

MEDICAL POLICY



SUBJECT: VIRTUAL COLONOSCOPY (CT COLONOGRAPHY)	EFFECTIVE DATE: 03/18/04
POLICY NUMBER: 6.01.32	REVISED DATE: 05/18/05, 03/16/06, 01/18/07, 08/16/07, 08/21/08, 08/20/09, 06/17/10, 06/16/11, 06/21/12, 06/20/13, 05/22/14
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- *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*
- *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*
- *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

POLICY STATEMENT:

- I. Based upon our criteria and review of peer reviewed literature, virtual colonoscopy is considered a **medically appropriate** option for either diagnosis or screening as follows:
 - A. In those patients in whom a conventional endoscopic colonoscopy of the entire colon is incomplete due to an inability to pass the colonoscope proximally. Failure to advance the colonoscope may be secondary to an obstructing neoplasm, spasm, redundant colon, chronic diverticular disease, extrinsic compression or aberrant anatomy/scarring from prior surgery; or
 - B. In those patients with concurrent medical conditions for whom conventional colonoscopy is contraindicated.
- II. Based upon our criteria and review of peer-reviewed literature, *computer-aided detection (CAD)* to identify and mark regions of interest with virtual colonoscopy has not been medically proven to be effective and is considered **investigational**.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

Refer to Corporate Medical Policy #11.01.10 regarding Clinical Trials.

POLICY GUIDELINES:

- I. **Contraindications** for a virtual colonoscopy include but are not limited to:
 - A. Active Crohn's disease, ulcerative colitis, inflammatory bowel disease or diverticulitis; or
 - B. Total hip replacement (metal in prosthesis may cause CT scan artifacts); or
 - C. Recent surgery; or
 - D. Pregnancy; or
 - E. Severe pain or cramps on day of examination.
- II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Virtual colonoscopy, also known as CT colonography, is a non-invasive imaging technique for examination of the colonic lumen that involves the generation of both 2-dimensional and 3-dimensional views of the colon and rectum using data derived from helical computed tomography, involving thin-section helical computed tomography (CT) to generate high-resolution 2-dimensional axial images of the colon. Two- or three-dimensional images, which resemble the endoluminal images obtained with conventional endoscopic colonoscopy, are then reconstructed offline. Virtual colonoscopy has been investigated as an alternative to conventional endoscopic colonoscopy specifically as an alternative screening technique for colon cancer.

While virtual colonoscopy requires a full bowel preparation similar to conventional colonoscopy, no sedation is required and the examination is less time consuming. However gas insufflation of the intestine, which may be uncomfortable to the patient, is required and interpretation of the images is a separate process. When polyps are detected with virtual colonoscopy, treatment requires that patients undergo a subsequent endoscopic colonoscopy, which may require another bowel preparation.

Proprietary Information of Excellus Health Plan, Inc.

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RATIONALE:

Reformatting software systems for interpretation of virtual colonoscopy have been approved by the FDA, such as but not limited to the Viatronix V3D-colon® virtual colonoscopy system (Viatronix, Inc., Stonybrook, NY) cleared for marketing by the FDA via the 510(k) process April 19, 2004, for use as a screening tool in detecting colon cancer. Computer-aided detection (CAD) for virtual colonoscopy has not yet received FDA approval.

Results of available studies indicate that CT colonography (CTC) (virtual colonoscopy) can have relatively high sensitivity and specificity for detection of cancerous colorectal lesions that are at least 6-10 mm in diameter, with lower sensitivity for precancerous, smaller, and flat lesions. The sensitivity of CTC in published studies is heterogeneous, varying widely, but improving as polyp size increases. CTC specificity in published studies is homogeneous, also improving as polyp size increases. CTC does not permit removal of lesions during the procedure as can be done during conventional colonoscopy. Results from the National CT Colonography Trial, ACRIN-6664 (NCT00084929), which is an interventional, screening, open-label trial of 2,600 participants who had a CTC followed by their scheduled colonoscopy showed that for large adenomas and cancers, the mean (\pm SE) per-patient estimated sensitivity, specificity, positive and negative predictive values, and area under the receiver-operating-characteristic curve for CT colonography were 0.90 ± 0.03 , 0.86 ± 0.02 , 0.23 ± 0.02 , $0.99\pm<0.01$, and 0.89 ± 0.02 , respectively. The sensitivity of 0.90 (i.e., 90%) indicated that CT colonography 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 ± 0.04 . The per-patient sensitivity for detecting adenomas that were 6 mm or more in diameter was 0.78. These findings support and extend previously published data regarding the role of CT colonography in screening patients with an average risk of colorectal cancer.

Since CTC requires bowel preparation and bowel insufflation, it is unclear if patient acceptance will be much higher than for conventional colonoscopy. Preliminary evidence 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, an unsuitable colon configuration, an obstructing neoplasm, or poor patient tolerance. CTC can also detect some extracolonic abdominal disorders that cannot be detected using conventional colonoscopy, however clinical evidence does not indicate the impact of CTC extracolonic findings on patient management and disease outcomes.

There is no direct evidence as to whether CTC improves health outcomes. Nor does the current evidence allow conclusions as to the comparative efficacy of CT colonography and other colon cancer screening techniques.

In May 2008 the American Cancer Society, American College of Radiology, and U.S. Multi-Society Task Force on Colorectal Cancer issued joint guidelines for screening and surveillance for early detection of colorectal cancer and adenomatous polyps. The guidelines outline a variety of options for colorectal screening, divided into two categories: (1) fecal tests to detect colorectal cancer and (2) structural exams to detect adenomas and colorectal cancer. CTC is recommended for colorectal screening every five years as a test to detect adenomatous polyps and cancer.

The American College of Physicians Guidance Statement recommends that physicians perform an individualized assessment of risk for colorectal cancer in all adults. Because the currently available colorectal cancer screening tests are believed to be similarly efficacious, shared decision making is important when selecting a screening test. Clinicians should discuss the benefits, harms, effectiveness, safety, and costs of the options available to screen for colorectal cancer. Computed tomography colonography is an option for screening in average-risk patients older than 50 years and is supported by some guidelines. Recommended screening interval for CTC is every 5 years.

Virtual colonoscopy is not endorsed for screening for colon cancer by the U.S. Preventive Services Task Force or the American Society of Gastrointestinal Endoscopy.

Computer-aided detection (CAD) for virtual colonoscopy/CT colonography is still under active development. Recent studies have been small and have found that use of CAD with an inexperienced reader is no better than interpretation by an experienced reader alone. Use of CTC with or without CAD for nonpolypoid lesions showed a sensitivity of 90% for both CAD and human readers. However the sensitivity for nonpolypoid adenomas, nonadenomatous and noncancerous lesions to be 66% or less for human readers and 55% or less for CAD. CTC may be useful for detecting nonpolypoid adenocarcinomas but is limited in detecting other nonpolypoid pathology.

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CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:	74261	Computed tomographic (CT) colonography, diagnostic, including image postprocessing, without contrast material
	74262	with contrast material(s) including non-contrast images, if performed
	74263	Computed tomographic (CT) colonography, screening, including image postprocessing

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HCPCS: No code(s)

ICD9:	159.0-159.9	Colon cancer (code range)
	V76.51	Special screening for malignant neoplasms; colon

ICD10:	C26.0-C26.9	Malignant neoplasm of other and ill-defined digestive organs (code range)
	Z12.11	Encounter for screening for malignant neoplasm of colon

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KEY WORDS:

Virtual colonoscopy, CT colonography.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

CMS has proposed a national coverage determination (NCD) for the use of screening computed tomography colonography (CTC) for colorectal cancer. There is a national coverage determination (NCD) for colorectal cancer screening tests. Screening computed tomographic colonography (CTC) is considered non covered, effective May 12, 2009. <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=281&ncdver=3&bc=AgAAgAAAAAA&>

There is currently a Local Coverage Determination (LCD) for CT Colonography. Please refer to the following LCD website for Medicare Members: [http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=25233&ContrId=181&ver=37&ContrVer=1&CtrctrSelected=181*1&Ctrctr=181&name=National+Government+Services%2c+Inc.+\(13202%2c+MAC+-+Part+B\)&s=41&DocType=All&bc=AggAAAIAAAAAAAA%3d%3d&](http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=25233&ContrId=181&ver=37&ContrVer=1&CtrctrSelected=181*1&Ctrctr=181&name=National+Government+Services%2c+Inc.+(13202%2c+MAC+-+Part+B)&s=41&DocType=All&bc=AggAAAIAAAAAAAA%3d%3d&)