

6.01.32	Virtual Colonoscopy/Computed Tomography Colonography	
Section 6.0 Radiology	Effective Date September 30, 2014	
Subsection	Original Policy Date June 1, 2003	Next Review Date September 2015

### Description

Computed tomography (CT) colonography, also known as "virtual colonoscopy," is an imaging technique of the colon. CT colonography has been investigated as an alternative to conventional endoscopic ("optical") colonoscopy. It has been most widely studied as an alternative screening technique for colon cancer, but has also been used in the diagnosis of colorectal cancer in people with related symptoms and for other colorectal conditions.

### **Related Policies**

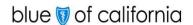
Monitored Anesthesia Care (MAC)

### **Policy**

Computed tomography (CT) colonography may be considered **medically necessary** for **any** of the following conditions:

- In patients for whom a conventional colonoscopy is indicated, but who are unable to undergo conventional colonoscopy for medical reasons (See Policy Guidelines)
- In patients with an incomplete conventional colonoscopy because of colonic stenosis or obstruction
- In patients for the purposes of colon cancer screening, because the clinical outcomes with this screening strategy are likely to be equivalent to optical colonoscopy (See Policy Guidelines)

CT colonography is considered **investigational** for all other indications that do not meet the conditions outlined in the policy statements above.



### **Policy Guidelines**

Medical contraindications to conventional (optical) colonoscopy may include:

- Continuous anticoagulation therapy
- High anesthesia risk (e.g., severe systemic disease)

### **Colon Cancer Screening**

The outcomes of Computed tomography (CT) colonography described in the literature represent outcomes under ideal conditions. This generally involves a comprehensive colon cancer screening program that includes rapid access to optical colonoscopy when necessary and systematic follow-up and surveillance of patients who generally have a more complicated follow-up schedule than do patients undergoing optical colonoscopy. Therefore, to achieve the outcomes described in the literature that are equivalent to optical colonoscopy, CT colonography needs to be offered as part of a comprehensive colon cancer screening program that optimizes follow-up of patients undergoing this procedure.

#### **General Information**

Computed tomography (CT) colonography should be performed with a minimum 16-row detector CT scanner.

Having adequate training was an important component in clinical trials of CT colonography.

#### Coding

There are specific category I CPT codes for this procedure:

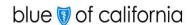
- 74261: Computed tomographic (CT) colonography, diagnostic, including image postprocessing; without contrast material
- 74262: Computed tomographic (CT) colonography, diagnostic, including image postprocessing; with contrast material(s) including non-contrast images, if performed
- 74263: Computed tomographic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

Primary CPT codes 74261 and 74262 should not be billed in conjunction with 72192-72194, 74150-74170, 74263, 76376, and 76377. CPT code 74263 should not be billed in conjunction with 72192-72194, 74150-74170, 74261, 74262, 76376, and 76377.

### **Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as



investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

### Rationale

### **Background**

Computed tomography (CT) colonography, also known as "virtual colonoscopy," is an imaging technique of the colon involving thin-section helical CT to generate high-resolution 2-dimensional axial images of the colon. Three-dimensional images, which resemble the endoluminal images obtained with conventional endoscopic colonoscopy, are then reconstructed offline. CT colonography has been investigated as an alternative to conventional endoscopic ("optical") colonoscopy. While CT colonography requires a full bowel preparation, similar to conventional colonoscopy, no sedation is required, and the examination is less time-consuming. However, the technique involves gas insufflation of the intestine, which may be uncomfortable to the patient, and training and credentialing of readers may be needed to achieve optimal performance.

Both CT colonography and standard optical colonoscopy can be used for the evaluation of a number of disorders of the colon and rectum, most notably colon cancer and colon cancer precursors, but also conditions such as inflammatory bowel disease and diverticulitis/diverticulosis. CT colonography has been most extensively studied as part of a colon cancer screening strategy.

### CT Colonography for Colon Cancer Screening

Colon cancer screening prevents morbidity from colon cancer by the detection of early colon cancers and the detection and removal of cancer precursors such as polyps. The detection of cancer and removal of polyps initially or ultimately require an optical colonoscopy. CT colonography ("virtual colonoscopy") is an imaging procedure that can identify cancers or polyps. The effectiveness and efficiency of virtual colonoscopy is dependent on its capability to accurately identify cancer or polyps, so that all or most patients who have such lesions are appropriately referred for colonoscopy for ultimate diagnosis and treatment and that polyps or cancer are not falsely identified.

Diagnostic Accuracy of CT Colonography for Colon Cancer and Polyps

The diagnostic characteristics of CT colonography as a colon cancer screening test have been investigated in many studies in which patients who are referred for optical colonoscopy agree to first undergo a CT colonography. Using a second-look unblinded colonoscopy aided by the results of the CT colonography as the reference standard, the diagnostic characteristics of CT colonography and the blinded colonoscopy can be calculated and compared. The sensitivity of CT colonography is a function of the size of the polyp; sensitivity is poorer for smaller polyps. A 2004 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment found variable sensitivity and specificity of CT colonography at that time, with many studies showing poor sensitivity. A subsequent meta-analysis of studies that examined the diagnostic performance of CT colonoscopy showed variation between studies but increasing sensitivity for larger polyps (Mulhall et al., 2005). Sensitivity was 48% for detection of polyps smaller than 6 mm, 70% for polyps 6 to 9 mm, and 85% for polyps larger than 9 mm. Characteristics of the CT scanner explained some of the variation between studies. In contrast, specificity was homogeneous (92% for detection of polyps smaller than 6 mm, 93% for polyps 6 to 9 mm, 97% for polyps larger than 9 mm).

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Diagnostic performance of CT colonography is highly dependent on the technology and techniques used. Thus, many of the older studies reviewed may no longer represent currently possible diagnostic performance of the test. A large study by Pickhardt et al. (2003) showed diagnostic test performance of CT colonography for polyps to be equivalent to that of optical colonoscopy. Other studies showed variable performance, with 2 large studies showing much lower sensitivity than optical colonoscopy (Cotton et al., 2004; Rockey et al., 2005). Results from the largest study of a screening population (n>2,500), the American College of Radiology Imaging Network (ACRIN) 6664 trial, were published in 2008 by Johnson et al. and reviewed in a 2009 TEC Assessment. This study used 16- to 64-row detector CT scanners, stool-tagging techniques, and minimum training standards for interpreters of the test. The results of this study showed 90% sensitivity of CT colonography for polyps 10 mm or larger and 86% specificity; positive and negative predictive values were 23% and 99%, respectively.

The diagnostic accuracy of CT colonography compared with colonoscopy was assessed in a 2012 study by Zalis et al., using a laxative-free bowel preparation technique for CT colonography. For adenomas 10 mm or larger, the sensitivity of CT colonography was similar but slightly lower than colonoscopy. For smaller adenomas, the sensitivity of CT colonography was lower than colonoscopy.

In 2014, Fini et al. reported results from a study of the diagnostic accuracy of CT colonography for clinically relevant colorectal lesions, defined as polyps or masses 6 mm or larger among first-degree relatives of patients with colorectal cancer. CT colonography was undertaken following a noncathartic bowel preparation among 344 patients, with optical colonoscopy undertaken on the following day. Sensitivity and specificity for lesions 6 mm or larger were 77% (95% confidence interval [CI]: 59% to 95%) and 99% (95% CI: 97% to 100%), respectively.

A meta-analysis, published in 2011 by de Haan et al., of diagnostic characteristics of CT colonography in screening populations, showed summary sensitivities and specificities that were similar to prior studies. Estimated sensitivities for polyps or adenomas 10 mm or larger were 83.3% and 87.9%, respectively, while specificities were 98.7% and 97.6%, respectively. A meta-analysis published in 2014 by Martin-Lopez et al., included 9 studies of colorectal cancer screening, excluding studies that were conducted for the diagnosis of colorectal cancer or in elderly, high-risk, or symptomatic patients. The patient-level pooled sensitivity and specificity of CT colonography were 66.8% (95% CI: 62.7% to 70.8%) and 80.3% (95% CI: 77.7% to 82.8%), respectively.

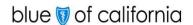
Sensitivity and specificity progressively increased with lesion size, with sensitivity of 91.2% (95% CI: 86.5% to 94.6%) and specificity of 87.3% (95% CI: 86.2% to 88.3%) for lesions greater than 10 mm.

The results of the ACRIN and other trials may be dependent on the technical standards required for performance of the test and the training and skill of the interpreters of the test. Standards of performance and interpretation of CT colonography consistent with those reported in the ACRIN trial will be necessary for CT colonography to be an effective screening test.

### **Section Summary**

There is some variability in the diagnostic accuracy of CT colonography in the literature; this is likely due to the improvement in technical performance over time. The most recent studies have reported that diagnostic accuracy for CT colonography is high and in the same range as optical colonoscopy for polyps greater than 10 mm.

Impact of CT Colonography for Colon Cancer Screening on Health Outcomes



Studies suggest that CT colonography for the screening for colon cancer or polyps has generally high specificity, with more variable estimates for sensitivity. At the same time, CT colonography may improve health outcomes overall because of improved screening adherence. The key question is whether a colorectal cancer screening strategy that relies on CT colonography as the initial test improves health outcomes compared with a strategy using standard optical colonoscopy as the initial test.

There is no direct evidence that evaluates the impact of CT colonography on health outcomes compared with optical colonoscopy. Modeling studies, generally done as part of cost-effectiveness analyses, can provide some insights into the health outcome benefits of CT colonography, as well as provide relevant data on cost-effectiveness.

As a companion piece to the 2009 clinical TEC Assessment on CT colonography, a 2009 TEC Special Report provided a critical appraisal of cost-effectiveness analyses of CT colonography to inform this policy document. Seven published studies were selected (Hassan et al., 2008; Hassan et al., 2007; Ladabaum et al., 2004; Pickhardt et al., 2007; Scherer et al., 2008; Vijan et al., 2007; Zauber et al., 2009).

Two studies completely simulated assumptions that are consistent with current diagnostic capability of CT colonography and recommended practice guidelines (Scherer et al., 2008; Zauber et al., 2009). In the 2009 study by Zauber et al., colonoscopy was slightly more effective and was less expensive than CT colonography. This was based on a model using 1,000 individuals who were 65 years-old. In spite of a somewhat lower per procedure cost, the strategy using CT colonography was found to be more expensive because CT colonography was performed every 5 years (compared with every 10 years for optical colonoscopy), and patients with polyps 6 mm or larger were referred for optical colonoscopy for polyp removal. In this model, the payment for colonoscopy without polypectomy was \$500 and for CT colonography was \$488. In the study by Scherer et al. (2008), the model was based on 1,000 individuals aged 50 years. In this analysis, the only model for CT colonography that was more effective than every 10-year optical colonoscopy was CT colonography every 5 years, with removal of polyps 6 mm or larger. Using these assumptions, this CT colonography approach saved 118.5 lives compared with 116.8 for every 10-year optical colonoscopy; the costs of the 2 approaches were \$2.95 million and \$1.86 million, respectively. In this analysis, the costs of each procedure were comparable, \$523 for CT colonography compared with \$522 for optical colonoscopy without polypectomy. Thus, the outcomes using CT colonography were comparable with optical colonoscopy, yet the CT colonography strategy was more costly. In this study, a sensitivity analysis showed that when the cost of CT colonography was 0.36 that of colonoscopy, CT colonography became less expensive.

A published cost-effectiveness analysis by Pickhardt et al. (2009) performed by the same authors as a previously published analysis, Hassan et al. (2008), but applied to a simulated Medicare-age population 65 years and older, reached similar conclusions as the previously published analysis, which also incorporates the benefits of aortic aneurysm screening. Another cost-effectiveness analysis of several colon cancer screening techniques by Heitman et al. (2010) compared several colon cancer screening techniques. This review reported that CT colonography was similar in effectiveness to several other established screening techniques but was more expensive and was, therefore a dominated, or unpreferred strategy.

Lansdorp-Vogelaar et al. (2011) conducted a systematic review of cost-effectiveness studies of colon cancer screening techniques and found 55 publications relating to 32 unique cost-effectiveness models. CT colonography was evaluated in 8 models. Although CT colonography was deemed cost-effective compared with no screening, it was dominated (i.e., both more expensive and less effective) by established screening

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strategies in 5 of the analyses. They found 1 study in which CT colonography would be the recommended screening strategy at a cost per life-year gained of less than \$50,000.

None of the aforementioned studies included the costs of anesthesia; costs for colonoscopy may be particularly high when anesthesiologists provide pain control.

In general, in these cost-effectiveness analyses, colonoscopy was the more effective screening test. CT colonography was a dominant option (more effective and less costly) only in the 1 study that added CT colonography's benefit of detection of aortic aneurysm and extracolonic cancers (Hassan et al., 2008). This study also incorporated long-term radiation effects. This benefit of detecting extra-colonic disease was calculated to account for up to 20% of the total health benefit achieved. Most of the benefit was estimated to be from early detection of aortic aneurysms. Screening for aneurysm using ultrasound has been demonstrated to be effective in older (i.e., age 65 or older) men and has been recommended for older male smokers. Screening for the other cancers assumed to be detected has not been shown to be effective. Further research is needed to bolster the data supporting considerable benefit of CT colonography regarding aortic aneurysm, especially in older people, and extracolonic cancer detection, as well as the costs and potential health risks of false positive findings.

Hanly et al. published a systematic review of cost-effectiveness studies of CT colonography in 2012. They concluded that CT colonography is cost-effective compared with no screening. They could not reach a conclusion regarding a comparison with colonoscopy, due to differences in study parameters and assumptions. They note that in early studies colonoscopy dominated CT colonography; that is, was both more effective and less expensive. More recent studies have had variable results, dependent on the threshold for colonoscopy referral and whether the costs and effects of acting on extra-colonic findings seen on CT colonography are accounted for.

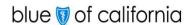
Due to differing assumptions, current studies vary in their evaluation of the comparative costs and effects of CT colonography and colonoscopy with currently available data and practice guidelines. Overall benefit without consideration of costs appears to be similar between the 2 tests regarding colon cancer prevention. Most studies did not consider the potential benefits of aortic aneurysm detection and extracolonic cancer detection. CT colonography was generally more expensive and in many studies less effective as a screening strategy than colonoscopy, and in other studies only slightly more effective.

### **Section Summary**

There are no long-term comparative studies that directly report on outcomes of CT colonography compared with optical colonoscopy. The determination of comparative outcomes of CT colonography and optical colonoscopy is complex, due to the differing patterns of follow-up associated with each strategy. Studies of cost-effectiveness have modeled outcomes of the 2 procedures and generally conclude that outcomes are similar, or that optical colonoscopy results in better outcomes. These analyses assume equal participation rates between the 2 strategies.

Impact of CT Colonography on Colon Cancer Screening Adherence

Compliance with recommendations for optical colonoscopy is suboptimal, with the most recent data suggesting a screening rate of about 60% (in the prior 10 years) among people aged 50 to 75 (Steele et al., 2008). CT colonography has been proposed as an alternative colon cancer screening technique that may improve patient compliance, compared with optical colonoscopy. A literature survey of studies that attempted to determine whether the availability of CT colonography would improve population



screening rates found a diffuse literature consisting of survey studies, patient satisfaction studies, and focus group studies. It is unclear how such studies provide a sufficient base of evidence to demonstrate that population adherence to colon cancer screening would improve through CT colonography.

Stoop et al. published a randomized controlled trial (RCT) in 2012 that evaluated the impact of CT colonography on colon cancer screening rates. This study was performed in the Netherlands, and members of the general population aged 50 to 75 years were randomized to an invitation for CT colonography or optical colonoscopy. The CT colonography protocol included a noncathartic preparation, consisting of iodinated contrast agent given the day before the exam and 1.5 hours before the exam, in conjunction with a low fiber diet. The participation rate in the CT colonography group was 34% (982 of 2,920), compared with a rate of 22% (1,276 of 5,924) in the optical colonoscopy group (p<0.001). The diagnostic yield per patient of advanced polyps was higher in the optical colonoscopy group, at 8.7 of 100 participants compared with 6.1 of 100 participants for CT colonography (p=0.02). However, the diagnostic yield of advanced neoplasia per invitee was similar, at 2.1 of 100 invitees for CT colonography compared with 1.9 of 100 invitees for optical colonoscopy (p=0.56). These data indicate that the increased participation rates with CT colonography offset the advantages of optical colonoscopy and that overall outcomes are likely to be similar between the 2 strategies. It is not known whether the same participation rates would be achieved if CT colonography employed a cathartic preparation or whether the different preparation regimens affect participation rates.

#### **Section Summary**

At least 1 well-done RCT reports that participation rates are improved with CT colonography compared with optical colonoscopy. The improved screening rate may offset, or even outweigh, any benefit of optical colonoscopy on outcomes. However, the available study used a noncathartic preparation, and it is not certain that similar screening rates would be achieved with a cathartic preparation.

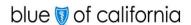
### CT Colonography for Situations Other than Colon Cancer Screening

While the largest body of evidence on the effectiveness of CT colonography relates to its use in colon cancer screening, CT colonography has been studied in for the diagnosis of other conditions of the colon and rectum.

Colon Cancer Diagnosis in Patients with Symptoms or Risk Factors

Several studies have evaluated the role of CT colonography in the diagnosis of colon cancer in patients who have had symptoms or positive findings on other screening modalities (i.e., fecal occult blood testing [FOBT]).

In 2014, Plumb et al. published findings from a systematic review and meta-analysis of studies evaluating the performance of CT colonography for the diagnosis of colon cancer among subjects with positive FOBT. FOBT is a recommended screening technique for colorectal cancer; positive tests are typically followed up with a colonoscopy. In this meta-analysis, the authors included only studies that used CT colonography in the evaluation of patients who had had a positive FOBT and compared colonography results with a reference test, conventional colonoscopy, segmental unblinded colonoscopy, or surgery with subsequent histopathology. Five articles were included in the authors' analysis, representing 4 studies with 622 patients. Pooled per-patient sensitivity and specificity for adenomas 6 mm or larger or colorectal cancer were 88.8% (95% CI: 83.6% to 92.5%) and 75.4% (95% CI: 58.6% to 86.8%), respectively.

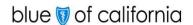


The Plumb meta-analysis focused on patients with positive FOBT testing, but several additional studies have evaluated the role of CT colonography for patients with symptoms of colorectal cancer. In 2013, Atkin et al. reported results from an RCT comparing colonoscopy and CT colonography in the evaluation of patients with symptoms suggestive of colorectal cancer. Given the challenges of conducting a study that would be adequately powered to detect small differences between CT colonography and colonoscopy in colorectal cancer and large polyp detection, the authors used rates of the need for additional evaluation after CT colonography as a primary outcome, with the assumption that such rates would strongly affect the evaluation of the benefits and costs of the procedure. The study randomly allocated patients aged 55 or older with symptoms suggestive of colorectal cancer in a 2:1 fashion to either colonoscopy or CT colonography. The study was not blinded. Both colonoscopy and CT colonography procedures were conducted with a full bowel preparation. The study's primary outcome was the proportion of patients who had additional colonic investigation, defined as any subsequent examination of the colon until diagnosis (usually histologic confirmation of a cancer or polyp) or until a patient was referred back to his or her family doctor. Additional diagnostic evaluation of the colon was required in 160 of 533 (30.0%) of those assigned to CT colonography, compared with 86 of 1.047 (8.2%) of those assigned to colonoscopy (p<0.001). The overall detection rate for colorectal cancer or large polyps did not differ between the groups (relative risk [RR]: 0.95; 95% CI: 0.70 to 1.27; p=0.69). The authors comment that the high referral rate for additional procedures could potentially be mitigated with wider implementation of CT colonography, radiologist training, and standardized protocols.

Simons et al. (2013) evaluated the miss rate (false negative rate) and sensitivity of colorectal cancer on CT colonography among patients who presented with symptoms of colorectal cancer. The authors included 1,855 consecutive patients who underwent CT colonography at a single center. These data were linked to a comprehensive population-based cancer registry to determine if patients were diagnosed with colorectal cancer in the 2 years after their CT colonography. Fifty-three patients were diagnosed with colorectal cancer, of whom 40 patients had had colorectal cancer suspected, 5 diagnosed with large polyps that appeared malignant on histology, and 5 diagnosed with an indeterminate mass on CT colonography. Two patients who developed cancer had not been diagnosed on CT colonography, and 1 patient who developed cancer had had an incomplete colonography, for an overall sensitivity of CT colonography of 94.3% (95% CI: 88% to 100%).

#### Diverticulitis/Diverticulosis

Chabok et al. (2013) reported results of a prospective study comparing CT colonography with optical colonoscopy for follow up of acute diverticulitis. One hundred eight patients presenting for follow-up of an episode of acute diverticulitis underwent evaluation with both CT colonography and optical colonoscopy. At one study site, half of patients were examined by colonoscopy first and then by CT colonography, and the other half were examined by CT colonography first. At the second study site, patients were evaluated alternately by CT colonography or colonoscopy as the first study. The evaluating radiologist and endoscopist interpreting the tests were blinded to the results of the second test. Patients reported their impressions on the procedure by a visual analog scale. Compared with colonoscopy, CT colonography had a sensitivity and specificity for the diagnosis of diverticular disease of 99% and 67%, respectively. Patients reported the colonoscopy was more painful and uncomfortable.



### CT Colonography in Patients with Contraindications to Optical Colonoscopy

CT colonography may also be indicated in patients who have contraindications to conventional colonoscopy or in patients who have incomplete conventional colonoscopy because of colonic obstruction or stenosis. A case series by Yucel et al. (2008) reported on 42 patients older than 60 years (mean: 71 years; range: 60 to 87 years) referred for CT colonography because of contraindications to the conventional procedure (n=12) or incomplete colonoscopy (n=30). Contraindications included anticoagulation therapy (n=8), increased anesthesia risk (n=3), or poor tolerance for colonoscopy preparation (n=1). The most common reasons for incomplete colonoscopy included diverticular disease, colonic redundancy, adhesions, and residual colonic content. Optimal distension of the entire colon was achieved in 38 patients (90%), and 39 (93%) of the patients had abnormal findings. Extracolonic findings potentially requiring further evaluation or treatment were observed in 26 patients (62%).

#### Summary

The available evidence supports the conclusion that the diagnostic accuracy of computed tomography (CT) colonography is in the same range as optical colonoscopy, with a moderate to high sensitivity and a high specificity for the detection of larger polyps and colorectal cancer. As a result, screening with CT colonography may provide similar diagnostic results to screening using conventional colonoscopy. Most modeling studies report that the overall health outcome benefits of a strategy that uses optical colonoscopy likely exceed the benefits of a strategy using CT colonography. However, these analyses assume equal participation rates in screening between the 2 strategies. Participation in screening may be higher with CT colonography than with optical colonoscopy, and this may ameliorate or offset any improved outcomes associated with optical colonoscopy.

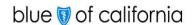
Health outcomes for colon cancer screening strategies that use CT colonography are likely comparable with strategies that use optical colonoscopy. Therefore, CT colonography may be considered medically necessary for colon cancer screening. However, the costs and benefits of a colon cancer screening strategy that employs CT colonography depend on numerous factors that may vary among screening programs. These include the relative costs of the CT colonography procedure, the costs of a colonoscopy procedure (including anesthesia, if applicable), the screening interval, and rates of need for subsequent colonoscopy following CT colonography.

For patients who have contraindications to colonoscopy, such as the need for continuous anticoagulation and/or high anesthetic risk, or in patients with an incomplete colonoscopy due to colonic obstruction or stenosis, CT colonography is a reasonable alternative, and therefore may be considered medically necessary.

#### **Practice Guidelines and Position Statements**

In 2012, the American College of Physicians (ACP) released updated guidelines for colorectal cancer screening (Qaseem et al., 2012). ACP's guideline development process involves the assessment of existing guidelines via the Appraisal of Guidelines for Research and Evaluation II instrument. ACP makes the following recommendations regarding colon cancer screening:

ACP recommends using a stool based test, flexible sigmoidoscopy, or optical colonoscopy as a screening test in patients who are at average risk. ACP recommends using optical colonoscopy as a screening test in patients who are at high risk. Clinicians should select the test based on the



benefits and harms of the screening test, availability of the screening test, and patient preferences.

The guidelines further note that CT colonography is an option for screening in averagerisk patients older than 50 years and is supported by some guidelines.

The 2008 edition of colorectal cancer screening guidelines released jointly by the American Cancer Society (ACS), the American College of Radiology, and the U.S. Multisociety Task Force on Colorectal Cancer recognizes 2 types of screening tests: colon cancer prevention and cancer detection (Levin et al., 2008). Colon cancer prevention tests detect both early cancer and adenomatous polyps. The cancer prevention options recommended were flexible sigmoidoscopy every 5 years, colonoscopy every 10 years, double-contrast barium enema every 5 years, or CT colonography every 5 years. For cancer detection, 3 types of fecal screening tests were supported: annual guaiac-based tests, annual fecal immunochemical tests, and stool DNA tests. The ACS endorses colon cancer prevention as the "primary goal of [colorectal cancer] screening" where resources and patient acceptance permit.

In the 2008 clinical guideline statement of the U.S. Preventive Services Task Force (USPSTF) on colorectal cancer screening, the evidence for CT colonography was judged to be insufficient to evaluate the benefits and harms. This guideline was based on concerns about potential harms of radiation exposure and potential for harm due to evaluation of extracolonic findings.

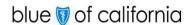
Given that much of the evidence supporting colorectal cancer screening is indirect, it is not so surprising that consensus groups reviewing the same evidence might come to different conclusions, as have the USPSTF and the ACS regarding CT colonography. Although both groups reviewed the same evidence and similar decision models to reach their conclusions, Pignone and Sox (2008) suggest that subtle differences in emphasis may underlie the differing conclusions. USPSTF is more concerned with the potential unknown effects of radiation exposure and workups for extracolonic findings, taking a more longitudinal perspective. The ACS report concentrates on the capability of CT colonography to detect large polyps in a single screening visit as the principal criterion to determine colon cancer prevention. Thus, the ACS report favors screening technologies with superior single-screening detection characteristics over less sensitive tests that have demonstrated efficacy with repeated screening.

A 2006 statement by ACS and the U.S. Multi-Society Task Force on Colorectal Cancer on colonoscopy surveillance after cancer resection recommended that in patients with obstructing colon cancers, CT colonography with intravenous contrast may be used to detect neoplasms in the proximal colon (Rex et al., 2006).

In 2008, the American College of Gastroenterology issued guidelines for colorectal cancer screening. They recommend colonoscopy every 10 years beginning at age 50 as the preferred screening strategy for the general population. Patients who decline colonoscopy or for whom colonoscopy is not feasible should be offered other screenings such as flexible sigmoidoscopy every 5 to 10 years, CT colonography every 5 years, and an annual fecal immunochemical test.

### Medicare National Coverage

On May 12, 2009, Centers for Medicare and Medicaid Services published a decision memo for CT colonography screening that states "The evidence is inadequate to conclude that CT colonography is an appropriate colorectal cancer screening test under section 1861(pp)(1) of the Social Security Act. CT colonography for colorectal cancer screening remains noncovered."

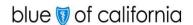


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### **Documentation Required for Clinical Review**

- History and physical and/or consultation notes including:
  - o Anesthesiologist pre-operative assessment
  - o Reason a conventional colonoscopy is not indicated

#### Post Service

Operative report

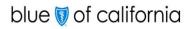
### Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

### MN/IE

The following service/procedure may be considered medically necessary in certain instances and investigational in others. Services may be medically necessary when policy criteria are met. Services are considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

Туре	Code	Description
CPT®	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

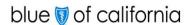


	performed		
	74263	Computed tomographic (CT) colonography, screening, including image postprocessing	
НСРС	None		
ICD-9 Procedure	88.01	Computerized axial tomography of abdomen	
	For dates of service on or after 10/01/2015		
ICD-10 Procedure	BD2400Z	Computerized Tomography (CT Scan) of Colon using High Osmolar Contrast, Unenhanced and Enhanced	
	BD240ZZ	Computerized Tomography (CT Scan) of Colon using High Osmolar Contrast	
	BD2410Z	Computerized Tomography (CT Scan) of Colon using Low Osmolar Contrast, Unenhanced and Enhanced	
	BD241ZZ	Computerized Tomography (CT Scan) of Colon using Low Osmolar Contrast	
	BD24Y0Z	Computerized Tomography (CT Scan) of Colon using Other Contrast, Unenhanced and Enhanced	
	BD24YZZ	Computerized Tomography (CT Scan) of Colon using Other Contrast	
	BD24ZZZ	Computerized Tomography (CT Scan) of Colon	
ICD-9 Diagnosis	All Diagnoses		
ICD-10	For dates of service on or after 10/01/2015		
Diagnosis	All Diagnoses		

# **Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
6/1/2003	BCBSA Medical Policy adoption	Medical Policy Committee
6/1/2004	Policy Review	Medical Policy Committee



12/7/2006	BCBSA Medical Policy adoption	Medical Policy Committee
5/8/2009	Policy Title Revision, Medically Necessary criteria added	Medical Policy Committee
6/26/2009	Policy Revision	Administrative Review
1/15/2010	Coding Update	Administrative Review
4/1/2011	Policy revision with position change	Medical Policy Committee
9/30/2014 Policy title change from CT Colonography (Virtual Colonoscopy)		Medical Policy Committee
	Policy revision with position change	

#### **Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

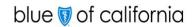
#### **Prior Authorization Requirements**

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation



of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.