

MEDICAL POLICY

SUBJECT: COLORECTAL CANCER SCREENING

EFFECTIVE DATE: 08/17/17, 05/17/18

POLICY NUMBER: 2.01.51

CATEGORY: Technology Assessment

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- *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*
- *If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.*
- *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT:

- I. Based on our criteria and assessment of the peer-reviewed literature, including the American Cancer Society (ACS) the National Comprehensive Cancer Network (NCCN), and the United States Preventative Services Task Force (USPSTF) the following colorectal cancer screening modalities are considered **medically necessary** for men and women 50 years or older, who are average risk for colon cancer:
 - A. Colonoscopy; or
 - B. Fecal occult blood test* (e.g., guaiac-based (gFOBT) or immunochemical (FIT)).Other screening options include:
 - C. Flexible sigmoidoscopy*; or
 - D. Virtual colonoscopy (CT colonography)*; or
 - E. DNA analysis of stool samples using the Cologuard® multi-targeted stool DNA test*.*If positive test results, colonoscopy should be performed.
- II. Based on our criteria and assessment of the peer-reviewed literature, , including the American Cancer Society (ACS) guidelines for colorectal cancer screening and the National Comprehensive Cancer Network (NCCN), colonoscopy is considered **medically necessary** for men and women earlier than 50 years who are at an increased or high risk of colorectal cancer.
- III. Based upon our criteria and review of peer reviewed literature, virtual colonoscopy is considered a **medically appropriate** option for diagnosis 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. Medical contraindications may include but are not limited to coagulopathy, intolerance to sedation, elderly greater than or equal to 80 years of age, and recent (within the last 60 days) myocardial infarction (MI).
- IV. Based on our criteria and assessment of the peer-reviewed literature, including the American Cancer Society (ACS) the National Comprehensive Cancer Network (NCCN), and the United States Preventative Services Task Force (USPSTF), colorectal cancer screening for adults aged 76 to 85 years should be individualized, taking into account the patient's overall health and prior screening history.

POLICY GUIDELINES:

- I. Increased or high risk of colorectal cancer includes the following:
 - A. A personal history of colorectal cancer or adenomatous polyps
 - B. A personal history of inflammatory bowel disease (e.g.,ulcerative colitis or Crohn's disease)
 - C. A strong family history of colorectal cancer or polyps (*Please Refer to Description Section*)
 - D. A known family history of a hereditary colorectal cancer syndrome such as familial adenomatous polyposis (FAP) or Lynch syndrome (hereditary non-polyposis colon cancer or HNPCC).

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- II. **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.

III. Recommended screening intervals for average risk individuals:

Screening modality	Interval
Fecal occult blood test (e.g., guiac-based or immunochemical (FIT))	Annually
DNA analysis of stool samples using the Cologuard® multi-targeted stool DNA test	Every 3 years
Virtual colonoscopy (CT colonography)	Every 5 years
Flexible sigmoidoscopy	Every 10 years (+/- FIT annually)
Colonscopy	Every 10 years

IV. Recommended screening intervals with colonoscopy for increased or high risk of colorectal cancer:

Risk	Intervals
Personal History: Individuals with 1 or 2 small (less than 1 cm) tubular adenomas with low-grade dysplasia	5 to 10 years after the polyps are removed depending on family history and other clinical factors
Personal History: Individuals with 3 to 10 adenomas, or a large (at least 1 cm) adenoma, or any adenomas with high-grade dysplasia or villous features	3 years after the polyps are removed; then every 5 years
Personal History: Individuals with more than 10 adenomas on a single exam	Within 3 years after the polyps are removed
Personal History: Individuals with sessile adenomas that are removed in pieces	2 to 6 months after adenoma removal
Personal History: Individuals who have had colon or rectal cancer removed by surgery	Within 1 year after cancer resection (or 1 year after colonoscopy to make sure the rest of the colon/rectum was clear); If normal, repeat in 3 years. If normal then, repeat test every 5 years.
Personal History: Individuals diagnosed with colon or rectal cancer	At time of colorectal surgery, or if no metastases, 3-6 months after surgery
Family History: Colorectal cancer or advanced adenomatous polyps (e.g., high-grade dysplasia, greater than or equal to 1 cm, villous or tubulovillous histology) in any first-degree relative before age 60, or in 2 or more first-degree relatives at any age (if not a hereditary syndrome).	Age 40, or 10 years before the youngest case in the immediate family, whichever is earlier; then every 5-10 years
Family History: Colorectal cancer or adenomatous polyps in any first-degree relative	Age 40; intervals the same as average risk

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aged 60 or older, or in at least 2 second-degree relatives at any age.	
Family history: Lynch syndrome (hereditary non-polyposis colon cancer or HNPCC), or at increased risk of Lynch syndrome based on family history without genetic testing	Age 20 to 25 years, or 10 years before the youngest case in the immediate family; repeat every 1 to 2 years
Familial adenomatous polyposis (FAP) diagnosed by genetic testing, or suspected FAP without genetic testing	Age 10 to 12 years; yearly flexible sigmoidoscopy to look for signs of FAP
Personal History of Inflammatory bowel disease: -Chronic ulcerative colitis -Crohn's disease	Cancer risk begins to be significant 8 years after the onset of pancolitis (involvement of entire large intestine), or 12-15 years after the onset of left-sided colitis; repeat every 1 to 2 years

V. 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:

Screening is the process of looking for cancer or pre-cancer in people who have no symptoms of the disease. Regular colorectal cancer screening is one of the most powerful weapons against colorectal cancer. Excluding skin cancers, colorectal cancer is the third most common cancer diagnosed in both men and women in the United States. Overall, the lifetime risk for developing colorectal cancer is a little less than 1 in 20 (5%) and is slightly lower for women than for men.

Colorectal cancer is the second leading cause of cancer death when numbers for both men and women are combined. The death rate (the number of deaths per 100,000 people per year) of colorectal cancer has been dropping for several decades. One reason for this is that today, colorectal polyps are more often found by screening and removed before they can develop into cancers.

It can take as many as 10 to 15 years for a polyp to develop into colorectal cancer. Regular screening can prevent many cases of colorectal cancer altogether by finding and removing certain types of polyps before they have the chance to turn into cancer. Screening can also help find colorectal cancer early, when it's small, hasn't spread, and is easier to treat. When colorectal cancer is found at an early stage before it has spread, the 5-year relative survival rate is about 90%. But only about 4 out of 10 colorectal cancers are found at this early stage. When cancer has spread outside the colon or rectum, survival rates are lower.

Colonoscopy

Colonoscopy is a screening modality which is able to detect colorectal polyps and cancer. A flexible tube with a tiny camera is inserted through the anus. The inside of the rectum and colon can be viewed for polyps, cancer, and diseases. The colonoscope is about 4 feet in length and allows the entire colon to be visualized. The exam takes about 30 minutes and sedation may be necessary. Tissue and polyps may be removed and sent to the lab to determine if the polyp is cancerous. Although colonoscopy is considered to be the reference standard against which the sensitivity of other colorectal cancer screening tests is compared, complications from the procedure may occur. There may be some discomfort and bloating from the air that is used to inflate the colon during the procedure. There is potential for the colonoscope to injure the intestinal wall, causing perforation, infection, or bleeding, although this is rare.

Flexible sigmoidoscopy

Flexible sigmoidoscopy is another screening modality which is able to detect colorectal polyps and cancer. A lighted endoscope with a tiny camera is passed through the rectum and lower part of the colon and allows the operator to visualize the sigmoid and descending colon on a small monitor screen. The sigmoidoscope is approximately 2 feet long

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consequently only the lower colon is able to be visualized. Bowel preparation is necessary prior to the test. The test usually takes about 10 to 20 minutes and sedation is not necessary. Small polyps may be removed and sent to the lab to determine if the polyp is cancerous.

Virtual colonoscopy

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.

Multi-targeted stool DNA test

Gene mutations that characterize colorectal neoplasia are detectable in exfoliated epithelial cells in the stool. Whereas neoplastic bleeding is intermittent, epithelial shedding is continual, potentially making fecal DNA testing more sensitive than other methods for screening.

Several genetic alterations have been associated with colorectal cancer. In the proposed multistep model of carcinogenesis, the tumor suppressor gene *p53* and the proto-oncogene *K-ras* are most frequently altered. Mutations in APC (Adenomatous polyposis coli) genes and epigenetic markers (e.g., hypermethylation of specific genes) have also been detected. Colorectal cancer is also associated with DNA replication errors in microsatellite sequences (termed microsatellite instability or MSI) in patients with hereditary nonpolyposis colorectal cancer (HNPCC) and in a subgroup of patients with sporadic colon carcinoma. Since cancer cells are shed into stool, tests have been developed that detect these genetic alterations in the DNA from shed colorectal cancer cells isolated from stool samples. This has been proposed for use in screening two populations of patients.

Fecal occult blood tests (FOBT)

Two types of FOBT are approved by the Food and Drug Administration (FDA) to screen for colorectal cancer: guaiac FOBT (gFOBT) and the fecal immunochemical (or immunohistochemical) test (FIT, also known as iFOBT). With both types of FOBT, stool samples are collected by the patient using a kit, and the samples are returned to the doctor. Guaiac FOBT uses a chemical to detect heme, a component of the blood protein hemoglobin. Because the guaiac FOBT can also detect heme in some foods (e.g., red meat), people have to avoid certain foods before having this test. FIT uses antibodies to detect human hemoglobin protein specifically. Dietary restriction are typically not required for FIT.

RATIONALE:

Colonoscopy

In the Updated Evidence Report and Systematic Review for the US Preventive Services Task Force (2016), the diagnostic accuracy of colonoscopy was evaluated by 4 prospective studies with fair to good quality evidence. Comparing colonoscopy with CTC or CTC plus colonoscopy, per-person (or per-lesion) sensitivity for adenomas \geq 10 mm was 89%-98%, and per-person sensitivity for adenomas \geq 6 mm was 75%-93%. Studies were not designed to assess diagnostic accuracy to detect cancers. There were limited studies with large number of endoscopists that were applicable to community practice. Harms from screening colonoscopy or colonoscopy in asymptomatic persons was estimated at 4 perforations/10,000 procedures (95% CI, 2-5/10 000) (number of studies = 26) and 8 major bleeds/10,000 procedures (95% CI,5-14/10,000) (number of studies = 22). Risk of perforations, bleeding, and other serious harms from colonoscopy increased with age.

Flexible sigmoidoscopy

In the Updated Evidence Report and Systematic Review for the US Preventive Services Task Force (2016), the effectiveness of screening for flexible sigmoidoscopy was evaluated in 4 RCTs. SIG consistently decreased CRC-

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specific mortality compared with no screening at 11-12 y of follow-up (IRR, 0.73; 95% CI, 0.66-0.82). The mortality benefit was limited to distal CRC. Only 1 trial evaluated more than a single round of screening. Variation in referral criteria led to differing rates of follow-up colonoscopy. Applicability to US practice is fair to poor. Flexible sigmoidoscopy is no longer widely used in the United States. Harms from screening flexible sigmoidoscopy were estimated at 1 perforation/10,000 procedures (95% CI, 0.4-1.4/10 000) (number of studies = 16) and 2 major bleeds/10,000 procedures (95% CI, 0.7-4/10 000) (number of studies = 10).

Virtual colonoscopy

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 (±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±<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.

The US Preventative Services Task Force Final Recommendation Statement: Colorectal Cancer Screening (2016) states the evidence for assessing the effectiveness of computed tomography (CT) colonography is limited to studies of its test characteristics. Computed tomography colonography can result in unnecessary diagnostic testing or treatment of incidental extracolonic findings that are of no importance or would never have threatened the patient's health or become apparent without screening (ie, overdiagnosis and overtreatment). Extracolonic findings are common, occurring in about 40% to 70% of screening examinations. Between 5% and 37% of these findings result in diagnostic follow-up, and about 3% require definitive treatment. As with other screening strategies, indirect harms from CT colonography can also occur from follow-up colonoscopy for positive findings. Radiation-induced cancer is a potential long-term concern with repeated use of CT colonography. No studies directly measured this risk, but radiation exposure during the procedure seems to be low, with a maximum exposure of about 7 mSv per examination.

Multi-targeted stool DNA test

The Cologuard® (Exact Sciences, Madison, WI) was approved by the FDA on August 11, 2014. The test includes molecular assays for aberrantly methylated BMP3 and NDRG4 promoter regions, mutant KRAS, and β-actin and an immunochemical assay for human hemoglobin.

The BCBS Association TEC Special Report (2014) evaluated fecal DNA analysis for CRC screening. The report found the Imperiale2 study to be of good quality but noted while fecal DNA testing had higher sensitivity than FIT for various types of colorectal lesions, these results represent the diagnostic characteristics of the fecal DNA test in a 1-time cross

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sectional study. How these study results may translate to reduced colorectal mortality in a screening program are uncertain. The study of the diagnostic characteristics of a test for detecting cancer and cancer precursors does not establish efficacy for prevention of CRC. Effective screening for CRC requires a screening program with established screening intervals and appropriate follow-up for positive tests. Given what is known about relative efficacy of different screening strategies from the results of modeling studies, the fecal DNA test would produce equivalent or better outcomes than FIT if both were used annually. However, the fecal DNA test has a considerably higher false-positive rate and would therefore consume greater health care resources than FIT at this screening frequency. Formal modeling studies of the fecal DNA test are needed to estimate the efficacy of the test in preventing CRC and help determine the optimal strategy for its use.

The US Preventative Services Task Force Final Recommendation Statement: Colorectal Cancer Screening (2016) states multitargeted stool DNA testing (FIT-DNA) is an emerging screening strategy that combines a FIT with testing for altered DNA biomarkers in cells shed into the stool. Multitargeted stool DNA testing has increased single-test sensitivity for detecting colorectal cancer compared with FIT alone. The harms of stool-based testing primarily result from adverse events associated with follow-up colonoscopy of positive findings. The specificity of FIT-DNA is lower than that of FIT alone, which means it has a higher number of false-positive results and higher likelihood of follow-up colonoscopy and experiencing an associated adverse event per screening test. There are no empirical data on the appropriate longitudinal follow-up for an abnormal FIT-DNA test result followed by a negative colonoscopy; there is potential for overly intensive surveillance due to clinician and patient concerns about the implications of the genetic component of the test.

Fecal occult blood tests (FOBT).

In the Updated Evidence Report and Systematic Review for the US Preventive Services Task Force (2016), the effectiveness of screening for gFOBT, Hemocult II was evaluated in 5 RCTs. Biennial screening with Hemocult II compared with no screening consistently resulted in reduction of CRC-specific mortality and ranged from 9% to 22% after 2-9 rounds of screening with 11-30 years of follow-up. There was variation in number of screening rounds, use of rehydrated samples, definition of “test positive,” and recommended diagnostic follow-up.

The prospective diagnostic accuracy of FIT was evaluated by 6 qualitative and 7 quantitative studies. In studies with colonoscopy follow-up for all, FIT sensitivity varied considerably across assays for each outcome. OC-Light had the highest sensitivity and specificity for CRC, from 88% and 91%, respectively, to 79% and 93%, respectively. OC FIT-CHEK had the best sensitivity and specificity for CRC, from 73% and 96%, respectively, to 92% and 87%. Variation in test performance resulted from the use of 18 different FITs (FIT families), different numbers of stool samples, and to some extent different assay cutoff values. Sparse data on most individual tests limited comparisons.

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.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:	45346	Sigmoidoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed
	45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
	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
	81528	Oncology (colorectal) screening, quantitative real-time target and signal amplification of

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- 82270 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result
 Blood, occult, by peroxidase activity (eg, guaiac), qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (ie, patient was provided 3 cards or single triple card for consecutive collection)
- 82274 Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations
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HCPCS:

- G0104 Colorectal cancer screening, flexible sigmoidoscopy
- G0105 Colorectal cancer screening; colonoscopy on individual at high risk
- G0121 Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk
- G0328 Colorectal cancer screening; fecal occult blood test, immunoassay, 1-3 simultaneous determinations
- G9936 Surveillance colonoscopy - personal history of colonic polyps, colon cancer, or other malignant neoplasm of rectum, rectosigmoid junction, and anus (*effective 1/1/2018*)
- G9937 Diagnostic colonoscopy (*effective 1/1/2018*)

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 article

KEY WORDS: Cologuard, CT Colonography, FIT, gFOBt, virtual colonoscopy, fecal DNA, fecal occult blood test

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Colorectal Cancer Screening Tests. Please refer to the following NCD website for Medicare Members: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=281&ncdver=5&bc=AgAAgAAAAQAAAA%3d%3d&>

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. <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=281&ncdver=5&bc=AgAAgAAAAAAAAAAAA%3d%3d&>

There is currently a Local Coverage Determination (LCD) for CT Colonography for Diagnostic Uses. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33562&ver=17&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=Active&bc=AggAAAIBAAAA&