonoscopy and fecal DNA testing for CRC screening have produced conflicting results (Davila, 2006). “Virtual colonoscopy is an evolving technique and is not currently recommended as the primary method of screening for CRC.”

**National Cancer Institute (NCI, 2007):** According to the NCI, there are a number of hurdles that have to be overcome before virtual colonoscopy (VC) becomes widely used. Technical improvements involving both the interpretation methodology and bowel preparation are being studied. Current sensitivity and specificity variances are attributable to a number of factors, including characteristics of the CT scanner and detector, width of collimation, mode of imaging, as well as variability in expertise of the radiologists.

**National Comprehensive Cancer Network (NCCN, 2007):** The NCCN published within their CRC screening guidelines the following statement concerning the use of virtual colonoscopy: “Virtual colonoscopy is evolving as a very promising technique for CRC screening. Data regarding virtual colonoscopy are too premature to warrant its use in screening. If the colonoscopy is incomplete, double-contrast barium enema or virtual colonoscopy also known as CT colonography would be an alternative screening option.”

### **Summary**

There is insufficient evidence within the peer-reviewed literature to support the use of computed tomographic colonography (CTC) as a screening tool for the early detection of colorectal cancer (CRC) within the general population. Additional studies are needed to determine the specific application that this test would have on general patient health outcomes if used as an alternative to the accepted standard

colonoscopy screen. A risk/benefit analysis needs to be conducted that will determine the impact of the additional ionizing radiation dose, improved efficacy of the procedure and patient acceptance of the procedure.

Evidence within the peer-reviewed literature does show that CTC may be a useful tool in symptomatic patients with a known colonic obstruction, those patients who are unable to complete a colonoscopy due to a stenosing colonic lesion or newly found obstruction. CTC may also be used for the screening of individuals, due to existing medical conditions, who cannot safely tolerate a conventional colonoscopy. The use of CTC in all other situations remains investigational at this time.

## Coding/Billing Information

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

### Covered when medically necessary:

CPT®* Codes	Description
0067T	CT colonography (i.e., virtual colonoscopy); diagnostic

HCPCS Codes	Description
	No specific codes

ICD-9-CM Diagnosis Codes	Description
153.0-153.9	Malignant neoplasm of colon
154.0	Malignant neoplasm of rectosigmoid junction
230.3	Carcinoma in situ of colon
230.4	Carcinoma in situ of rectum
	Multiple/Varied

### Experimental/Investigational/Unproven/Not Covered:

CPT®* Codes	Description
0066T	CT colonography (i.e., virtual colonoscopy); screening

HCPCS Codes	Description
	No specific codes

ICD-9-CM Diagnosis Codes	Description
	Multiple varied

\*Current Procedural Terminology (CPT®) ©2006 American Medical Association: Chicago, IL.

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