Clinical Policy Title: Virtual colonoscopy (CT colonography)

Clinical Policy Number: 08.01.07

Effective Date: January 1, 2017
Initial Review Date: October 19, 2016
Most Recent Review Date: October 19, 2016
Next Review Date: October 2017

Related policies:
CP# 08.01.02 Capsule endoscopy for visualizing the gastrointestinal tract
CP# 02.01.08 Familial polyposis gene testing
CP# 02.10.10 Colaris® testing for Lynch syndrome
CP# 08.01.04 Fecal DNA for colorectal cancer detection

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of virtual colonoscopy, also known as CT colonography (CTC), to be clinically proven and, therefore, medically necessary when any of the following criteria are met:

- A conventional colonoscopy is contraindicated due to presence of lower gastrointestinal bleeding, colonic stenosis, colonic obstructions, diverticulosis, or diverticulitis.
- The patient had complications with a prior colonoscopy.
- The patient is taking anti-coagulation medicine, or is otherwise at risk for a bleeding disorder.
- The patient has an elevated risk from sedation during a colonoscopy, from conditions such as Chronic Obstructive Pulmonary Disease, hypotension from sedation, a recent acute myocardial infarction, recent colonic surgery, or a previous adverse reaction to anesthesia.
- The patient has obstructive colorectal cancer.
If any of the above criteria is met, CTC can be performed every five years from age 50 to 75 for patients not at risk, and younger than 50 for patients with documented risk factors including relatives with colorectal cancer at an early age and genetic diagnosis of hereditary nonpolyposis colorectal cancer.

CTC is considered investigational or experimental, for patients with inflammatory bowel disease, including Crohn’s, ulcerative colitis, or diverticulitis.

**Limitations:**

No other indications for virtual colonoscopy are indicated.

Note: The following CPT/HCPCS codes are not listed in the Pennsylvania Medicaid fee schedule:

74261 - Computed tomographic (CT) colonography, diagnostic, including imaging postprocessing; without contrast material

74262 - Computed tomographic (CT) colonography, diagnostic, including imaging postprocessing; with contrast material(s) including non-contrast images, if performed

74263 - Computed tomographic (CT) colonography, screening, including imaging postprocessing

**Alternative covered services:**

Conventional colonoscopy.
Double contrast barium enema.
Fecal immunochemical test.
Fecal occult blood test (FOBt).
Flexible sigmoidoscopy.

**Background**

Colonoscopy has long been the most recommended procedure for colorectal cancer screening. Along with the ability to detect malignancies, colonoscopy can detect pre-cancerous polyps, which can often be removed during the same procedure. Greater use of the test and its ability to detect and remove polyps before they become cancerous constitute a major factor in the 43% and 46% declines in age-adjusted U.S. colorectal cancer incidence and mortality from 1985 to 2013 (Howlader, 2016).

Colonoscopy is recommended for men and women every 10 years beginning at age 50 for persons not at risk of colorectal cancer. Persons with a documented risk factor can be screened earlier than age 50. Colonoscopy is not recommended for persons age 76-85 in the absence of a consideration that supports screening; and is not recommended for persons over age 85 under any circumstances (USPSTF, 2015).
The recommendation to perform a colonoscopy based on the observation that polyps often take 10-15 years to develop into cancer. However, in 2012, 35% of American adults were not up to date with colon cancer screening (CDC, 2013). Alternative means of cancer screening to colonoscopy include flexible sigmoidoscopy, double-contrast barium enema, and virtual colonoscopy – also known as CT colonography (CTC) – every five years; stool DNA test - every three years; and annual Fecal Occult Blood test (FOBt) and fecal immunochemical test (ACS, 2016).

CTC has several advantages over colonoscopy. It is more comfortable for the patient, does not require sedation (so there is no anesthetic risk like in colonoscopy), and does not disqualify any patients for certain medical reasons, as colonoscopy sometimes does. CTC also requires less time to complete and return to normal activities than colonoscopy, it carries no risk of surgical complications (4 and 8 per 10,000 colonoscopy patients, respectively, experience perforations and major bleeds (Lin, 2016)) and lacks the patient unwillingness factor that some have with colonoscopy.

The major disadvantage of CTC compared to colonoscopy is its inability to detect as many small polyps, and thus CTC should be performed every five years, as opposed to every ten for colonoscopy. Providers of CTC are unable to take tissue samples or remove polyps simultaneously as they can with colonoscopy. CTC also exposes the patient to radiation from computerized tomography, although radiation-free medical resonance can be used instead of a CT scan.

While a dry, clean colon is needed to maximize CTC effectiveness, there is no consensus for optimal bowel preparation. Some CTC procedures are performed using minimum-laxative preparation that employs a fecal tagging technique, such as barium or an iodinated contrast agent (Nagata, 2009).

**Searches**

Keystone First searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on September 6, 2016. Search terms were: “virtual colonoscopy” and “CT colonography.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
• **Guidelines based on systematic reviews.**
• **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**
The 2008 guideline jointly issued by the American Cancer Society, the US Multi Society Task Force on Colorectal Cancer, and the American College of Radiology on detecting colorectal cancer and adenomatous polyps supported use of CTC. However, since CTC does not always detect small polyps, the panel recommended CTC every five years, vs. 10 years for conventional colonoscopy (Levin, 2008). Guidelines from the American College of Gastroenterologists (Rex, 2009) and the National Comprehensive Cancer Network (NCCN, 2015) concurred with the five-year cycle. The U.S. Preventive Services Task Force (USPSTF) agreed that while CTC is effective for detecting colorectal cancer and large polyps, no such statement can be made for smaller polyps (Whitlock, 2008).

The NCCN added “there is not a consensus on the use of CT colonography as a primary screening modality” for colorectal cancer (NCCN, 2015). The American College of Radiology (ACR) 2014 Practice Parameter for the Performance of Computed Tomography (CT) Colonography in Adults lists particular indications when CTC should be performed (ACR, 2014).

A study of 2112 asymptomatic subjects who underwent colonoscopy and colonography on the same day found that 90% of polyps at least 10 mm in diameter detected by colonoscopy were also detected by colonography, while 65% of polyps 6 mm in diameter were detected by both tests (Johnson, 2008). These results helped serve as a basis for the ACR recommendation that individuals with one or more polyps at least 10 mm in diameter (or three or more polyps at least 6 mm) should be referred for colonoscopy (ACR, 2014). In Europe, the standard for referring patients for endoscopic polypectomy is at least one polyp at least 6 mm detected at CTC (Laghi, 2015). There is an absence of consensus governing removal of any polyp less than 6 mm (Levin, 2008).

The U.S. Centers for Medicare and Medicaid Services made a decision in 2009 not to expand Medicare coverage to include CTC as a screening mechanism for colorectal cancer. CMS, which provides Medicare coverage for colonoscopy every 10 years (every two years for high-risk individuals); FOBT every year; and flexible sigmoidoscopy and barium enema every four years, declared there was a lack of evidence to support efficacy of CTC. During a 30 day comment period just prior to the decision, 16 comments supported the decision not to expand Medicare coverage, compared to 337 that opposed it, including numerous medical specialty societies (CMS, 2009).

An early meta-analysis of 24 studies and 2610 patients found that CTC detected 96% of cancers, 93% of large polyps, and 86% of large and medium polyps combined, but much lower rates for small polyps (Halligan, 2005). The 96% detection rate was also documented in a more recent meta-analysis of 49 studies, with the figure rising to 100% when cathartic and tagging agents were combined in bowel preparation (Pickhardt, 2011). No differences in sensitivity of polyp detection were observed between 2-dimensional and 3-dimensional CTC (Rosman, 2007).
Another early meta-analysis (33 studies, n=6393) of CTC found rising sensitivity as polyp size increased (48% <6 mm, 70% 6-9 mm, 85% >9 mm), but a consistent specificity, i.e. 92%, 93%, 97% (Mulhall, 2005). The most recent U.S. Preventive Services Task Force review found that CTC detected adenomas greater than 6 mm at the same rate (sensitivity 73% to 98%) as those undergoing colonoscopy, based on seven studies (Lin, 2016).

Colonoscopy is uniformly regarded as the most efficacious means of screening for polyps and cancers, although it still does not detect all of these growths. One study of 1731 polyps in persons undergoing CTC and later colonoscopy found 66 of these were false positives for CTC, and 78 were potential false positives for colonoscopy, an insignificant difference (Pooler, 2016). CTC reliability was also tested by comparing initial and follow up tests (4.5 to 10.7 years difference) for 1429 patients who were initially negative for polyps at least 6 mm. The second test found reduced proportions of patients with lesions over 6 mm (14.3% to 12.1%), and large polyps (5.2% to 3.8%). Study authors concluded that CTC every 5 to 10 years is an acceptable means of colorectal cancer screening (Pickhardt, 2016).

The ability of CTC to detect tumors outside the bowel wall has been documented. A recent review of 13 studies showed this type of colon carcinoma was detected by CTC in 90% of T3-T4 tumors. Sensitivity of detection of tumor invasion depth >5 mm (77%) and nodal involvement (71%) were both relatively high (Nerad, 2016).

However, a June 2016 USPSTF recommendation statement, while recommending CTC every five years as one option for colorectal cancer screening, also questioned the efficacy of this procedure as extracolonic findings are identified in 40 to 70% of screening exams, of which only 3% require treatment. The resulting diagnostic testing and (sometimes) treatment of these findings (“of no importance”) should be considered in any assessment of effectiveness (Bibbins-Domingo K, 2016).

CTC has also been studied as a test in patients who have a positive Fecal Occult Blood Test (FOBt), often conducted when colonoscopy is incomplete or infeasible. A meta-analysis of five studies consisting of 622 FOBt-positive subjects found an 88.8% sensitivity rate for CTC in detecting colorectal cancer or adenomas >6 mm (Plumb, 2014).

CTC detection of polyps using minimum-laxative bowel preparation has been compared to full-laxative preparation. One study compared 50 patients given minimal preparation (45 mL sodium diatrizoate in the three days before, plus 10 mL of sodium picosulfate the night before CTC) with a similar number of patients given complete laxative preparation. The detection of polyps at least 6 mm was 88% in the minimum preparation group, vs. 97% for the maximum group; but specificity was relatively low, at 68%, vs. 92% for the maximum group (Nagata, 2009).
Research has also been conducted on the ability of magnetic resonance (MR) to detect polyps during virtual colonoscopy. One systematic review of 13 studies (n=1285) compared MR with conventional colonoscopy; MR detected 100% of cancers and 88% of polyps over 10 mm, with 99% specificity (Zitja, 2010). In a group of 315 patients with no bowel cleansing given MR colonography, 83% of polyps over 5 mm were detected, compared to just 10% of lesions under 5 mm (Kuehle, 2007).

A cost-effectiveness analysis concluded that CTC conducted every five years was equally effective to sigmoidoscopy every five years plus annual FOBT, but less effective than colonoscopy performed every ten years, assuming a $488 cost for CTC and a $500 cost for colonoscopy, which is the CMS payment for the procedure without polypectomy (Zauber, 2009). A meta-analysis of 16 studies found CTC to be more cost effective than no screening, flexible sigmoidoscopy, and FOBT, while comparisons between CTC and colonoscopy were mixed (Hanly, 2012). Medicare costs are 29% less for CTC than for colonoscopy (Pyenson, 2015). A systematic review of seven studies (n=765) found that CT colonography would save 20.8 million euros a year in the United Kingdom if it was used as a single substitute for colonoscopy (Porte, 2016).

Policy updates:

None.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bibbins-Domingo (2016)</td>
<td>Key points:</td>
</tr>
<tr>
<td>USPSTF updated colon cancer screening recommendations</td>
<td>• CTC every five years over age 50 is recommended as one option for screening.</td>
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<tr>
<td></td>
<td>• Knowledge of CTC effectiveness is limited to studies of test characteristics.</td>
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<tr>
<td></td>
<td>• CTC can result in unneeded diagnostic/therapeutic services, as extracolonic findings occur in 40-70% of exams, with only 3% requiring treatment.</td>
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<td>“Evidence to bound the potential harms of this technology is still lacking, particularly in regard to incidental findings”</td>
</tr>
<tr>
<td>Nerad (2016)</td>
<td>Key points:</td>
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<tr>
<td>CTC detection of tumors beyond the bowel wall</td>
<td>• 13 studies of CTC in patients with colon carcinoma.</td>
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<td>• 90% sensitivity (T3-T4 tumors beyond the bowel wall detected).</td>
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<td>• 77% detection of tumor invasion depth &gt;5 mm.</td>
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<td>• 71% detection of nodal involvement.</td>
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<tr>
<td>Pickhardt (2011)</td>
<td>Key points:</td>
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<tr>
<td>Sensitivity study of CTC for colorectal cancer</td>
<td>• Meta-analysis, 49 studies (n=11,151), 414 colorectal cancers.</td>
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<tr>
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<td>• CTC sensitivity was 96.1% (398 of 414).</td>
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<td>• No cancers were missed by CTC when cathartic and tagging agents were combined in the bowel preparation.</td>
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<tr>
<td>Halligan (2005)</td>
<td>Key points:</td>
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<tr>
<td>Sensitivity study of CTC for colorectal cancer and polyps</td>
<td>• Meta-analysis (24 studies, 2610 subjects).</td>
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<tr>
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<td>• 96% of 150 cancers and 93% of 206 large polyps detected.</td>
</tr>
<tr>
<td></td>
<td>• Detection of small polyps much lower.</td>
</tr>
</tbody>
</table>
Citation | Content, Methods, Recommendations
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Mulhall (2005) | Sensitivity and specificity of CTC by size of polyp

Key points:
- Meta-analysis (33 studies, 6393 subjects).
- CTC detected rising proportion of polyps, according to size (48% <6 mm, 70% 6-9 mm, 85% > 9 mm).
- Specificity consistent across polyp sizes (92%, 93%, 97%).

**Glossary**

**Colonoscopy** — A test for colorectal cancer and pre-cancerous polyps using a flexible tube 48-72 inches in length. During the procedure, tissue samples and abnormal growths may be removed.

**Colorectal cancer** — Malignancies of the colon and rectum, which can be detected using multiple techniques.

**CT colonography** — See virtual colonoscopy.

**Fecal occult blood test** — A screening procedure for colorectal cancer involving the placement of small stool samples on a card or cloth.

**Flexible sigmoidoscopy** — An examination of the rectum and lower large intestine using a long, flexible tubular instrument.

**Virtual colonoscopy** — A screening procedure for colorectal cancer and pre-cancerous polyps, that uses imaging techniques of the interior lining of the large intestine and rectum (also CT colonography).

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


Pickhardt PJ, Pooler BD, Mbah I, Weiss JM, Kim DH. Colorectal findings at repeat CT colonography screening after initial CT colonography screening negative for polyps larger than 5 mm. Radiology. 2016 Aug 22:160582 [E pub ahead of print].


Clinical trials:

Searched clinicaltrials.gov on September 8, 2016 using terms “CT colonography” and “virtual colonoscopy.” | Open Studies. 14 studies found, four (4) relevant.
Fox Chase Cancer Center. Comparative effectiveness of CTC and OC. ClinicalTrials.gov website. 
https://clinicaltrials.gov/ct2/show/NCT02143115?term=%22CT+colonography%22&recr=Open&rank=10

Kings College, London. CT colonography as the initial diagnostic imaging tool for patients with suspected colorectal cancer (CTCS). ClinicalTrials.gov website. 

University College London Hospitals. Performance and evaluation for CT colonography screening (PERFECTS). ClinicalTrials.gov website. 

https://clinicaltrials.gov/ct2/show/NCT01181739?term=%22CT+colonography%22&recr=Open&rank=11

CMS National Coverage Determinations (NCDs):
No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):


L34055 Virtual Colonoscopy (CT Colonography). CGS Administrators LLC (Kentucky and Ohio). 
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34055&ver=3&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&K
erageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=%22CT+colonography%22&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAACA AAAAAA%3d%3d&. Accessed September 8, 2016.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>74261</td>
<td>Computed tomographic (CT) colonography, diagnostic, including imaging postprocessing; without contrast material</td>
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<thead>
<tr>
<th>ICD-10 Code</th>
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<tr>
<td>C18.0-C18.9</td>
<td>Malignant neoplasm of colon</td>
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<tr>
<td>C19</td>
<td>Malignant neoplasm of rectosigmoid junction</td>
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<tr>
<td>D68.61-D68.9</td>
<td>Coagulation defects</td>
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<td>K56.60-K56.69</td>
<td>Intestinal obstruction</td>
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<td>Z79.01</td>
<td>Long term (current) use of anticoagulants</td>
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<td>Z92.89</td>
<td>Personal history of complication of medical care</td>
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<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
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