BlueCross BlueShield of Alabama

Effective for dates of service on or after April 1, 2013, refer to:
https://www.bcbsal.org/providers/policies/careCore.cfm

Name of Policy:
Virtual Colonoscopy/CT Colonography

Policy #: 042
Category: Radiology
Latest Review Date: February 2013
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

CT colonography, a three-dimensional computed tomographic colonography, often referred to as "virtual colonoscopy" combines high resolution two and three dimensional images of the colon via computer software to simulate endoscopic colonoscopy. CT colonography has been investigated as an alternative to conventional endoscopic (optical) colonoscopy and also as an alternative screening technique for colon cancer. The procedure generally involves no sedation. Required are the bowel prep as in endoscopic colonoscopy; gas insufflation, which may be uncomfortable for the patient; spiral CT scan and computer processing which has been described as difficult and time consuming. Training and credentialing of reader may be needed to achieve optimal performance.

Virtual colonoscopy (VC), or computed tomographic (CT) colonography, is a non-invasive radiological technique that allows visualization of the entire colon. The data acquired from the CT scan is transferred to a computer workstation. Using specific advanced graphical software, two-dimensional (axial, coronal, and sagittal reformations) and three-dimensional (endoluminal) images are created. The 3D images resemble the endoluminal images obtained with conventional endoscopic colonoscopy.

Virtual colonoscopy has been investigated as an alternative to conventional endoscopic colonoscopy, specifically as an alternative screening technique for colon cancer. VC requires a full bowel preparation, similar to conventional colonoscopy, and colon insufflation, which may be uncomfortable to the patient. VC does not require sedation, is less time consuming, and involves little risk of complication. However, VC only provides images of the colon and does not allow for biopsy or polyp removal at the time of the exam.

Policy:

Effective for dates of service on or after April 1, 2013, refer to:
https://www.bcbsal.org/providers/policies/careCore.cfm

Effective for dates of service prior to April 1, 2013

Virtual Colonoscopy or Computed Tomography Colonography used as a screening test for colorectal polyps and cancer **does not meet** Blue Cross and Blue Shield of Alabama's criteria for coverage and will be considered **investigational**.

Virtual colonoscopy or computed tomography colonography does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage when used as an alternative to optical colonoscopy, even though performed for signs or symptoms of the disease.

A **diagnostic virtual colonoscopy meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for evaluation of the colon when an instrument colonoscopy of the entire colon is incomplete due to obstructive or stenosing colonic lesions resulting in an inability to pass the colonoscope proximally.

A **diagnostic virtual colonoscopy meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for evaluation of the colon in patients for whom a conventional colonoscopy is indicated but who are unable to undergo conventional colonoscopy for medical reasons such as being on continuous anticoagulation therapy or having high anesthesia risk.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

Colon cancer screening prevents morbidity from colon cancer by detection of early colon cancers and by detection and removal of cancer precursors such as polyps. The detection of cancer and the 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 of accurately identifying 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

The diagnostic characteristics of CT colonography as a colon cancer screening test have been investigated in many studies where 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 the CT colonography and of 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 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 examining the diagnostic performance of CT colonoscopy showed variation between studies, but increasing sensitivity for larger polyps. 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, and 97% for polyps larger than 9 mm).

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 published in 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. Results from the largest study of a screening population (n>2,500),

the ACRIN 6664 trial, were recently published and reviewed in a 2008 TEC Assessment. This study used 16–64 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 results of the ACRIN trial may have been dependent on the technical standards required for performance of the test and the training and skill of the interpreters of the test. If these practices can be replicated in the community, then it is likely that improved health outcomes similar to those in the trial can be achieved. 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.

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 97.9%, respectively.

Conclusions
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. This is especially true for large polyps greater than 10 mm, for which the diagnostic performance of CT colonography is likely to be as good as optical colonoscopy.

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 and colleagues reported on 42 patients older than 60 years (mean: 71 years; range: 60–87 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%).

Impact of CT colonography on health outcomes
There is no direct evidence that evaluates the impact of CT colonography on health outcomes compared to 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.

Given the chain of logic and other underlying evidence that supports the practice of accepted colon cancer screening techniques such as optical colonoscopy, a 90% sensitivity of CT

colonography for detection of polyps 10 mm or larger is consistent with an improvement in health outcomes. The 86% specificity of CT colonography would result in some false-positive tests, which, in turn, would result in some unnecessary follow-up colonoscopies. However, compared with optical colonoscopy, there are several other types of health outcomes that may differ in terms of convenience, cost, detection of unrelated health problems, and radiation exposure. These are difficult to quantify and are probably small in magnitude compared to the health benefit of identifying and removing cancer precursors.

As a companion piece to the 2008 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.

Two studies completely simulated assumptions that are consistent with current diagnostic capability of CT colonography and recommended practice guidelines. In the study by Zauber, colonoscopy was slightly more effective and was less expensive than CT colonography. This was based on a model using 1000 65-year old individuals. Despite 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 to 10 years for optical colonography) 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, the model was based on 1000 50-year old individuals. In this analysis, the only model for CT colonography (CTC) that was more effective than every 10 year optical colonoscopy was CTC every 5 years with polyp removal for polyps of 6 mm or larger. Using these assumptions, this CTC approach saved 118.5 lives compared to 116.8 for every 10 year optical colonoscopy; the costs of the two approaches were $2.95 million and $1.86 million respectively. In this analysis, the costs of each procedure were comparable, $523 for CTC compared to $522 for optical colonoscopy without polypectomy. Thus, the outcomes using CT colonography were comparable to optical colonoscopy, yet the CTC strategy was more costly. In this study, a sensitivity analysis showed that when the cost of CTC was 0.36 that of colonoscopy, CTC became less expensive.

A published cost-effectiveness analysis performed by the same authors as a previously published analysis, 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 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 un-preferred strategy.

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

In general, in these cost-effectiveness analyses, colonoscopy was generally the more effective screening test, and its incremental cost-effectiveness ratio was consistent with a reasonable value for its benefits. The quantity of health benefit afforded by either test is fairly similar.

CT colonography was a dominant or cost-effective option only in the one study that added CT colonographys benefit of detection of aortic aneurysm and extracolonic cancers. 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 individuals, and extracolonic cancer detection, as well as the costs and potential health risks of false-positive findings.

Due to differing assumptions, current cost-effectiveness 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 two 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.

Conclusions

There are no long-term comparative studies that directly report on outcomes of CT colonography compared to 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 two procedures and generally conclude that outcomes are similar, or that optical colonoscopy results in better outcomes. These analyses assume equal participation rates between the two strategies.

Impact of CT colonography on colon cancer screening adherence

Compliance with recommendations for optical colonoscopy is suboptimal. CT colonography has been proposed as an alternative colon cancer screening technique that may improve patient compliance, compared to optical colonoscopy. A literature survey of studies which attempt 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 50-75 years were randomized to an invitation for CT colonography or optical colonoscopy. The CT colonography protocol included a non-

cathartic 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% (982/2,920), compared to a rate of 22% (1,276/5,924) in the optical colonoscopy group ($p<0.0001$). The diagnostic yield per patient of advanced polyps was higher in the optical colonoscopy group, at 8.7/100 participants compared to 6.1/100 participants for CT colonography ($p=0.02$). However, the diagnostic yield of advanced neoplasia per invitee was similar, at 2.1/100 invitees for CT colonography compared to 1.9/100 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 two 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.

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

Summary
The available evidence supports the conclusion that the diagnostic accuracy of CT colonography is in the same range as optical colonoscopy, with a moderate to high sensitivity and a high specificity for larger polyps. As a result, screening with CT colonography may provide similar diagnostic results to screening using conventional colonoscopy. The majority of 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 two 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.

A strategy that employs CT colonography is generally more costly than a strategy that employs optical colonoscopy. This increased cost relates to a more frequent screening interval and the need for subsequent colonoscopy for removal of polyps. Thus, for use in colorectal cancer screening, CT colonography is considered not medically necessary when patients are able to undergo optical colonoscopy. When it is determined at a local level that CT colonography is not more costly than optical colonoscopy, then CT colonography may be considered medically necessary.

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.

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. Multi-society Task Force on Colorectal Cancer recognizes two types of screening tests: colon cancer prevention and cancer detection. 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 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 suggest that subtle differences in emphasis may underlie the differing conclusions. The 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 the ACS on colonoscopy surveillance after cancer resection recommended that in patients with obstructing colon cancers, CT colonography with IV contrast may be used to detect neoplasms in the proximal colon.

A position statement by the American College of Gastroenterology in 2006 (prior to the publication of the ACRIN 6664 trial) also expressed concerns over additional areas of uncertainty such as the radiation risk, interpretation, and management of extracolonic findings, and the cost-effectiveness of CT colonography.

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Medicare National Coverage
On May 12, 2009, the 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 §1861(pp)(1) of the Social Security Act. CT colonography for colorectal cancer screening remains non-covered.

Key Words:

Virtual Colonoscopy, computed tomographic (CT) Colonography, endoscopic colonoscopy, colorectal cancer

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.
Pre-certification requirements: Required when ordered by a provider in a Blue Cross and Blue Shield of Alabama's Preferred or Participating Network for a patient covered by Blue Cross and Blue Shield of Alabama who will receive outpatient imaging service(s) from a Preferred Medical Doctor (PMD) or Preferred Radiology Participating (PRP) provider for dates of service on or after July 1, 2006.
Reviews to verify accuracy of pre-certification information will be conducted.

Coding:

CPT code:

74150	Computerized axial tomography, abdomen; without contrast material.
74160	Computerized axial tomography, abdomen; with contrast material(s).
74170	Computerized axial tomography, abdomen; without contrast material: followed by contrast material(s) and further sections.
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
76376	3d rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality; with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation
76377	3d rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation

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Medical Policy Group, January 2011
Medical Policy Group, June 2012 **(4)**: Updated Key Points and References. No policy changes made.
Medical Policy Group, December 2012 **(3)**: 2013 Coding Updates: Verbiage change to Codes 76376 & 76377
Medical Policy Group, February 2013 **(2)** Updated policy with link to CareCore National© medical policies effective April 1, 2013
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Medical Policy Group, November 2013 **(2)**: Updated CareCore link

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