COMPUTED TOMOGRAPHIC COLONOGRAPHY

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INSTRUCTIONS FOR USE
This protocol provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee’s document (e.g., Certificate of Coverage (COC) or Evidence of Coverage (EOC)) may differ greatly. In the event of a conflict, the enrollee’s specific benefit document supersedes this protocol. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Protocol. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Protocols, Policies and Guidelines as necessary. This protocol is provided for informational purposes. It does not constitute medical advice. This policy does not govern Medicare Group Retiree members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

COMMERCIAL, MEDICARE AND MEDICAID COVERAGE RATIONALE

Computed tomographic colonography is medically necessary for any of the following:

- As a diagnostic tool for symptomatic patients who are unable to undergo a complete colonoscopy (such as individuals with an obstructive tumor and others who may be unable to tolerate the procedure)
- Patients on anticoagulation therapy who cannot safely discontinue treatment and would be at risk of bleeding from a more invasive procedure

Computed tomographic colonography is not medically necessary as a diagnostic tool for the following:

- Crohn’s disease
- Diverticulitis
There is insufficient evidence to support the use of computed tomographic colonography in the diagnosis of Crohn's disease and diverticulitis. Widespread use of computed tomographic colonography in Crohn's disease is currently not supported due to the potential of false-negative findings. Computed tomographic colonography was compared to conventional colonoscopy in patients with symptomatic diverticular disease. While use of CTC for diverticulitis is more promising, there was only one study available for review involving 50 patients. Further studies are needed to determine the safety and efficacy of computed tomographic colonography as a follow-up diagnostic tool for Crohn's disease or diverticulitis.

Centers for Medicare and Medicaid Services (CMS)
Medicare does not cover screening computed tomographic colonography (CTC). See the excerpt from the National Coverage Determination (NCD) for Colorectal Cancer Screening Tests (210.3) below. There is no Local Coverage Determination for Nevada. Accessed October 2016.

Colorectal Cancer Screening Tests (210.3)
Nationally Non-Covered Indications
All other indications for colorectal cancer screening not otherwise specified in the Act and regulations, or otherwise specified above remain nationally non-covered. Non-coverage specifically includes:

1. All screening sDNA tests, effective April 28, 2008, through October 8, 2014. Effective for dates of service on or after October 9, 2014, all other screening sDNA tests not otherwise specified above remain nationally non-covered.

2. Screening computed tomographic colonography (CTC), effective May 12, 2009.

For Medicare and Medicaid Determinations Related to States Outside of Nevada:
Please review Local Coverage Determinations that apply to other states outside of Nevada.
http://www.cms.hhs.gov/mcd/search

Important Note: Please also review local carrier Web sites in addition to the Medicare Coverage database on the Centers for Medicare and Medicaid Services’ Website.

DESCRIPTION OF SERVICES

Colonoscopy is the "gold standard" screening test; however, it is invasive and frequently requires sedation or anesthesia, so screening rates are low.

Computed tomography colonography (CTC), also referred to as virtual colonoscopy, is perceived by some persons to be a less invasive method of colon cancer screening than optical colonoscopy. It has been developed to obtain detailed 2-dimensional (2D) and 3-dimensional (3D) colonoscopic images of the colon and rectum using helical computed tomography (CT). These images are then reconstructed to produce computer-generated 3D images suitable for interpretation by a gastrointestinal radiologist. If suspicious lesions are detected, the patient usually undergoes further testing, including possible biopsy, by conventional colonoscopy. Since CTC is believed by some to be less invasive than conventional colonoscopy and does not require sedation, it may be more acceptable to patients and thereby improve compliance with colorectal cancer screening recommendations. Computed tomographic colonography may not detect lesions <6mm in size which could result in delay in treatment and/or conversion to colonoscopy.
Surveillance and Monitoring for Colorectal Cancer

In a systematic review and meta-analysis for the US Preventive Services Task Force, Lin, et al. reviewed the effectiveness, diagnostic accuracy, and harms of screening for CRC which included CTC. Based on 7 studies of CTC with bowel preparation (n = 5328), the per-person sensitivity to detect adenomas 10 mm and larger ranged from 67% to 94%, and specificity ranged from 96% to 98%. The per-person sensitivity to detect adenomas 6 mm and larger ranged from 73% to 98%, and specificity ranged from 89% to 91%. Two studies (N = 1169) evaluated CTC without bowel preparation. Although the data were limited, the sensitivity of CTC without bowel preparation to detect adenomas 6 mm and larger appeared to be lower than the sensitivity of CTC protocols including bowel preparation. Evidence suggested little to no risk of serious adverse events, including perforation, from CTC based on 11 prospective studies (n = 10,272) performed in screening populations. The authors concluded that multiple screening tests, including CTC, have differing levels of evidence to support their use in CRC screening, ability to detect CRC and precursor lesions, and risk of serious adverse events in average-risk adults. They make no endorsement regarding a preferred screening modality (2016).

Pickhardt et al. (2011) performed a systematic review and meta-analysis of studies assessing the sensitivity of computed tomographic colonography (CTC) and optical colonoscopy (OC) for detecting CRC. Forty-nine studies provided data on 11,151 patients. The sensitivity of CTC was 96.1%. The sensitivity of OC, derived from a subset of 25 studies including 9223 patients, was 94.7%. No heterogeneity (bias across studies) was observed with CTC, whereas a moderate degree of heterogeneity was found with OC. The authors concluded that CTC is highly sensitive for CRC, especially when both cathartic and tagging agents are combined in the bowel preparation.

A meta-analysis by Chaparro et al. (2009) evaluated the diagnostic accuracy of CTC for the detection of polyps and colorectal tumors in 47 studies (10,546 patients) that compared CTC to the reference standard of conventional colonoscopy. Overall per-polyp sensitivity of CTC was 59% (56–61%), for polyps 6–9 mm in size and 76% (73–79%) for polyps larger than 9 mm. Overall CTC specificity was 83%. The authors concluded that CTC is highly specific for the detection of colorectal polyps and tumors larger than 10mm in size. However, growths of this size would require conventional colonoscopy or surgery for removal.

Stoop et al. (2012) reported on a population-based randomized trial that compared the participation and diagnostic yield of colonoscopy and non-cathartic CTC in average-risk individuals (n=2258) in a population-based program of colorectal cancer (CRC) screening. Subjects were randomly allocated (2:1) to primary screening for CRC by colonoscopy or by CTC. Based on the study results, the authors concluded that participation in CRC screening with CTC was significantly better than with colonoscopy, but colonoscopy identified significantly more advanced neoplasia per 100 participants than CTC. The diagnostic yield for advanced neoplasia per 100 subjects was similar for both strategies, which appears to indicate that both techniques can be used for population-based screening for CRC. The authors also noted that cost-effectiveness and perceived burden should be taken into account.

A prospective study by Graser et al. (2008) compared the performance characteristics of 5 different screening tests for the detection of advanced colon cancer. The tests included CT colonography (CTC), colonoscopy, flexible sigmoidoscopy, fecal immunochemical stool testing (FIT) (n= 285) and fecal
occult blood testing (FOBT) (n=276). Three hundred and seven participants completed the study. Each participant collected stool samples for FOBT and FIT stool testing prior to endoscopy. After CTC, patients had a colonoscopy and flexible sigmoidoscopy. Lesions were rated as positive if they were detected by both CTC and colonoscopy. Lesions were also considered positive if the lesion was within the same size category or if there was a deviation of no more than one size category. Only polyps detected in the rectum and sigmoid colon were included for analysis of flexible sigmoidoscopy. A total of 221 adenomas were detected in patients receiving CTC and colonoscopy. The sensitivities for adenomas of all sizes was much higher for colonoscopy, with 212 of 221 (95.9%) lesions detected compared with 155 adenomas (70.1%) detected by CTC. In contrast, CTC detected 31 of 33 (93.9%) lesions in the large adenoma group and 43 of 46 (93.5%) lesions in the advanced colon cancer group. Compared with colonoscopy, the sensitivity was 100% and 97.8% respectively. In contrast, for adenomas >10 mm, sigmoidoscopy identified 68%, FIT identified 33.3% and FOBT identified 23.8%. The authors concluded that CTC performs equally as well as colonoscopy in detecting advanced adenomas.

Kim et al. (2007) compared primary CTC in 3120 consecutive adults to primary optical colonoscopy (OC) screening in 3163 consecutive adults. The main outcome measures included detection of advanced neoplasia (advanced adenomas and carcinomas) and total number of harvested polyps. Primary CTC and OC screening resulted in similar detection rates for advanced neoplasia (3.2% for CTC and 3.4% for OC), although the numbers of polypectomies (561 CTC vs. 2434 OC) and complications were considerably smaller in the CTC group (7 colonic perforations/OC group vs. CTC group). The authors therefore concluded that these findings support the use of CTC as a primary screening test before therapeutic OC.

Regge et al. (2009) conducted a multicenter, cross-sectional study to assess the accuracy of CTC in detecting advanced colorectal cancer (CRC). There were 937 asymptomatic patients who were at increased risk of CRC. Each patient underwent both CTC followed by colonoscopy on the same day. Sensitivity and specificity of CTC in detecting advanced neoplasia (for example, advanced adenoma or CRC) 6 mm or larger was the main outcome measurement. CTC identified 151 of 177 participants with advanced neoplasia 6 mm or larger (sensitivity 85.3%). CTC correctly classified results as negative for 667 of 760 participants without these lesions (specificity 87.8%). The positive and negative predictive values were 61.9% and 96.3% respectively. The authors concluded that CTC had a negative predictive value of 96.3% compared with colonoscopy and is potentially as effective as colonoscopy for screening persons at increased risk.

The United States Preventive Services Task Force (USPSTF) stated that it found “convincing evidence that screening for colorectal cancer in adults aged 50 to 75 years reduces colorectal cancer mortality.” It noted, however, a lack of head-to-head studies demonstrating that any of the screening strategies are more effective than others and that the screening tests have varying levels of evidence supporting their effectiveness, as well as different strengths and limitations. In particular, USPSTF noted that there is “a growing body of evidence on the test performance characteristics of CT colonography” but there is a lack of evidence regarding potential harms, particularly in regard to incidental findings. It called for more consistent and complete reporting, in studies with longer-term follow-up, of the downstream consequences of initial detection, subsequent workup, and definitive treatment of extracolonic findings for better understanding of the net benefit associated with this screening approach (2016).
In its 2016 Colorectal Cancer Screening guidelines, the National Comprehensive Cancer Network (NCCN) stated the following:

- CT colonography is considered a primary screening modality.
- Data on optimal frequency, polyp size leading to referral for colonoscopy, and protocol for evaluating extra-colonic lesions are evolving.
- The American College of Radiology has recommended that the reporting of polyps < 5mm in size is not necessary. If polyps of this size are reported, the decision to refer for colonoscopy with polypectomy versus surveillance colonoscopy should be individualized.

**Crohn's Disease**

Ichikawa, et al. retrospectively examined the performance of computed tomographic colonography (CTC) for noncolorectal cancerous conditions. A total of 47 examinations were performed on 44 patients with the following illnesses: 15 patients with impossible or incomplete colonoscopy, 7 with diverticular disease, 6 with noncolorectal malignancy, 6 with Crohn’s disease, 4 with suspected submucosal tumor on colonoscopy, 2 with ischemic colitis, and 4 with various other diseases. Colonic findings were diagnosed on CTC in 36 examinations, and extracolonic findings were identified in 35 of 44 patients. In all, 17 patients had undergone colonoscopy previously, 9 (52.9%) of whom did not require further colonoscopy by CTC. Five patients underwent colonoscopy after CTC. The authors concluded that CTC examinations could be performed safely. Unlike colonoscopy or CT without preparation, CTC revealed colonic and extracolonic findings and may reduce the indication of colonoscopy in patients with noncolorectal cancerous conditions (2011).

In a comparative study of 16 patients by Biancone et al. (2003), the findings from virtual colonoscopy (VC) were compared to conventional colonoscopy (CC) for assessing postoperative recurrence of Crohn's disease. CC showed perianastomotic recurrence in 15 of 16 patients while VC detected 11 of the 15 patients. CC identified stenosis in 8 of the 16 while VC detected stenosis in 7 of the 16 patients; therefore, there was a false-negative reading in 1 of the 16 patients. The authors therefore concluded that although the widespread use of VC in Crohn's disease is currently not indicated because of possible false-negative findings, this technique may represent an alternative to CC in noncompliant postsurgical patients with a rigid stenosis not allowing passage of the endoscope.

**Diverticulitis**

In a prospective study by Hjern et al. (2007), 50 patients diagnosed with diverticulitis were assessed to determine whether computed tomographic colonography (CTC) is a viable alternative to colonoscopy. All 50 patients underwent CTC immediately followed by conventional colonoscopy. The results were blinded to the examiners. Diverticular disease was found in 48 of the 50 (96%) patients utilizing CTC and in 45 of 50 (90%) patients with conventional colonoscopy. These results indicate that CTC can provide at least the same level of accuracy as conventional colonoscopy. The authors conclude that CTC appears to have a better diagnostic potential for imaging of diverticular disease-specific findings when compared with colonoscopy, and is a reasonable alternative in follow-up of patients with symptomatic diverticular disease. The study design, however, did require that the CTC be completed prior to conventional colonoscopy which may have introduced a biased response favoring CTC. In addition, residual gas from CTC may have contributed to greater discomfort during the subsequent colonoscopy. Further studies are needed to determine the efficacy of computed tomographic colonography as a follow-up diagnostic tool for diverticulitis.
A study conducted by Obana et al. (2013), enrolled a total of 52 patients with the aim of evaluating the ability of contrast-enhanced computed tomography (CE-CT) in the detection of colonic diverticular bleeding (CDB). Patients were enrolled based on their ability to undergo both a CE-CT and a total colonoscopy. The patients were also known to have hematochezia and were clinically suspected of CDB. The detection rate for CE-CT was only 15.4%. The detection rate for the total colonoscopy was 38.5%. Based on the results this study concluded that though the CE-CT may play a complementary role to colonoscopy in patients with suspected CDB it is not recommended for all cases due to the low detection rate demonstrated during the course of the study. Optical colonoscopy still remains the primary recommended screening tool.

In its 2014 guidelines addressing colonoscopic surveillance for prevention of CRC in individuals with ulcerative colitis, Crohn's disease or adenomas, the National Institute for Health and Clinical Excellence (NICE) (United Kingdom) stated the following:

- Consider CT Colonography (CTC) as a single examination if colonoscopy is not clinically appropriate (e.g., because of comorbidity or because colonoscopy cannot be tolerated).
- Consider double contrast barium enema as a single examination if CTC is not available or not appropriate.
- Consider CTC or double contrast barium enema for ongoing surveillance if colonoscopy remains clinically inappropriate, with a discussion of the risks and benefits.

Professional Societies

American College of Radiology (ACR)

The 2014 revision of the ACR Practice Parameters for the Performance of Computed Tomography (CT) Colonography in Adults lists the following indications and contraindications for a CTC examination which include, but are not limited to:

A. Indications

1. Screening examination in individuals who are at average or moderate risk for developing colorectal carcinoma. Screening of individuals who are at moderate risk for colorectal cancer may be managed individually based on clinical context or local practice patterns.
2. Surveillance examination in patients with a history of previous colonic neoplasm, depending on the appropriate clinical context
3. Diagnostic examination in symptomatic patients, particularly in the setting of incomplete colonoscopy, including, but not limited to, those with the following:
   a. Abdominal pain
   b. Diarrhea
   c. Constipation
   d. Gastrointestinal bleeding
   e. Anemia
   f. Intestinal obstruction
   g. Weight loss
4. Following incomplete screening, surveillance, or diagnostic colonoscopy and for characterization of colorectal lesions indeterminate on optical colonoscopy.
5. Patients who may be at increased risk for complications during optical colonoscopy (e.g. advanced age, anticoagulant therapy, sedation risk, prior incomplete colonoscopy.)
6. Follow-up of patients with a colonic stoma or after colectomy. Intubation of the stoma should be performed with caution to avoid colonic injury or perforation.
7. Prior to laparoscopic surgery for colorectal cancer in order to accurately localize the tumor or search for synchronous lesions

B. Contraindications

1. The relative contraindications or conditions that require caution in performing a CTC examination include, but are not limited to, the following:
   a. Symptomatic acute colitis
   b. Acute diarrhea
   c. Recent acute diverticulitis
   d. Recent colorectal surgery
   e. Symptomatic colon-containing abdominal wall hernia
   f. Recent deep endoscopic biopsy or polypectomy/mucosectomy
   g. Known or suspected colonic perforation
   h. Symptomatic or high-grade small bowel obstruction

2. CTC is not indicated for the following:
   a. Routine follow-up of inflammatory bowel disease
   b. Hereditary polyposis or nonpolyposis cancer syndromes
   c. Evaluation of anal canal disease
   d. The pregnant or potentially pregnant patient. (Refer to the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation.)

American Cancer Society (ACS)
The ACS colorectal cancer (CRC) guidelines (published in collaboration with the U.S. Multi-Society Task Force and the American College of Radiology) recommend CRC screening of average-risk adults beginning at age 50 years. CTC is an acceptable screening test which is recommended every 5 years if the initial CTC is negative for significant polyps. However, if current studies detect polyps larger than 5 mm, the patient should be referred for colonoscopy. Additionally, CTC surveillance could be offered to those patients who would benefit from screening but either decline colonoscopy or who are not good candidates for colonoscopy for one or more reasons. If colonoscopy is contraindicated because the patient is not likely to benefit from screening due to life-limiting comorbidity, then neither CTC nor any other CRC screening test would be appropriate (2014).

American Gastroenterological Association (AGA)
The AGA recommends that the test be performed once every 5 years for average risk individuals who do not have any signs or symptoms. It is recommended that patients at higher risk for colorectal cancer, including those with a family history or a personal history of polyps or colon cancer should talk to their gastroenterologist about scheduling a colonoscopy since patients with these features are more likely have colon polyps that will require a colonoscopy to remove them (2008).

American Society for Gastrointestinal Endoscopy (ASGE)
A 2009 ASGE technology status report on CTC found that the accuracy for detection of polyps improves with increasing polyp size and is comparable with colonoscopy for polyps 10 mm or larger. However, the detection of polyps smaller than 10 mm and flat polyps is inferior to colonoscopy, and this should be considered by providers and patients when considering screening options. CTC is
preferred to a barium enema for evaluation of the colon proximal to an obstructing lesion and in patients with an incomplete colonoscopy.

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Helical CT scanners are regulated by the FDA as Class II devices, and numerous systems have met all requirements of the 510(k) approval process. The complete list of commercially available helical CT scanners is too extensive for inclusion here; however, major manufacturers of devices used in the studies selected for detailed review include Siemens Medical Solutions, General Electric Medical Systems, and Philips Medical Systems.


**APPLICABLE CODES**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT® Codes (Medically Necessary in Certain Circumstances)</th>
<th>Description</th>
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<tbody>
<tr>
<td>74261</td>
<td>Computed tomographic (CT) colonography, diagnostic, including image post processing; without contrast material.</td>
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<tr>
<td>74262</td>
<td>Computed tomographic (CT) colonography, diagnostic, including image post processing; with contrast material(s) including non-contrast images, if performed.</td>
</tr>
<tr>
<td>74263</td>
<td>Computed tomographic (CT) colonography, screening, including image post processing</td>
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**REFERENCES**


The foregoing Health Plan of Nevada/Sierra Health & Life Health Operations protocol has been adopted from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee.