Clinical Policy Title: Virtual colonoscopy (CT colonography)

Clinical Policy Number: CCP.1269

Effective Date: January 1, 2017
Initial Review Date: October 19, 2016
Most Recent Review Date: October 2, 2018
Next Review Date: October 2019

Related policies:
CCP.1055 Capsule endoscopy
CCP.1050 Familial polyposis gene testing
CCP.1097 COLARIS® testing for Lynch syndrome
CCP.1319 Colorectal cancer screening

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’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 Prestige Health Choice 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. Prestige Health Choice’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. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of virtual colonoscopy, also known as CT colonography, 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, CT colonography can be performed every five years from age 50 to 75 for patients not at risk, and starting at age 40 or 10 years before the diagnosis of the youngest affected relative (whichever is younger) for patients with documented risk factors including relatives with colorectal cancer under age 60 and genetic diagnosis of hereditary nonpolyposis colorectal cancer (Rex, 2017; Levin, 2008).

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

**Limitations:**

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

No other indications for virtual colonoscopy are indicated.

**Alternative covered services:**

• Conventional colonoscopy.
• Double contrast barium enema.
• Fecal immunochemical test.
• Fecal occult blood test.
• 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 47 and 48 percent declines in age-adjusted U.S. colorectal cancer incidence and mortality from 1985 to 2015 (Noone, 2018).

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 (U.S. Preventive Services Task Force, 2015).
The recommendation to perform a colonoscopy is based on the observation that polyps often take 10-15 years to develop into cancer. However, in 2012, 35 percent of American adults were not up to date with colon cancer screening (Centers for Disease Control, 2013). Alternative means of cancer screening to colonoscopy include flexible sigmoidoscopy, double-contrast barium enema, and virtual colonoscopy – also known as CT colonography – every five years, stool DNA test - every three years, and annual Fecal Occult Blood test and fecal immunochemical test (American Cancer Society, 2016).

CT colonography 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. CT colonography also requires less time to complete and return to normal activities than colonoscopy, it carries no risk of surgical complications (4 - 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 CT colonography compared to colonoscopy is its inability to detect as many small polyps, and thus CT colonography should be performed every five years, as opposed to every ten for colonoscopy. Providers of CT colonography are unable to take tissue samples or remove polyps simultaneously as they can with colonoscopy CT colonography 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 CT colonography effectiveness, there is no consensus for optimal bowel preparation. Some CT colonography procedures are performed using minimum-laxative preparation that employs a fecal tagging technique, such as barium or an iodinated contrast agent (Nagata, 2009).

**Searches**

Prestige Health Choice 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.

We conducted searches on August 14, 2018. 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 CT colonography. However, since CT colonography does not always detect small polyps, the panel recommended CT colonography every five years, versus 10 years for conventional colonoscopy (Levin, 2008). The most recent guideline, from the U.S. Multi Society Task Force on Colorectal Cancer, upheld the recommendation for CT colonography every five years (Rex, 2017).

The latest guidelines from the American Cancer Society concurred with the five-year recommendation (Wolf, 2018). The U.S. Preventive Services Task Force agreed that while CT colonography is effective for detecting colorectal cancer and large polyps, no such statement can be made for smaller polyps (Whitlock, 2008).

The National Comprehensive Cancer Network declared that CT colonography is useful for the detection of large polyps. It recommends the test every five years, and recommends rescreening in three years (or colonoscopy) if 1 - 2 polyps of 6 - 9 mm are detected (Provenzale, 2018). The American College of Radiology 2014 Practice Parameter for the Performance of Computed Tomography (CT) Colonography in Adults lists particular indications when CT colonography should be performed (American College of Radiology, 2014).

However, a 2016 U.S. Preventive Services Task Force recommendation statement, while recommending CT colonography every five years as one option for colorectal cancer screening, also questioned the efficacy of this procedure as extra colonic findings are identified in 40 to 70 percent of screening exams, of which only three percent require treatment (U.S. Preventive Services Task Force, 2016).

The U.S. Centers for Medicare and Medicaid Services made a decision in 2009 not to expand Medicare coverage to include CT colonography as a screening mechanism for colorectal cancer. The Centers, which provides Medicare coverage for colonoscopy every 10 years (every two years for high-risk individuals); Fecal Occult Blood test every year; and flexible sigmoidoscopy and barium enema every four years, declared there was a lack of evidence to support efficacy of CT colonography. 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 (Center for Medicare and Medicaid Services, 2009).
A study of 2112 asymptomatic subjects who underwent colonoscopy and colonography on the same day found that 90 percent of polyps at least 10 mm in diameter detected by colonoscopy were also detected by colonography, while 65 percent of polyps 6 mm in diameter were detected by both tests (Johnson, 2008). These results helped serve as a basis for the American College of Radiology 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 (American College of Radiology, 2014). In Europe, the standard for referring patients for endoscopic polypectomy is at least one polyp at least 6 mm detected at CT colonography (Laghi, 2015). There is an absence of consensus governing removal of any polyp less than 6 mm (Levin, 2008).

A systematic review/meta-analysis compared prevalence of colorectal cancer between those who did and did not undergo virtual colonoscopy. Studies of those who did undergo the test (21 studies, n=1673) had a higher prevalence than those in studies of those who did not undergo the test (27 studies, n=111,873), a difference of 5.7 versus 3.9 percent, significant at $P = .004$ (Flor, 2018).

An early meta-analysis of 24 studies and 2610 patients found that CT colonography detected 96 percent of cancers, 93 percent of large polyps, and 86 percent of large and medium polyps combined, but much lower rates for small polyps (Halligan, 2005). The 96 percent detection rate was also documented in a more recent meta-analysis of 49 studies, with the figure rising to 100 percent 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 CT colonography (Rosman, 2007).

Another early meta-analysis (33 studies, n=6393) of CT colonography found rising sensitivity as polyp size increased (48 percent <6 mm, 70 percent 6-9 mm, 85 percent >9 mm), but a consistent specificity, i.e. 92, 93, and 97 percent (Mulhall, 2005). The most recent U.S. Preventive Services Task Force review found that CT colonography detected adenomas greater than 6 mm at the same rate (sensitivity 73 to 98 percent) as those undergoing colonoscopy, based on seven studies (Lin, 2016). The most recent systematic review of 19 articles (n=11,540) determined sensitivity and specificity of polyps at least 6 mm to be 80 and 89 percent; the same figures were 87 and 97 percent for polyps at least 10 mm (Yu, 2017).

A systematic review/meta-analysis of colorectal cancer prevalence three years after CT colonography included 12 studies from 2002-2015 (n=19,867). CT colonography detected 643 colorectal cancers, while 29 additional (post-imaging) colorectal cancers were detected, which equaled 1.61 post-imaging colorectal cancers per 1000 CT colonographies (Obaro, 2018).

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 CT colonography and later colonoscopy found 66 of these were false positives for CT colonography, and 78 were potential false positives for colonoscopy, an insignificant difference (Pooler, 2016).
CT colonography 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 percent), and large polyps (5.2 to 3.8 percent). Study authors concluded that CT colonography every 5 - 10 years is an acceptable means of colorectal cancer screening (Pickhardt, 2017).

The ability of CT colonography 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 CT colonography in 90 percent of T3-T4 tumors. Sensitivity of detection of tumor invasion depth >5 mm (77 percent) and nodal involvement (71 percent) were both relatively high (Nerad, 2016).

The resulting diagnostic testing and (sometimes) treatment of extracolonic findings should be considered in any assessment of effectiveness (Bibbins-Domingo K, 2016). A systematic review/meta-analysis of 44 studies (n=49,676) patients from 1994 to 2017) identified 4.9 percent of CT colonographies with potentially important extracolonic findings, which declined by nine percent per year since 2006 (Pickhardt, 2018).

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

CT colonography 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 CT colonography) with a similar number of patients given complete laxative preparation. The detection of polyps at least 6 mm was 88 percent in the minimum preparation group, versus 97 percent for the maximum group; but specificity was relatively low, at 68 versus 92 percent for the maximum group (Nagata, 2009).

Research has also been conducted on the ability of magnetic resonance to detect polyps during virtual colonoscopy. One systematic review of 13 studies (n=1285) compared magnetic resonance with conventional colonoscopy; magnetic resonance detected 100 percent of cancers and 88 percent of polyps over 10 mm, with 99 percent specificity (Zitja, 2010). In a group of 315 patients with no bowel cleansing given magnetic resonance colonography, 83 percent of polyps over 5 mm were detected, compared to just 10 percent of lesions under 5 mm (Kuehle, 2007).

A cost-effectiveness analysis concluded that CT colonography conducted every five years was equally effective to sigmoidoscopy every five years plus annual Fecal Occult Blood test, but less effective than colonoscopy performed every ten years, assuming a $488 cost for CT colonography 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 CT colonography to be more cost effective than no screening, flexible
sigmoidoscopy, and Fecal Occult Blood test, while comparisons between CT colonography and colonoscopy were mixed (Hanly, 2012). Medicare costs are 29 percent less for CT colonography 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, 2017).

Policy updates:

A total of three guidelines/other and three peer-reviewed references were added to, and three guidelines/other removed from this policy in August 2018.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pickhardt (2017)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Repeat CT colonography</td>
<td>• Single institution study based on 5640 subjects screened with CT colonography before 2010; no polyps at least 6 mm were detected.</td>
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<tr>
<td>after initial screening</td>
<td>• 1429 of these subjects returned for repeat CT colonography, a mean of 5.7 years later.</td>
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<tr>
<td>fails to detect large</td>
<td>• Rate of positive detection of large polyps during repeat CT colonography was 3.8 percent (%), significantly lower than 5.2% during original screening (P &lt; .02).</td>
</tr>
<tr>
<td>polyps</td>
<td>• No differences in detection of advanced neoplasia and colorectal cancer between initial and repeat tests.</td>
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<td></td>
<td>• More advanced right sided lesions detected during follow up.</td>
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<tr>
<td></td>
<td>• Findings uphold 5-10 year cycle for repeat CT colonography testing.</td>
</tr>
<tr>
<td>Bibbins-Domingo (2016)</td>
<td>Key points:</td>
</tr>
<tr>
<td>U.S. Preventive Services</td>
<td>• CT colonography every five years over age 50 is recommended as one option for screening.</td>
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<tr>
<td>Task Force updated colon</td>
<td>• Knowledge of CT colonography effectiveness is limited to studies of test characteristics.</td>
</tr>
<tr>
<td>cancer screening</td>
<td>• CT colonography 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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<tr>
<td>recommendations</td>
<td>• “Evidence to bound the potential harms of this technology is still lacking, particularly in regard to incidental findings.”</td>
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<tr>
<td>Nerad (2016)</td>
<td>Key points:</td>
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<tr>
<td>CT colonography detection</td>
<td>• 13 studies of CT colonography in patients with colon carcinoma.</td>
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<tr>
<td>of tumors beyond the bowel</td>
<td>• 90% sensitivity (T3-T4 tumors beyond the bowel wall detected).</td>
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<td>wall</td>
<td>• 77% detection of tumor invasion depth &gt;5 mm.</td>
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<td></td>
<td>• 71% detection of nodal involvement.</td>
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<tr>
<td>Pickhardt (2011)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Sensitivity study of CT</td>
<td>• Meta-analysis, 49 studies (n=11,151), 414 colorectal cancers.</td>
</tr>
<tr>
<td>colonography for colorectal</td>
<td>• CT colonography sensitivity was 96.1% (398 of 414).</td>
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<td>cancer</td>
<td>• No cancers were missed by CT colonography 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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<td></td>
<td>• Meta-analysis (24 studies, 2610 subjects).</td>
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</tbody>
</table>
Sensitivity study of CT colonography for colorectal cancer and polyps

- 96% of 150 cancers and 93% of 206 large polyps detected.
- Detection of small polyps much lower.

Mulhall (2005)

Sensitivity and specificity of CT colonography by size of polyp

Key points:

- Meta-analysis (33 studies, 6393 subjects).
- CT colonography 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%).

References

Professional society guidelines/other:


Laghi A, Neri E, Regge D. Editorial on the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastrointestinal and Abdominal Radiology (ESGAR) guideline on clinical indications


**Peer-reviewed references:**


**Centers for Medicare & Medicaid Services National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.

**Local Coverage Determinations:**


**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>
</tr>
<tr>
<td>74262</td>
<td>Computed tomographic (CT) colonography, diagnostic, including imaging postprocessing; with contrast material(s) including non-contrast images, if performed</td>
</tr>
<tr>
<td>74263</td>
<td>Computed tomographic (CT) colonography, screening, including image postprocessing</td>
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<td>ICD-10 Code</td>
<td>Description</td>
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<tr>
<td>C18.0-C18.9</td>
<td>Malignant neoplasm of colon</td>
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<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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<tr>
<td>K56.600-K56.699</td>
<td>Intestinal obstruction</td>
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<td>K57.00-K57.93</td>
<td>Diverticular disease of intestine</td>
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<td>T41.205A-T41.205S</td>
<td>Adverse effect of unspecified general anesthetics</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>
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