KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Virtual Colonoscopy or CT Colonography

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Colorectal Cancer Screening Tests (210.3)
Decision Memo	Decision Memo for Screening Computed Tomography Colonography (CTC) for Colorectal Cancer (CAG-00396N)*
Local Coverage Determinations (LCD)	None
KPWA Medical Policy	**Screening** Per Medicare, for Virtual Colonoscopy or CT Colonography: The evidence is inadequate to conclude that CT colonography is an appropriate colorectal cancer screening test under §1861(pp) (1) of the Social Security Act. However, for Kaiser Permanente Medicare Advantage members, virtual colonoscopy or CT colonography for colorectal cancer screening after a positive fecal immunochemical (FIT) or fecal occult blood test (FOBT) may be considered medically necessary if the patient meets the non-Medicare criteria below. **Diagnostic** Virtual Colonoscopy or CT Colonography: Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, ***Virtual Colonoscopy or CT Colonography*** for medical necessity determinations. Use the non-Medicare criteria below.

For Non-Medicare Members

Computed tomographic (CT) colonography, also known as virtual colonoscopy, utilizes helical computed tomography of the abdomen and pelvis to visualize the colon lumen, along with 2D or 3D reconstruction. The test requires colonic preparation similar to that required for fiberoptic colonoscopy, and air insufflation to achieve colonic distention.

Per the USPSTF, virtual colonoscopy can be covered for *"screening purposes"* (not diagnostic). A screening test is done on an asymptomatic patient to evaluate for the possibility of a condition that puts them at risk. If signs or symptoms of colon disease are present, further testing is considered diagnostic and therefore a CT colonography is not the preferred test and is not covered (CT or MRI is the preferred imaging study).

CT colonography is indicated only in patients having **ONE of the following** qualifying conditions:
1. Instrument colonoscopy of the entire colon is incomplete and/or contraindicated due to colon obstruction;
2. A coagulation disorder known to increase bleeding risk;
3. Lifetime anticoagulation or long-term anticoagulation therapy with increased patient risk if discontinued;

4. Significant medical or surgical complications from previous standard colonoscopy;
5. Medical condition that places the patient at increased risk with use of conscious sedation;
6. CT colonography is not a covered service when utilized in preoperative cancer staging, and in this clinical situation as standard CT or MRI is the preferred imaging study.

Note: Personal preference or patient refusal to undergo colonoscopy, in the absence of one of the qualifying criteria above, is not a covered indication for CT colonography.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Colorectal cancer is the third most common cancer and the second leading cause of cancer-related deaths in the United States. A majority of cases can be prevented with colonoscopic removal of the precursor adenomatous polyp. With early detection, patients with cancer limited to the colonic wall will have a corrected 5-year survival of around 90%, whereas for those with lymphatic spread this figure drops to 30%. Although standard colonoscopy is a total colonic examination that allows lesion biopsy and resection, it is an invasive procedure, may fail to demonstrate the entire colon in up to 5% of cases examined by an experienced gastroenterologist, and could miss up to 20% of all adenomas. (Yee J, 2001).

Computed tomography colonography, commonly referred to as virtual colonoscopy, is a new method of imaging the colon. It uses data from thin sections helical computed tomography of the clean, air-distended colon, combined with advanced imaging software to create two-dimensional and three-dimensional images of the colon that simulate the endoluminal view seen at endoscopy. Since first introduced by Vining and colleagues in 1994, its performance has improved due to the development of fast helical CT scanners, and advances in the computer software for image reconstruction.
A variety of techniques have been described, but all share the same basic principles: Full bowel cleaning, air distension of the colon using a rectal enema tube, taking thin-section images of the colon in the supine and prone positions, and image interpretation using a combination of axial and multiplanar or endoluminal reconstructions.

The concept of virtual colonoscopy is appealing and appears to many as a potentially attractive method of screening for colorectal cancer. Compared to the standard optical colonoscopy, virtual colonoscopy is less invasive, does not require sedation, analgesia, or recovery time, and allows the entire colon to be visualized in the majority of patients. It might also provide additional information by evaluating colonic wall thickness and imaging abdominal structures outside the colon and may be more acceptable to patients.

However there are a number of potential limitations to this procedure. First of all, it requires a complete and thorough colon cleansing. Poor colonic preparation or distension limits the accuracy of CT colonography. Colonic lavage preparation often results in excess residual fluid or stools in the colon, that may simulate or cover the presence of a lesion. Another significant limitation is that virtual colonoscopy may be less effective at detecting smaller polyps and flat adenomas. In addition, unlike conventional colonoscopy, virtual colonoscopy is only a diagnostic test; the detected polyps cannot be resected during the procedure. If suspicious lesions are detected, the patient undergoes further testing, usually by conventional colonoscopy. (Hawes 2002).

The original MTAC review in June 2001 evaluated virtual colonoscopy as a screening tool, and for evaluation of high-risk patients. The second review in October 2002 focused on virtual colonoscopy for detecting of colorectal polyps among high risk, elderly or frail patients. At both meetings, virtual colonoscopy failed MTAC diagnostic test criteria. The current review is on virtual colonoscopy as a screening method for average risk asymptomatic individuals and was initiated in response to the publication of the Pickhardt study on virtual colonoscopy in a screening population.

Medical Technology Assessment Committee (MTAC)

Virtual Colonoscopy

06/13/2001: MTAC REVIEW

Evidence Conclusion: The available evidence suggests that virtual colonoscopy is not yet as effective as conventional colonoscopy at identifying colorectal polyps and carcinomas. Virtual colonoscopy may be relatively

effective at identifying lesions ≥ 10 mm in size, but further study is needed to verify this. No studies to date have examined the use of virtual colonoscopy for general screening or compared the acceptability of virtual compared to conventional colonoscopy.
Articles: The literature search yielded 57 articles. Articles that were opinion pieces, reviews, dealt with technical aspects of virtual colonoscopy, or had small sample sizes were excluded. There were 4 empirical studies with sample sizes ≥ 50. The two studies with the strongest methodologies were reviewed. Fenlon HM, Nunes DP, Schroy PC, Barish MA, Clarke PD, Ferrucci JT. A comparison of virtual and conventional colonoscopy for the detection of colorectal polyps. N Engl J Med 1999; 341: 1496-503. See Evidence Table. Spinzi G, Belloni G, Martegani A, Sangiovanni A, Del Favero C, Minoli G. Computed tomographic colonography and conventional colonoscopy for colon diseases: A prospective, blinded study. Am J Gastroenterol 2001; 96: 394-400. See Evidence Table.

The use of Virtual Colonoscopy for colon cancer screening failed Kaiser Permanente *Medical Technology Assessment Criteria*

10/09/2002: MTAC REVIEW
Virtual Colonoscopy
Evidence Conclusion: Previously, virtual colonoscopy did not meet GHC Medical Technology Assessment Committee as a screening tool for colorectal polyps and carcinomas. The purpose of the current re-review is to evaluate the use of the technology among high-risk patients, the frail, and the elderly. The available literature does not provide evidence for the use of virtual colonoscopy for the elderly and frail patients. The study (Laghi 2002) currently reviewed, as well as the Fenlon study reviewed for MTAC in June 2001, show that the sensitivity of virtual colonoscopy was good for colorectal carcinomas and large colorectal polyps in the selected symptomatic or high-risk patients. The two studies were appropriate for comparison of diagnostic tests and measured the performance of CT colonography relative to conventional colonoscopy. Virtual colonography was able to detect 100% of the colorectal carcinomas identified by conventional colonoscopy in the two studies. In Laghi's study the sensitivity was 92% for the detection of polyps 10 mm diameter or larger, 82% for those 6-9 mm, but as low as 50% for those less than 5 mm diameter, with an overall sensitivity of 78%. The corresponding values in Fenlon's study were almost similar with a slightly less overall sensitivity most probably because of the higher rate of the smaller polyps in the population studied. The sensitivity in Fenlon's study was (91%, 82%, 50% and 71% respectively). In bothstudies the sensitivity of virtual colonoscopy dropped considerably for polyps with a diameter of 5 mm or less. There is no clear consensus as to the importance of identifying and removing such tiny polyps. The per-patient specificity was 97% in Laghi's study and 84% in Fenlon's study. These high-risk patients with detected lesions may still need to undergo conventional colonoscopy for biopsy or removal of lesions. Neither study examined the impact of CTC on colorectal cancer morbidity, mortality or patient management. The inter-observer variability was not examined or discussed.
Articles: The literature search yielded 84 articles. The majority were opinion pieces, reviews, or dealing with technical aspects of virtual colonoscopy. There were 5 empirical studies, one had a very small sample size and poor methodology, and two were conducted in the same center by the same researchers but one included more patients. The study with the larger size was selected for critical appraisal. The remaining two were retrospective studies conducted on frail or elderly patients, one used non-helical CT scan, and the other was conducted to evaluate the accuracy of CT scans in detecting caecal carcinomas using oral contrast media and minimal preparation. *The study critically appraised is:* Laghi A, Iannaccone R, Carbone I, et al. Detection of colorectal lesions with virtual computed colonography. *Am J Surg* 2002; 183:124-131. See Evidence Table.

The use of virtual colonoscopy in colorectal screening for the frail elderly does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/11/2004: MTAC REVIEW
Virtual Colonoscopy
Evidence Conclusion: The two best new studies were evaluated. Pickhardt found a higher sensitivity and specificity of virtual colonoscopy than Johnson. Both included asymptomatic populations, but individuals in the Johnson study were at higher than average risk of colorectal neoplasia (i.e. personal or strong family history of colorectal neoplasia). The difference in the study population does not explain the lower sensitivity in Johnson because any bias introduced by having a higher risk sample would tend to increase, not decrease the sensitivity. The populations in the Pickhardt and Johnson studies may actually have been quite similar. The prevalence of adenomatous polyps ≥1 cm was 4% in Pickhardt and 5% in Johnson. The better performance of virtual colonoscopy in the Pickhardt study may be due in part to the routine use of 3-D CT images by Pickhardt. Johnson generally used 2-D images, and 3-D images were used for regions with suspected abnormalities. In addition, Johnson used conventional colonoscopy as the reference standard whereas Pickhardt used a reference standard

developed for the study—conventional colonoscopy enhanced by information from the virtual colonoscopy. Neither of the new studies included polyps < 5mm which many experts believe are not clinically significant. Previous studies of virtual colonoscopy evaluated by MTAC have found low sensitivity for these smaller polyps. In summary, the Pickhardt study is the first to suggest that virtual colonoscopy has comparable sensitivity and specificity to conventional colonoscopy in asymptomatic individuals. The Johnson study suggests that the sensitivity of virtual colonoscopy is relatively low and that interobserver variability is high. Replication of the findings obtained in the Pickhardt study would strengthen the evidence.

Articles: The search yielded 103 articles, many of which were reviews, opinion pieces or dealt with technical aspects of the procedure. There were five prospective blinded studies comparing the diagnostic accuracy of virtual colonoscopy to conventional colonoscopy in asymptomatic populations. The two largest studies, each of which had samples larger than 700 individuals, were critically appraised. The others had sample sizes of 205, 158 and 80. The following articles were reviewed: Johnson CD, Harmsen WS, Wilson LA. Prospective blinded evaluation of computed tomographic colonography for screen detection of colorectal polyps. *Gastroenterol* 2003; 125: 311-319. See Evidence Table. Pickhardt PJ, Choi JR, Hwang I. et al. Computed tomographic virtual colonoscopy to screen for colorectal neoplasia in asymptomatic adults. *N Engl J Med* 2003; 349: 2191-2000. See Evidence Table.

The use of virtual colonoscopy in colorectal screening does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/18/2009: MTAC REVIEW
Virtual Colonoscopy

Evidence Conclusion: Diagnostic accuracy in the Regge et al., 2009 study is not dramatically different than previous studies, particularly when considering that it was conducted in a population at increased risk of CRC. There is still no high-grade evidence on the impact of screening with CT colonography on CRC mortality. Although it is not invasive like colonoscopy, CT colonography requires the same colonic preparation and involves exposure to radiation, and patients who test positive still require a colonoscopy for polyp removal.

Articles: Regge D, Laudi C, Galatola G et al. Diagnostic accuracy of computed tomographic colonography for the detection of advanced neoplasia in individuals at increased risk of colorectal cancer. JAMA 2009; 301: 2453-2461. See Evidence Table 6 and Evidence Table 7.

Update of evidence but the evidence does not change the previous review.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC 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

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
06/13/2001	05/04/2010[MDCRPC],03/01/2011[MDCRPC], 01/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013[MPC], 02/04/2014[MPC], 12/02/2014[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC],03/07/2023[MPC], 05/07/2024[MPC], 05/06/2025[MPC]	9/12/2023

[MPC] Medical Policy Committee

Revision History	Description
07/25/2016	Changed NCD to (210.0)
06/06/2017	Adopted KPWA policy for Medicare members
09/25/2017	Added Decision Memo language
08/31/2021	Added NCD 210.3. Effective January 1, 2022, virtual colonoscopy or CT colonography for colorectal cancer screening after a positive fecal immunochemical (FIT) or fecal occult blood test (FOBT) may be considered medically necessary for Medicare members when the patient meets the non-Medicare clinical review criteria.
12/05/2022	Clarified USPSTF language with Director of Clinical Knowledge & Implementation.
09/12/2023	Updated content for clarity around USPSTF recommendation.