Virtual Gastrointestinal Endoscopy

Number: 0535

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers virtual colonoscopy using computed tomography (CT colonography) performed every 5 years a medically necessary preventive service for colorectal cancer screening of average-risk asymptomatic persons 50 years of age or older.

Aetna considers diagnostic virtual colonoscopy medically necessary for colonic evaluation of:

- Symptomatic members with a known colonic obstruction when standard optical colonoscopy is contraindicated; or
- Symptomatic members with an incomplete colonoscopy due to diverticulosis, obstructive or stenosing colonic lesions, or redundant colon; or
- Members who are receiving chronic anti-coagulation that cannot be interrupted; or
- Members with complications from prior optical colonoscopy; or
- Members with active diverticulitis and an increased risk of perforation; or
- Members with increased sedation risk (e.g., chronic...
obstructive pulmonary disease or previous adverse reaction to anesthesia).

Aetna considers virtual colonoscopy using CT experimental and investigational for all other indications including the following (not an all-inclusive list) because its clinical value for indications other than those listed above, has not been established:

- Diagnosis of colorectal cancer or inflammatory bowel disease (Crohn's disease and ulcerative colitis) in persons without known colonic obstruction or an incomplete optical colonoscopy due to obstructive or stenosing colonic lesions, with or without diverticulosis.

Aetna considers virtual colonoscopy using magnetic resonance imaging (MRI) (also known as MRI colonography) experimental and investigational for the screening or diagnosis of colorectal cancer, diverticulitis, inflammatory bowel disease, or other indications because its value for these indications has not been established.

Aetna considers virtual upper gastrointestinal endoscopy using CT for the detection and evaluation of upper gastrointestinal lesions experimental and investigational because its value for these indications has not been established.

**Background**

Virtual endoscopy combines the features of endoscopic viewing and computerized tomography (CT) data to create a virtual image that is artificially generated by a computer. In the evaluation of gastrointestinal cancers, virtual endoscopy has been most commonly used in colorectal carcinomas and to a much lesser extent in gastric carcinomas. The clinical application of virtual endoscopic techniques is also being used with other procedures such as bronchoscopy, gastroscopy, cystoscopy, sinus imaging, virtual angioscopy, and cerebral
ventriculography (Oto, 2002; Dykes, 2001).

**Virtual Colonoscopy:**

Computed tomographic colonography (CTC), also known as virtual colonoscopy, was developed as a minimally invasive method to examine the colon. This test has been suggested for use in screening and to detect abnormalities in the colon and rectum (eg, colorectal cancer [CRC] and polyps). It involves the use of helical computed tomography (CT) and computer generated images to produce high-resolution two- and three-dimensional (3D) images of the colon and rectum. Prior to virtual colonoscopy, standard bowel cleansing preparations are needed to evacuate any stool and fluid from the colon. During the procedure, a rectal tube is inserted and the colon is distended using room air or carbon dioxide and images are then taken by a helical CT scanner. Using a conventional workstation and a dynamic display of images, a radiologist conducts virtual examinations of the bowel, simulating the way endoscopists view the colon. The results are interpreted by a radiologist. If suspicious lesions are detected, the individual generally must undergo further testing via conventional colonoscopy. Virtual colonoscopy provides a method for processing data that can display computer images of the colon in a more anatomic life-like format and is being promoted by some as a non-invasive screening test for colorectal neoplasia.

The U.S. Preventive Services Task Force (USPSTF, 2016) recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years (A recommendation). The USPSTF stated that the decision to screen for colorectal cancer in adults aged 76 to 85 years should be an individual one, taking into account the patient’s overall health and prior screening history (C recommendation). The USPSTF concluded with high certainty that screening for colorectal cancer in average-risk, asymptomatic adults aged 50 to 75 years is of substantial net benefit.

The USPSTF (2016) listed CT colonography performed every 5
years as an acceptable colorectal cancer screening strategy for average-risk persons. The USPSTF stated that multiple screening strategies are available to choose from, with different levels of evidence to support their effectiveness, as well as unique advantages and limitations, although there are no empirical data to demonstrate that any of the reviewed strategies provide a greater net benefit.

The USPSTF (2016) found that the evidence for assessing the effectiveness of computed tomography (CT) colonography is limited to studies of its test characteristics. The USPSTF noted that computed tomography colonography can result in unnecessary diagnostic testing or treatment of incidental extracolonic findings that are of no importance or would never have threatened the patient’s health or become apparent without screening (ie, overdiagnosis and overtreatment). The USPSTF noted that extracolonic findings are common, occurring in about 40% to 70% of screening examinations. Between 5% and 37% of these findings result in diagnostic follow-up, and about 3% require definitive treatment. As with other screening strategies, indirect harms from CT colonography can also occur from follow-up colonoscopy for positive findings.

The USPSTF (2016) stated that radiation-induced cancer is a potential long-term concern with repeated use of CT colonography. No studies directly measured this risk, but radiation exposure during the procedure seems to be low, with a maximum exposure of about 7 mSv per examination. In comparison, annual background radiation exposure in the United States is 3 mSv per year per person.

Virtual colonoscopies should only be performed at centers with an appropriate generation of CT scan -- a minimum 4 detector CT scanner; collimation of 3 mm or less, overlapping sections at an interval that is 2/3 or less of the collimation, and scan times should be 30 seconds or less in order to minimize respiratory motion.

Pickhardt et al (2003) reported that CT virtual colonoscopy with
the use of a three-dimensional (3-D) approach is an accurate screening method for the detection of colorectal neoplasia in asymptomatic average-risk adults and compares favorably with optical colonoscopy in terms of the detection of clinically relevant lesions. However, in an editorial that accompanied the study by Pickhardt et al, Morrin and LaMont (2003) stated that “if the results of this well-designed study are reproducible on a wider scale, and if the important questions regarding the appropriate size threshold and surveillance of smaller polyps can be resolved, then screening virtual colonoscopy is ready for prime time”.

A study by Cotton et al (2004) reported that the accuracy of CT colonography (virtual colonoscopy) for the detection of colorectal cancer is less reliable than previously thought. CT colonography involves the examination of computer-generated images of the colon constructed from data obtained from an abdominal computed tomographic examination. Several studies have suggested a high degree of sensitivity for CT colonography; however, those results were obtained at single, specialized centers. Cotton reported on a new study that was designed to evaluate the accuracy of CT colonography in routine practice at 9 major hospital centers.

In this study, researchers assessed the accuracy of CT colonography in 615 patients aged 50 years or older who were referred for routine, clinically indicated colonoscopy (Cotton et al, 2004). Colonoscopy was performed within 2 hours of the colonography and results were compared. The sensitivity of CT colonography for detecting 1 or more lesions sized at least 6 mm was 39 % and for lesions sized at least 10 mm, it was 55 %. These results were significantly lower than those for conventional colonoscopy, with sensitivities of 99 % and 100 %, respectively. CT colonography missed 2 of 8 cancers. The accuracy of CT colonography varied considerably between centers. At the 1 center that had "substantial" prior experience with CT colonography, the sensitivity was 82 % for lesions of 6 mm or more. Sensitivity at all of the other centers combined was 24 %, with no improvement in accuracy as the number of
cases at each center was increased. Preference questionnaires after both procedures were performed showed that 46% of the patients preferred CT colonography versus 41% who preferred conventional colonoscopy. The authors stated that "even if the results of CT colonography continue to be good in the hands of experts, it has yet to be proven that this expertise can be taught and disseminated reliably into daily practice". The authors concluded that CT colonography is not yet ready for widespread clinical application; techniques and training need to be improved.

The American Cancer Society guidelines on colorectal cancer screening recommend several methods of screening, including virtual colonoscopy, based in part upon the presumption that the availability of multiple methods of screening will improve compliance (Levin et al, 2008). Colorectal cancer screening guidelines from the American Cancer Society recommend CT colonography (virtual colonoscopy) performed every 5 years as an acceptable alternative to optical colonoscopy performed every 10 years for screening of average-risk persons. Virtual colonoscopy is similar to optical colonoscopy in that it requires completion of a pre-procedure cathartic regimen. If a lesion is found on virtual colonoscopy, the patient must return another day and complete another cathartic regimen for an optical colonoscopy to remove the lesion. By contrast, optical colonoscopy allows for identification and removal of a lesion in 1 procedure.

An assessment of CT colonography prepared by the Institute for Clinical and Economic Review (ICER) for the Washington State Health Care Authority (Scherer et al, 2008) found that, in direct comparison to optical colonoscopy, CT colonography every 10 years is substantially more expensive and marginally less effective in preventing cases of cancer (47 versus 52 in a lifetime cohort of 1,000 individuals) and cancer deaths (24 versus 26). The investigators reported that only 1 CT colonography screening strategy is as effective as optical colonoscopy every 10 years, and that strategy is to perform CT colonography every 5 years with colonoscopy referral for polyps greater than 6 mm. For this strategy, the cost per life-year
gained for CT colonography versus optical colonoscopy was $630,700. The assessment noted that the preponderance of the data suggests that, among patients who experienced both CTC and colonoscopy, a small majority preferred CT colonoscopy. The assessment stated that it is unclear whether preferences elicited among some patients for CTC would result in a larger number of unscreened individuals in a population being screened. The review found no studies examining whether the availability of CT colonography results in increased numbers of individuals being screened within a population.

ICER (2008) prepared an update to their assessment after publication of the National CT Colonography Trial, conducted by the American College of Radiology Imaging Network (ACRIN) (citing Johnson, et al., 2008). In the ACRIN study, the largest multicenter study of CTC published to date, over 2,500 asymptomatic patients were scheduled for optical colonoscopy at 15 clinical sites across the U.S. Patients first received CTC, followed by same-day colonoscopy in most cases. CTC sensitivity and specificity for detecting polyps ≥ 10 mm in size were 90% and 86%. Sensitivity and specificity for polyps ≥ 6 mm were somewhat lower (78%, 88%). The range of sensitivity across individual radiologist interpreters was 67%-100%. Extracolonic findings were reported in 66% of the participants; 16% were deemed to require either additional evaluation or urgent care. No data on the subsequent outcomes or costs due to incidental findings were reported. The ICER update noted that a key new piece of evidence given in this study is the relatively broad range of performance across radiologists, all of whom received special training in CTC evaluation and/or had performed more than 500 interpretations. The ICER updated stated that decision-makers should consider whether the variability in performance demonstrated in the ACRIN study suggests that the actual performance in the general community is likely to be lower than that reported in this study. The ICER assessment stated that other questions remain unanswered, such as the effects of a cumulative radiation dose from CTC tests every 5-10 years as well as the impact of extracolonic findings from CTC on net health benefits and cost-effectiveness within the population.
Rex and colleagues (2009) updated the American College of Gastroenterology (ACG)'s recommendation on colorectal cancer (CRC) screening. The CRC screening tests are now grouped into cancer prevention tests and cancer detection tests. Colonoscopy every 10 years, beginning at age 50, remains the preferred CRC screening strategy. It is recognized that colonoscopy is not available in every clinical setting because of economic limitations. It is also realized that not all eligible persons are willing to undergo colonoscopy for screening purposes. In these cases, patients should be offered an alternative CRC prevention test (flexible sigmoidoscopy every 5 to 10 years, or a CT colonography every 5 years) or a cancer detection test (fecal immunochemical test for blood, FIT).

On May 12, 2009, the Centers for Medicare & Medicaid Services (CMS) issued a final coverage determination that refused coverage of CTC for colorectal screening. It stated that the evidence is inadequate to conclude that CTC is an appropriate colorectal cancer screening test.

A number of studies have reported on individuals expressed preferences for colorectal cancer screening with CTC versus optical colonoscopy (see, e.g., Hawley et al., 2008; Moawad, et al, 2010). It is unclear whether preferences elicited among some patients for CTC would result in a larger number of unscreened individuals in a population being screened.

A randomized controlled trial from the Netherlands (Stoop et al, 2012) found that the diagnostic yield for advanced neoplasia was similar for CT colonography and colonoscopy. Participation in colorectal cancer screening with CT colonography was significantly better than with colonoscopy, but colonoscopy identified significantly more advanced neoplasia per 100 participants than did CT colonography. The randomized controlled clinical trial (de Wijkerslooth, et al., 2012) also found that people invited to screening via CT colonography perceived the procedure (ahead of it) as less burdensome than colonoscopy. After actually having undergone the procedure, CT colonography screenees perceived it as having been more burdensome than colonoscopy screenees. Intended participation in a future round of screening was comparable. Rex (2012) commented on these studies, noting that the
generalizability of these results to the U.S. population is uncertain because the use of screening colonoscopy is much more widespread in the U.S. than Europe. Nevertheless, these findings suggest that, over time, the reputation of CT colonography from the standpoint of patient burden and acceptability, even using the noncathartic approach, would likely diminish relative to colonoscopy (Rex, 2012). In addition, these results do not take into account that patients had no knowledge of test performance, which was substantially better for colonoscopy than CT colonography. Rex stated that understanding test performance characteristics is bound to influence the relative acceptability of the two tests.

Several studies have compared the results of CTC in the elderly, finding performance similar to CTC in the nonelderly population (Johnson et al, 2012; Cash et al, 2012; Macari et al, 2011; Kim et al, 2010).

Keegan et al (2010) evaluated the ability of CTC to perform at high levels of sensitivity and specificity for CRC screening in an asymptomatic population. Searches were done in PubMed, Cochrane Library, TRIP Database, and UpToDate, utilizing the terms CT colonography, colonoscopy, virtual colonoscopy, screening, and colon cancer. In PubMed the following limits and terms were used: published in the last 5 years, humans, meta-analysis, randomized controlled trial, and English. A meta-analysis by Mulhall et al revealed 2 studies meeting inclusion/exclusion criteria: Pickhardt et al and Macari et al. Searching Pickhardt et al through "related articles" in PubMed yielded the Wessling et al study. The authors concluded that CTC can achieve high accuracy, but only under specific conditions using multi-detector CT scanners, primary 3-D data interpretation, well-prepared patients, collimation of less than or equal to 1.25 mm, and data interpretation by an experienced radiologist. They stated that cost-effectiveness and compliance in the general population, as well as radiation exposure and follow-up requirements with colonography for CRC screening, need further study.

Rockey (2010) stated that CTC has received considerable attention in the last decade as a colon-imaging tool. The technique has also been proposed as a potential primary colon cancer-screening method in the United States. The accuracy of
the technique for the detection of large lesions seems to be high, perhaps in the range of colonoscopy. Overall, the field is rapidly evolving. Available data suggest that CTC, although a viable colon cancer screening modality in the United States, is not ready for widespread implementation, largely because of the lack of standards for training and reading and the limited number of skilled readers.

Hanly et al (2012) systematically reviewed evidence on, and identified key factors influencing, cost-effectiveness of CTC screening. PubMed, Medline, and the Cochrane library were searched for cost-effectiveness or cost-utility analyses of CTC-based screening, published in English, January 1999 to July 2010. Data was abstracted on setting, model type and horizon, screening scenario(s), comparator(s), participants, uptake, CTC performance and cost, effectiveness, ICERs, and whether extra-colonic findings and medical complications were considered. A total of 16 studies were identified from the United States (n = 11), Canada (n = 2), and France, Italy, and the United Kingdom (1 each). Markov state-transition (n = 14) or micro-simulation (n = 2) models were used. Eleven considered direct medical costs only; 5 included indirect costs. Fourteen compared CTC with no screening; 14 compared CTC with colonoscopy-based screening; fewer compared CTC with sigmoidoscopy (8) or fecal tests (4). Outcomes assessed were life-years gained/saved (13), QALYs (2), or both (1). Three considered extra-colonic findings; and 7 considered complications. Computed tomography colonography appeared cost-effective versus no screening and, in general, flexible sigmoidoscopy and fecal occult blood testing. Results were mixed comparing CTC to colonoscopy. Parameters most influencing cost-effectiveness included: CTC costs, screening uptake, threshold for polyp referral, and extra-colonic findings. The authors concluded that evidence on cost-effectiveness of CTC screening is heterogeneous, due largely to between-study differences in comparators and parameter values. They stated that future studies should (i) compare CTC with currently favored tests, especially fecal immunochemical tests; (ii) consider extra-colonic findings; and (iii) conduct comprehensive sensitivity analyses.
Kolligs (2012) stated that the highest evidence for all screening tests has been demonstrated for guaiac-based fecal occult blood testing. Colonoscopy is a diagnostic and therapeutic tool and it serves as the reference standard for other tests in clinical studies. Fecal immunochemical tests have a higher sensitivity than guaiac-based tests. Several novel techniques are under development and could be adopted by screening programs in the future. Next to colonoscopy, CTC and colon capsule endoscopy have the highest sensitivity for colorectal neoplasia. Molecular tests that are based on the detection of genetic and epigenetic changes of DNA released by the tumor into feces or blood have a high potential and could potentially replace occult blood tests in the future. The author concluded that colonoscopy is the primary instrument for screening for colorectal neoplasia. Fecal occult blood testing should only be performed if colonoscopy is denied and CTC has not yet been approved for screening in Germany.

Members of an advisory panel convened by the U.S. Food and Drug Administration (FDA, 2013) were in agreement that radiation patients receive in CT colonography is not likely to be significant. Some FDA panelists expressed concern that CT colonography is less sensitive in smaller polyps less than 6 millimeters. Others noted that CT colonography was not able to reliably detect “flat” or serrated polyps, which may contribute
to 30% of all colon cancers. Panelists also expressed concern that untrained professionals would be reading the CTC and missing possible lesions that need follow-up. The benefits and harms of detection of extracolonic findings were also discussed. Panelists suggested that CT colonography may provide a useful option for patients who have contraindications to sedation or those on anticoagulants.

The AIM Specialty Health’s appropriate use criteria on “Imaging of the abdomen & pelvis” (2014) stated that indications for diagnostic CT colonography included the following:

- Complications from prior fiberoptic colonoscopy
- Diverticulitis, with increased risk of perforation
- Failed or incomplete fiberoptic colonoscopy of the entire colon, due to inability to pass the colonoscope proximally
- Increased sedation risk (e.g., chronic obstructive pulmonary disease or previous adverse reaction to anesthesia)
- Known colonic obstruction, when standard fiberoptic colonoscopy is contraindicated
- Lifetime or long-term anticoagulation, with increased patient risk if discontinued

The American College of Radiology’s Appropriateness Criteria on “Left lower quadrant pain -- suspected diverticulitis” (McNamara et al, 2014) stated that “In the future, less invasive examinations may become clinically relevant, including quantitative CT perfusion studies, diffusion-weighted MRI, and MR colonography”.

Villa and colleagues (2015) stated that a thorough and complete colonoscopy is critically important in preventing colorectal cancer. Factors associated with difficult and incomplete colonoscopy include a poor bowel preparation, severe diverticulosis, redundant colon, looping, adhesions, young and female patients, patient discomfort, and the expertise of the endoscopist. For difficult colonoscopy, focusing on bowel preparation techniques, appropriate sedation and adjunct techniques such as water immersion, abdominal
pressure techniques, and patient positioning can overcome many of these challenges. Occasionally, these fail and other alternatives to incomplete colonoscopy have to be considered. If patients have low risk of polyps, then non-invasive imaging options such as CTC can be considered. Novel applications such as Colon Capsule and Check-Cap are also emerging. In patients in whom a clinically significant lesion is noted on a non-invasive imaging test or if they are at a higher risk of having polyps, balloon-assisted colonoscopy can be performed with either a single- or double-balloon enteroscope or colonoscope. The application of these techniques enables complete colonoscopic examination in the vast majority of patients.

*Magnetic Resonance Colonography*:

Magnetic resonance (MR) colonography is a diagnostic test generally performed by a radiologist and is purported to be utilized to detect colorectal polyps and CRC. This outpatient procedure also requires standard bowel cleansing preparations. The colon is then distended with a contrast medium that has been placed via a rectal tube. Magnetic resonance imaging (MRI) data reportedly creates a 3D image of the interior surface of the colon.

An assessment by the Ontario Ministry of Health and Long-Term Care (2009) concluded that magnetic resonance colonography (MRC) and CTC with 16-slice or 64-slice scanners have equal sensitivity for the detection of colorectal cancer, as well as for the detection of large and medium sized polyps; however, MRC does not carry the associated risks of ionizing radiation. The assessment found that MRC and CTC with 16-slice or 64-slice scanners can reliably detect most colorectal cancers and large colorectal polyps; however, about 20 % of medium-sized colorectal polyps will be missed by both techniques. The report found, however, that none of the techniques can reliably detect small polyps and MRC has a much lower sensitivity for the detection of small polyps compared with CTC.
Graser et al (2013) examined if MRC can be used to screen for colorectal adenomas and cancers. These investigators analyzed data from 286 asymptomatic adults (40 to 82 years old) who underwent 3 Tesla MRC and colonoscopic examinations on the same day. Fecal occult-blood testing (FOBT) was performed before bowel preparation. Colonoscopists were initially blinded to the findings on MRC and unblinded after withdrawal from the respective segments. Sensitivities for adenoma and per-patient sensitivities and specificities were calculated based on the unblinded results of colonoscopy. These researchers detected 133 adenomas and 2 cancers in 86 patients; 37 adenomas were greater than or equal to 6 mm, and 20 adenomas were advanced. Sensitivities of MRC and colonoscopy for adenomas greater than or equal to 6 mm were 78.4 % (95 % confidence interval [CI]: 61.8 to 90.2) and 97.3 % (95 % CI: 85.8 to 99.9); for advanced adenomas these values were 75 % (95 % CI: 50.9 to 91.3) and 100 % (95 % CI: 83.2 to 100.0), respectively. Magnetic resonance colonography identified 87.1 % (95 % CI: 70.2 to 96.4), colonoscopy 96.8 % (95 % CI: 83.3 to 99.9), and FOBT 10.0 % (95 % CI: 2.1 to 26.5) of individuals with adenomas greater than or equal to 6 mm and 83.8 % (95 % CI: 58.6 to 96.4), 100 % (95 % CI: 81.5 to 100.0), and 17.6 % (95 % CI: 3.8 to 43.4) of individuals with advanced neoplasia. Specificities of MRC, colonoscopy, and FOBT for individuals with adenomas greater than or equal to 6 mm were 95.3 % (95 % CI: 91.9 to 97.5), 96.9 % (95 % CI: 93.9 to 98.6), and 91.8 % (95 % CI: 87.6 to 94.9), respectively. The authors concluded that 3 Tesla MRC detects colorectal adenomas greater than or equal to 6 mm and advanced neoplasia with high levels of sensitivity and specificity. Although MRC detects colorectal neoplasia with lower levels of sensitivity than colonoscopy, it strongly outperforms one-time FOBT.

**Virtual Upper Endoscopy:**

Virtual upper endoscopy is a noninvasive procedure that reportedly uses 3D imaging and CT to capture detailed pictures of the inside surfaces of organs of the gastrointestinal (GI) tract and simulates conventional upper endoscopy images. Virtual
upper endoscopy is purported to diagnose the etiology of symptoms such as nausea, gastric reflux, abdominal pain and unexplained weight loss as well as identifying inflammation, ulcers, precancerous conditions and hernias. Individuals undergoing a virtual upper endoscopy do not need to have anesthesia administered. It is suggested that when the procedure is completed, the interpreting physician has the capability to modify the captured pictures by magnifying the images or altering the image angles.

Potential clinical applications of virtual upper GI endoscopy include the evaluation of early gastric carcinoma, advanced gastric carcinoma, leiomyoma, lymphoma, and benign ulcer. For dedicated imaging of the stomach, an oral contrast agent (e.g., water) is administered to opacify and distend the stomach and GI tract and an intravenous contrast agent is used (e.g., Omnipaque 350) for complete evaluation.

Virtual upper GI endoscopy has not been studied as extensively as virtual colonoscopy. A limited number of studies have been published and most of these studies have been conducted outside the United States involving small numbers of patients. Early reports of 3-D imaging of the stomach by spiral CT were limited to shaded-surface display (Ogata et al, 1999). However, the development of multidetector row scanners has improved the visualization of subtle tumors by allowing thinner collimation. The detection rate of gastric lesions using virtual GI endoscopy has been reported to be between 73 % to 96.7 % in early gastric cancer and between 90 % to 100 % in advanced gastric cancer (Kim et al, 2001; Bhandari et al, 2004). The overall accuracy, sensitivity, and specificity for endoscopic ultrasound and 3-D multi-detector row CT in the pre-operative determination of depth of invasion of gastric cancer (T stage) have been reported to be 87.5 %, 82.4 %, and 96 %; and 83.3 %, 69.1 %, and 94.4 %, respectively. The accuracy, sensitivity, and specificity of endoscopic ultrasound and 3-D multi-detector row CT for lymph node staging were reported to be 79.1 %, 57 %, and 89.5 %; and 75 %, 57.4 %, and 89.3 %, respectively (Bhandari et al, 2004).
In a prospective study, Kim et al (2005) evaluated the accuracy of multi-detector row CT gastrography for the pre-operative staging of gastric cancer, with pathologic and surgical results as the reference standard. A total of 106 patients with endoscopically proved gastric cancer underwent unenhanced and contrast material-enhanced multi-detector row CT gastrography, with effervescent granules used as oral contrast material. Gastric cancer was detected in 92 (87 %) of 106 patients with transverse CT imaging and in 104 (98 %) with volumetric CT imaging. The overall accuracy of the tumor staging was 77 % with transverse CT imaging and 84 % with volumetric CT imaging (p < 0.001). The overall accuracy for lymph node staging was 62 % with transverse CT imaging and 64 % with volumetric CT imaging (p = 0.057). For staging of metastases, there was no difference between transverse and volumetric CT imaging (86 % for both) (p > 0.99). The authors concluded that multi-detector row CT gastrography with multi-planar reformation and virtual endoscopy, compared with transverse CT imaging, can improve the accuracy of preoperative staging of gastric cancer. This difference was significant for tumor staging but not for the staging of lymph nodes and metastases.

A prospective study of the pre-operative assessment of gastric cancer tumors using 32-multi-detector row CT was carried out by Kikuchi et al (2006) on patients (n = 74) with adenocarcinoma of the stomach (T1 tumors, n = 38; T2 and T3 tumors, n = 36). In 35 (47 %) out of the 74 patients, the primary lesions could be detected on 2-D images obtained by CT. In these patients, virtual endoscopic images of these tumors could be created. A total of 27 advanced cancer tumors (75 %) were assessed based on 2-D CT images and 27 larger tumors (greater than 40 mm) (69 %) were assessed based on 2-D CT images. Significant differences were found with respect to depth of tumor (p < 0.0001) and tumor size (p < 0.0001) between tumors that could or could not be assessed on multi-detector CT. The authors concluded that future studies are required to fully explore the ability of multi-detector CT to assess tumor volume in advanced gastric cancer cases and to
In a prospective study, Mazzeo et al (2004) assessed the diagnostic capabilities of multi-detector CT in various esophageal pathologic conditions. A total of 33 patients underwent a multi-detector CT study after esophageal distention by means of effervescent powder administered after induction of pharmacologic esophageal hypotonia. All acquired images were post-processed with 2-D and 3-D software tools. The CT data were compared with the results of conventional radiology (n = 33), endoscopy (n = 28), endoscopy ultrasonography (n = 14), or surgery (n = 14). Follow-up ranged between 4 and 15 months. Final diagnoses were leiomyoma (n = 6), squamous cell carcinoma (n = 6), adenocarcinoma (n = 4), esophageal infiltration by thyroid cancer (n = 1), benign polyposis (n = 2), chronic esophagitis (n = 5), post-sclerotherapy stenosis (n = 1), and no abnormalities (n = 7). Pathologic wall thickening was observed in 25 of 33 cases (76%), with values ranging between 3.6 and 36 mm (mean, 9.6 mm). Spiral CT demonstrated 21 true-positive cases, and 7 true-negative cases. There were 4 false-negative cases and 1 false-positive case. Sensitivity was 84%, specificity was 87%, diagnostic accuracy was 85%, positive-predictive value was 95%, and negative-predictive value was 64%. The authors concluded that evaluation of the esophagus with multi-detector CT is a promising technique and easy to use, allowing panoramic exploration, virtual endoluminal visualization, accurate longitudinal and axial evaluations, and simultaneous evaluation of T (tumor penetration) and N (lymph node involvement) parameters.

The first virtual gastroscopy study in North American patients assessed the feasibility of performing virtual gastroscopy on 10 patients with no reported GI abnormalities. The authors stated that the anatomy of the stomach including the lumen, the cardia, the pylorus, gastric folds and the incisura angularis were well-visualized using 3-D spiral CT. It was not possible to visualize the esophagus by virtual endoscopy because of difficulties keeping the lumen patent long enough to provide.
accurate imaging. The authors concluded that further development is needed before virtual gastroscopy can be considered for clinical application (Ezzeddine et al, 2006).

Virtual gastroscopy is also being evaluated to assess the gastric mucosa in patients who have undergone laparoscopic Roux-en-Y gastric bypass. One small case series reported promising results (Alva et al, 2008).

Conventional upper GI endoscopy provides direct visualization of the mucosa, permits evaluation of color changes that may be indicative of pathology, and suspicious lesions can be biopsied and the tissue sample evaluated histologically. While virtual upper GI endoscopy using CT is a promising method for the detection and evaluation of upper GI lesions, randomized controlled studies comparing it to conventional upper GI endoscopy are needed to determine its clinical value.

**Appendix**

Virtual colonoscopies should only be performed at centers with an appropriate generation of multi-detector CT scan -- a minimum 4 detector CT scanner; collimation of 3 mm or less, overlapping sections at an interval that is 2/3 or less of the collimation, and scan times should be 30 seconds or less in order to minimize respiratory motion (Taskar et al, 1995; Scherer et al, 2008). In addition, scans should be read by trained readers by virtue of having read least 30 CT scans (Halligan et al, 2005; ACR, 2006).

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<thead>
<tr>
<th>CPT Codes / HCPCS Codes / ICD-10 Codes</th>
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<tr>
<td><strong>Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by &quot;+&quot;:</strong></td>
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<tr>
<td><strong>Virtual Colonoscopy:</strong></td>
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<td><strong>Diagnostic:</strong></td>
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<td>CPT codes covered if selection criteria are met:</td>
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<td>74261</td>
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**Other HCPCS codes related to the CPB:**

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<th>Code</th>
<th>Description</th>
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<td>G0105</td>
<td>Colorectal cancer screening; colonoscopy on individual at high risk</td>
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<td>G0106</td>
<td>Colorectal cancer screening; alternative to G0104, screening sigmoidoscopy, barium enema</td>
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<tr>
<td>G0120</td>
<td>Colorectal cancer screening; alternative to G0105, screening colonoscopy, barium enema</td>
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<tr>
<td>G0121</td>
<td>Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk</td>
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<tr>
<td>G0122</td>
<td>Colorectal cancer screening; barium enema</td>
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**ICD-10 codes covered if selection criteria are met:**

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<th>Code</th>
<th>Description</th>
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<td>Intestinal adhesions [bands] with obstruction (postprocedural) (postinfection)</td>
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<td>K56.60-K56.69</td>
<td>Other and unspecified intestinal obstruction</td>
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<td>K57.00-K57.93</td>
<td>Diverticular disease of intestine</td>
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<tr>
<td>T41.0X5+, T41.1x5+, T41.205+, T41.295+, T41.3X5+, T41.45x+, T88.59x+</td>
<td>Adverse effect of anesthetics</td>
</tr>
<tr>
<td>Z79.01</td>
<td>Long term (current) use of anticoagulants [that cannot be interrupted]</td>
</tr>
<tr>
<td>Z88.4</td>
<td>Allergy status to anesthetic agent status</td>
</tr>
</tbody>
</table>

**ICD-10 codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Z12.11</td>
<td>Encounter for screening for malignant neoplasm of colon</td>
</tr>
</tbody>
</table>

**Screening:**

**CPT codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>74263</td>
<td>CT colonography, screening, including image postprocessing</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>T41.0X5+</td>
<td>Adverse effect of anesthetics</td>
</tr>
<tr>
<td>T41.1X5+</td>
<td>Adverse effect of anesthetics</td>
</tr>
<tr>
<td>T41.205+</td>
<td>Adverse effect of anesthetics</td>
</tr>
<tr>
<td>T41.295+</td>
<td>Adverse effect of anesthetics</td>
</tr>
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</tr>
<tr>
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</tr>
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</tbody>
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<tbody>
<tr>
<td>Z79.01</td>
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</tr>
<tr>
<td>Z88.4</td>
<td>Allergy status to anesthetic agent status</td>
</tr>
</tbody>
</table>

**Virtual Upper Gastrointestinal (GI) Endoscopy:**

There is no specific code for virtual upper gastrointestinal (GI) endoscopy.

**ICD-10 codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C15.3 - C17.0</td>
<td>Malignant neoplasm of esophagus, stomach, and duodenum</td>
</tr>
<tr>
<td>C78.4</td>
<td>Secondary malignant neoplasm of small intestine</td>
</tr>
<tr>
<td>D00.1 - D01.0</td>
<td>Carcinoma in situ of esophagus, stomach and colon</td>
</tr>
<tr>
<td>D01.49</td>
<td>Carcinoma in situ of other parts of intestine [duodenum]</td>
</tr>
<tr>
<td>D13.0 - D13.39</td>
<td>Benign neoplasm of esophagus, stomach, duodenum, jejunum, and ileum</td>
</tr>
<tr>
<td>D37.1 - D37.5</td>
<td>Neoplasm of uncertain behavior of stomach, intestines, and rectum</td>
</tr>
<tr>
<td>D37.8</td>
<td>Neoplasm of uncertain behavior of other digestive organs [esophagus]</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>D49.0</td>
<td>Neoplasm of unspecified nature of digestive system</td>
</tr>
<tr>
<td>K20.0 -</td>
<td>Diseases of esophagus, stomach, and duodenum</td>
</tr>
<tr>
<td>K31.9</td>
<td></td>
</tr>
<tr>
<td>K50.00 -</td>
<td>Noninfectious enteritis and colitis, and other</td>
</tr>
<tr>
<td>K68.9</td>
<td>diseases of intestines and peritoneum</td>
</tr>
<tr>
<td>Z12.13</td>
<td>Encounter for screening for malignant neoplasm of small intestine</td>
</tr>
</tbody>
</table>

**MRI Colonography:**

No specific code

**ICD-10 codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>K57.20 -</td>
<td>Diverticulitis of large intestine [colon]</td>
</tr>
<tr>
<td>K57.33</td>
<td></td>
</tr>
</tbody>
</table>

**The above policy is based on the following references:**

**Virtual Colonoscopy**


31. Mundy L, Merlin T. Virtual colonoscopy: Non-invasive CT scanning technique for screening patients with possible


39. Winawer SJ. Screening of colorectal cancer: Progress and problems. Recent Results Cancer Res. 2005;166:231-244.


41. Danish Centre for Evaluation and Health Technology Assessment (DACEHTA). Colon examination with CT
colonography. A health technology assessment.


50. American College of Radiology (ACR). ACR guideline for the performance of computed tomography (CT) colonography in adults. ACR Practice Guidelines. Reston,
58. Broadstock M. Computed tomographic (CT) colonography for the detection of colorectal cancer; a Technical Brief. NZHTA Technical Brief Series. Christchurch, New Zealand: New Zealand Health Technology Assessment (NZHTA); 2007;6(6).


83. Tessier-Vetzel D, Potier P. Virtual colonoscopy. Meta-analysis of diagnostic accuracy. Indications and conditions of use. Short Text of the Technological Evaluation Report. Saint-Denis La Plaine, France: Diagnostic and Therapeutic Procedures Assessment Department, French National Authority for Health/ Haute Autorite de Sante (HAS); 2010.
87. Kim DH, Pooler BD, Weiss JM, Pickhardt PJ. Five year


100. Rex DK. CT colonography: Expect the best, get the worst. JWatch Gastroenterol. 2012; March 2.


Amendment to
Aetna Clinical Policy Bulletin Number:0535
Virtual Gastrointestinal Endoscopy

There are no amendments for Medicaid.