BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Virtual Colonoscopy/CT Colonography

Policy # 00136
Original Effective Date: 09/18/2002
Current Effective Date: 03/07/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider computed tomography colonography to be **eligible for coverage**.

Patient Selection Criteria
Coverage eligibility for computed tomography colonography will be considered when any of the following criteria are met:

- Patients who cannot undergo conventional complete colonoscopy; or
- Patients with an incomplete conventional colonoscopy because of colonic stenosis or obstruction.

Note: *Computed tomography colonography should be performed with a minimum 16-row detector computed tomography scanner.*

When Services Are Considered Investigational
Note: Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers computed tomography colonography when patient selection criteria are not met to be **investigational.***

Background/Overview

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, specifically as an alternative screening technique for colon cancer.

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, specifically as an alternative screening technique for colon cancer. 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.

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FDA or Other Governmental Regulatory Approval

Centers for Medicare and Medicaid Services (CMS)
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 noncovered."

Rationale/Source

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
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 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. 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 American College of Radiology Imaging Network (ACRIN) 6,664 trial, were recently published 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 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.

The diagnostic accuracy of CT colonography compared to 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.

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 for polyps greater than 10 mm.

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 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.

Two studies completely simulated assumptions that are consistent with current diagnostic capability of CT colonography and recommended practice guidelines. In the 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 to every 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 et al., 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 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 CT colonography compared to $522 for optical colonoscopy without polypectomy. Thus, the outcomes using CT colonography were comparable to 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 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 unpreferred 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.

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

Virtual Colonoscopy/CT Colonography

Policy # 00136
Original Effective Date: 09/18/2002
Current Effective Date: 03/07/2014

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. 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.

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 to no screening. They could not reach a conclusion regarding a comparison to 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 upon 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 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.

Virtual Colonoscopy/CT Colonography

Policy # 00136
Original Effective Date: 09/18/2002
Current Effective Date: 03/07/2014

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.

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Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	74261, 74262, 74263
HCPCS	No codes
ICD-9 Diagnosis	153.0 thru 153.9, 560.9, V76.51
ICD-9 Procedure	88.01

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Original Effective Date: 09/18/2002
Current Effective Date: 03/07/2014

09/11/2002	Medical Policy Committee review
09/18/2002	Managed Care Advisory Council approval
10/05/2004	Medical Director review
11/16/2004	Medical Policy Committee review. Format revision. No substance change to policy.
11/29/2004	Managed Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged
11/01/2006	Medical Director review
11/15/2006	Medical Policy Committee approval. Coverage eligibility unchanged.
01/07/2009	Medical Director review
01/14/2009	Medical Policy Committee approval. Title changed from “Virtual Colonoscopy/CT Colonography as a Screening Test for Colorectal Cancer” to “Virtual Colonoscopy/CT Colonography” Coverage changed from investigational to eligible for coverage with criteria.
01/07/2010	Medical Director review
01/20/2010	Medical Policy Committee approval. No change to coverage. Coding revision.
01/06/2011	Medical Director review
01/19/2011	Medical Policy Committee approval. No change to coverage
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/09/2014	Medical Policy Committee review
01/15/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 01/2015

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);

2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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