

Computed Tomographic Colonography

Policy Number: 2024T0320Z Effective Date: January 1, 2024

Instructions for Use

Table of Contents	Page
Application	1
Coverage Rationale	1
Documentation Requirements	1
Applicable Codes	2
Description of Services	2
Benefit Considerations	2
Clinical Evidence	2
U.S. Food and Drug Administration	8
References	
Policy History/Revision Information	10
Instructions for Use	10

Related Comm	ercial/Indiv	idual Excl	hange Policy

Preventive Care Services

Community Plan Policy

<u>Computed Tomographic Colonography</u>

Application

UnitedHealthcare Commercial

This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

Coverage Rationale

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

- As a diagnostic tool for individuals on anticoagulation therapy
- As a diagnostic tool for symptomatic individuals who are unable to undergo or tolerate a complete colonoscopy
- As a screening test for colon cancer for average risk individuals

Due to insufficient evidence of efficacy, computed tomographic colonography is unproven and not medically necessary as a diagnostic tool for the following conditions:

- Diverticulitis
- Inflammatory bowel disease

Documentation Requirements

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 documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

 Computed Tomographic Colonography
 Page 1 of 10

 UnitedHealthcare Commercial and Individual Exchange Medical Policy
 Effective 01/01/2024

 Proprietary Information of UnitedHealthcare. Copyright 2024 United HealthCare Services, Inc.
 Effective 01/01/2024

CPT Codes*	Required Clinical Information			
Computed Tomographic Colonography				
74261	• Provider should call the number on the member's ID card when referring for radiology services			
74262	Medical notes documenting the following, when applicable:			
74263	 Recent history and physical 			
	 Co-morbid medical condition(s) 			
	 Documentation to support medical necessity 			
	 Applicable CPT code 			

*For code descriptions, refer to the <u>Applicable Codes</u> section.

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 Guidelines may apply.

CPT Code	Description
74261	Computed tomographic (CT) colonography, diagnostic, including image postprocessing; without contrast material
74262	Computed tomographic (CT) colonography, diagnostic, including image postprocessing; with contrast material(s) including non-contrast images, if performed
74263	Computed tomographic (CT) colonography, screening, including image postprocessing

CPT° is a registered trademark of the American Medical Association

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 (VC), is a less invasive method of colon cancer screening than optical colonoscopy (OC). It has been developed to obtain detailed 2-dimensional 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 individual usually undergoes further testing, including possible biopsy, via conventional colonoscopy (CC). Since CTC is less invasive than CC and does not require sedation individuals may find it more acceptable, thereby improving compliance with colorectal cancer (CRC) screening recommendations.

Benefit Considerations

Most benefit plans include coverage for proven and medically necessary diagnostic computed tomographic colonography with member cost-sharing. In certain circumstances, screening computed tomographic colonography may be covered as a preventive care services benefit without member cost-sharing. Refer to the member specific benefit plan document for details, and the Medical Policy titled <u>Preventive Care Services</u>.

Clinical Evidence

Colorectal Cancer Screening

Chini et al. (2022) conducted a systematic review to assess the diagnostic accuracy of optical colonoscopy (OC) and computed tomography colonography (CTC) for colorectal lesions. Their study included 18 studies (16 single center, 2 multicenter) with a

Computed Tomographic Colonography UnitedHealthcare Commercial and Individual Exchange Medical Policy Proprietary Information of UnitedHealthcare. Copyright 2024 United HealthCare Services, Inc.

Page 2 of 10 Effective 01/01/2024 total of 4,426 participants. The authors reported that OC may miss 10-20% of colorectal polyps and 5% of colorectal tumors, and that 10-15% of colonoscopies (22-33% in older patients) are not completed for several reasons (e.g., abnormal colonic shape or length, presence of obstructing colonic tumors or stenosis). In these cases, CTC would be performed to evaluate the nonvisualized parts of the colon and found that the CTC increased the diagnostic yield of lesions and allowed the assessment of extracolonic findings. The authors also reported that CTC identified the precise segmental location of colorectal tumors which is not always possible with OC due to the difficulty in identifying anatomical landmarks and that CTC allows for accurate tumor staging. The authors concluded that, while OC is widely accepted as the gold standard for the detection of colorectal polyps and CRC, CTC is a better modality for the visualization of the whole colon, detection of synchronous lesions, and accurate localization of tumors. They also stated that the accuracy of CTC is comparable to that of OC for polyps >10 mm, acceptable but not equal to OC for lesions between 5 and 9 mm, and poor for lesions <5 mm.

In a 2021 update to a 2012 clinical evidence assessment on Computed Tomography Colonography for Colorectal Cancer Screening, ECRI states that a large body of evidence supports the use of CTC for CRC screening, but guidelines vary widely. Seven systematic reviews were assessed that addressed the diagnostic accuracy and clinical utility for CRC screening. Evidence from three systematic reviews indicate the diagnostic accuracy is comparable to colonoscopy, may be as effective as colonoscopy in preventing cases of CRC in screening populations of patients with and without CRC family history and is an alternative to colonoscopy in patients unable or unwilling to undergo colonoscopy. Evidence from 2 SRs indicates that patients use CTC at similar rates as colonoscopy but prefer CTC; however, another SR reports that patients prefer capsule endoscopy to CTC. Patients with positive results from CTC screening require follow-up diagnostic colonoscopy. One SR indicates that CTC complications are rare and that incidental extracolonic findings with CTC result in additional diagnostic testing in up to 11.4% of patients. Guidelines recommend colonoscopy (because of its higher accuracy) or FIT (because of greater adherence) as the preferred screening methods but consider CTC's accuracy adequate when these tests are not feasible.

Pickhardt et al. (2021) performed a systematic review and meta-analysis comparing the diagnostic performance of the available noninvasive CRC screening tests, including multitarget stool DNA (mt-sDNA) testing, fecal immunochemical testing (FIT), and CTC, with an emphasis on comparison of positive predictive value (PPV) and detection rate (DR) for advanced neoplasia (AN). The review and meta-analysis included 10 mt-sDNA published studies, 27 CTC published studies, and 88 FIT published studies involving 2,355,958 asymptomatic adults. Meta-analysis with hierarchic Bayesian modeling was conducted in accordance with Cochrane Collaboration and PRISMA guidelines to determine test positivity rates (TPRs) leading to optical colonoscopy, as well as PPVs and DRs for both AN and CRC. Different positivity thresholds were considered for FIT and CTC. The authors reported that the meta-analysis showed that overall CRC prevention via screen detection of AN (AN DR) was highest with CTC, intermediate with mt-sDNA testing, and lowest with FIT (regardless of FIT threshold) and that both FIT and CTC with polyp size threshold of 6 mm or larger (CTC6). This study was limited by the inclusion of only an asymptomatic screening patient population, lack of consideration for the issues of uptake, adherence or patient preference, potential selection bias, heterogeneity in study design and reported outcomes. The authors concluded that among noninvasive CRC screening tests, CTC10 most effectively targets AN, preserving detection while also decreasing unnecessary colonoscopies compared with mt-sDNA testing and FIT.

In a 2020 meta-analysis, Bai et al. explored the diagnostic value of CTC compared with conventional colonoscopy in individuals at high risk for colorectal cancer. A total of 14 full-text articles, involving 3578 patients were included. The results showed CTC had high diagnostic accuracy for detecting polyps \geq 6 mm and \geq 10 mm in patients at high risk of developing colorectal cancer and it had a higher sensitivity and specificity for detecting polyps \geq 10 mm than polyps \geq 6 mm. However, the results should be used cautiously due to the significant heterogeneity.

Gao et al. (2019) conducted a meta-analysis of 25 prospective studies that investigated the diagnostic value of CTC and magnetic resonance colonography (MRC) for colorectal screening. A total of 2,985 participants were selected for evaluation with17 studies that focused on the assessment of CTC while 18 studies focused on MRC. The authors found that CTC and MRC had higher values for early colorectal cancer diagnosis, but the diagnostic odds ratio showed no difference between the two. Limitations of the study were few and included heterogeneity and published study bias.

A systematic review and meta-analysis compared the diagnostic value of MRC versus CTC for CRC. Upon review of 23 studies, the authors found that MRC and CTC for diagnosing CRC were associated with higher sensitivity, specificity, positive likelihood ratio (PLR), negative likelihood ratio (NLR), and area under the receiver operating characteristic (ROC). When indirectly comparing MRC and CTC, CTC was found to be associated with higher PLR and area under the ROC for diagnosing CRC

 Computed Tomographic Colonography
 Page 3 of 10

 UnitedHealthcare Commercial and Individual Exchange Medical Policy
 Effective 01/01/2024

 Proprietary Information of UnitedHealthcare. Copyright 2024 United HealthCare Services, Inc.
 Effective 01/01/2024

compared with MRC. The focus of future studies was suggested to be on specific characteristics of individuals to directly compare the diagnostic value of MRC and CTC for CRC. Limitations include heterogeneity, data restricted data analysis and publication bias. (Sun et al., 2018).

Regge et al. (2017) conducted 2 randomized controlled trials to compare participation and detection rates with flexible sigmoidoscopy (FS) and CTC in a screening setting. Outcome measures were participation rate (proportion of individuals examined) and detection rate of AN. Individuals with polyps \geq 6 mm at CTC, or 'high-risk' distal lesions at FS were referred for colonoscopy. Participation for CTC and FS was 30.4% (298 of 980) and 27.4% (267of 976), respectively. In the detection trial, 2,673 subjects had FS and 2,595 had CTC. The detection rate for AN using FS was 4.8% (127 of 2,673, including 9 CRCs). With CTC, detection rate was 5.1% (133 of 2,595, including 10 CRCs). Distal AN detection rate was 3.9% (109 of 2,673) and 2.9% (76 of 2,595) with FS and CTC, respectively. Proximal AN detection rate was 1.2% (34 of 2,595) vs 2.7% (69 of 2,595) for FS and CTC, respectively. The authors concluded that participation and detection rates were comparable with both technologies. AN detection rate was twice as high in the proximal colon and lower in the distal colon with CTC than with FS

Sali et al. (2015) compared reduced CTC (r-CTC) and full cathartic preparation CTC (f-CTC), fecal immunochemical test (FIT), and colonoscopy as primary screening tests for CRC through a simple randomized trial with 16,087 participants. Individuals were randomized to one of the 4 screening interventions. Primary outcomes were participation and detection rates for cancer or adenomatous neoplasia. Participants who tested positive to FIT or CTC (at least one polyp \geq 6mm) were referred for colonoscopy. Participation rates were 50.4% (4677 of 9,288), 28.1% (674 of 2,395), 25.2% (612 of 2,430), and 14.8% (153 of 1,036), and detection rates for adenomatous neoplasia were 1.7% (79/4677), 5.5% (37/674), 4.9% (30/612), and 7.2% (11/153) for first-round FIT, r-CTC, f-CTC, and colonoscopy, respectively. The authors concluded that reduced preparation increases participation in CTC. Lower attendance and higher detection rate of CTC as compared with FIT are key factors for the optimization of its role in CRC screening.

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 = 2,258) in a population-based program of 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 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.

Bhatia et al. (2013) conducted a prospective comparative study between July 2008-June 2010 to evaluate the diagnostic performance of intravenous (IV) contrast enhanced CTC in the diagnosis of clinically suspected colorectal polyps in 30 children, using CC as the gold standard. All of the patients underwent IV CTC followed by CC, with 30 IV CTC and 31 CC being performed. Statistical analysis was performed to obtain diagnostic performance values of IV CTC on a per polyp (sensitivity and positive predictive value) and per patient (sensitivity, specificity, positive predictive value and negative predictive value) basis. Via IV CTC, 63 polyps were detected in 28 patients of which 53 polyps were eligible for inclusion in the statistical analysis. 60 polyps were detected by CC in 28 patients of which 50 polyps were eligible. The per polyp sensitivity and positive predictive values were 94% and 87%, respectively. The per patient sensitivity, specificity, positive predictive value, and negative predictive values were 96%, 50%, 96%, and 50%, respectively. Twenty polyps in 10 patients were visualized only after IV contrast administration of which 5 polyps in 5 patients were likely to have been missed in the absence of the IV contrast injection, as these polyps were submerged in fluid. Four patients would have had either an underestimation of polyps or a false negative result if the IV contrast had not been injected. The authors concluded that CTC is capable of serving as a safe and efficient non-invasive tool for evaluating clinically suspect colorectal polyps in the pediatric population, and that administration of IV contrast improves the sensitivity of polyp detection on CTC.

Other Intestinal Disorders

There is insufficient evidence regarding the effectiveness for CTC as a diagnostic tool for diverticulitis and/or inflammatory bowel disease; additional well designed RCTs are needed along with long-term effects for safety and efficacy.

Diverticulitis

A retrospective cohort study by Mäntymäki et al. (2023) was conducted to analyze the risk of CRC after CT verified uncomplicated and complicated acute diverticulitis in short-term and long-term follow-up to evaluate the feasibility of the

Computed Tomographic Colonography UnitedHealthcare Commercial and Individual Exchange Medical Policy Proprietary Information of UnitedHealthcare. Copyright 2024 United HealthCare Services, Inc. primary CT imaging in separating patients with uncomplicated and complicated acute diverticulitis. The study population of 270 patients was divided into those with uncomplicated (n=170) and complicated (n=100) diverticulitis with a mean age of 61 years in the uncomplicated acute diverticulitis group and 64 years in the complicated acute diverticulitis group. Patient charts were reviewed 9-18 years after the initial acute diverticulitis episode. After CT verification of acute diverticulitis, 146 (54%) patients had further evaluation of their colon. Of these, 65 patients underwent endoscopy, 26 underwent CT colonography, 66 underwent barium enema, 5 underwent abdominal CT, and 16 had more than one examination. The authors reported that colorectal cancer (CRC) was found in 7 (2.6%) patients, but CRC was associated with acute diverticulitis and 3.0% (3/100) in complicated acute diverticulitis, and that long-term follow-up showed no additional CRC in patients with complicated acute diverticulitis. Limitations of the study include the retrospective design, the small number of participants who had further evaluations, and the heterogeneity of follow-up studies, The authors concluded that the risk of underlying CRC is very low in CT-verified uncomplicated acute diverticulitis but is increased in complicated acute diverticulitis.

A retrospective study by Njølstad et al. (2021) evaluated the need for routine CTC after an episode of CT-verified uncomplicated sigmoid diverticulitis to rule out underlying colorectal malignancy. The study retrospectively evaluated 312 patients who were referred for routine colonic evaluation by CTC following an episode of acute diverticulitis from January 2012 to March 2018. There were 89 patients excluded because of a lack of a diagnostic CT of the abdomen at time of diagnosis, a presentation that included atypical colonic involvement, or due to CT findings suggestive of complicated disease (e.g., abscess or perforation). CTC exams were routinely reviewed by experienced abdominal radiology consultants on the day of the procedure and patients were referred to same-day optical colonoscopy if significant polyps were detected, or if colorectal malignancy could not be excluded. For these patients, medical records were reviewed for optical colonoscopy results and histology reports if applicable. Among the remaining 223 patients with CT-verified uncomplicated sigmoid diverticulitis, no patients were found to have underlying colorectal malignancy. Twenty-seven patients were referred for optical colonoscopy based on CTC findings with 18 of them consequently undergoing polypectomy, all with either hyperplastic or adenomatous histology. The authors concluded the study showed that routine colonic evaluation by CTC following an episode of CT-verified uncomplicated sigmoid diverticulitis may be unwarranted and should be reserved for patients with protracted or atypical clinical course. The study was limited by its retrospective design which may have introduced selection bias, the small sample size, and the lack of long-term follow-up The authors recommended future prospective studies with larger sample sizes and longer-term follow up to prove the clinical usefulness of this procedure.

A study conducted by Obana et al. (2013) enrolled a total of 52 patients with the aim of evaluating the ability of contrastenhanced CT (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 rates for CE-CT and total colonoscopy were 15.4% versus 38.5%, respectively. Based on the results, this study concluded that though 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. OC still remains the primary recommended screening tool.

With colonoscopy being the standard, Chabok et al. (2013) conducted a prospective comparative study assessing CTC in the follow-up of diverticulitis, evaluating patient acceptance and diagnostic accuracy for diverticular disease, adenomas and cancer in 108 individuals. Half received colonoscopy first, followed immediately by CTC. The other half had the examinations in the reverse order, with results blinded to the examiners. The success rate was 91% and 86% for colonoscopy and CTC, respectively. Examination time was equal for both methods. While 83% of the participants received sedation during colonoscopy, they experienced colonoscopy as more painful and uncomfortable. Diverticulosis and polyps were detected in 94% and 20% with colonoscopy and in 94% and 29% with CTC, respectively. Sensitivity and specificity for CTC in the detection of diverticulosis was 99% and 67%, with a good agreement. Regarding detection of polyps, the sensitivity and specificity were 47% and 75%, respectively. The authors concluded that CTC was less painful and unpleasant and can be used for colonic investigation in the follow-up of diverticulitis. It is considered a viable alternative, especially in cases of incomplete colonoscopy or in a situation with limited colonoscopy resources.

In a prospective study by Hjern et al. (2007), 50 patients diagnosed with diverticulitis were assessed to determine whether CTC is a viable alternative to colonoscopy. Participants underwent CTC immediately followed by CC. 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 CC. These results indicate that CTC can provide at least the same level of accuracy as CC. The authors concluded that CTC appears to have a better diagnostic potential for imaging of diverticular disease-specific findings when compared with

Computed Tomographic Colonography UnitedHealthcare Commercial and Individual Exchange Medical Policy

Proprietary Information of UnitedHealthcare. Copyright 2024 United HealthCare Services, Inc.

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 CC 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 CTC as a follow-up diagnostic tool for diverticulitis.

Inflammatory Bowel Disease

Prabhakar et al. (2015) performed a study comparing the findings of CTC to CC in patients with ulcerative colitis (UC). Participants (n = 20) with known UC per biopsy and in clinical remission underwent CTC and CC within 1 week of each test. The results were blinded to the examiners. Sensitivity and specificity on CTC for detecting granular appearance were 81% and 73.8%, respectively; and for pseudopolyps were 82.1% and 84.5%, respectively. Loss of haustral folds, wall thickening, pericolonic vascularity, and pericolonic lymph nodes seen on CTC were found to correlate with intraluminal findings seen on CC. Participants preferred CTC over CC. The authors concluded that CTC can be used as an alternative to CC for evaluating patients with UC who are in remission.

Ichikawa, et al. retrospectively examined the performance of CTC for non-colorectal cancerous conditions. A total of 47 examinations were performed on 44 patients with the following illnesses/conditions: impossible or incomplete colonoscopy (n = 15), diverticular disease (7), non-colorectal malignancy (6), Crohn's disease (CD) (6), suspected submucosal tumor on colonoscopy (4), ischemic colitis (2), various other diseases (4). 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 per 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 non-colorectal cancerous conditions (2011).

Clinical Practice Guidelines

American Cancer Society (ACS)

In their guideline for CRC screening for average risk adults, the ACS recommends that adults aged 45 years and older with an average risk of CRC undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) examination, depending on patient preference and test availability. As a part of the screening process, all positive results on non-colonoscopy screening tests should be followed up with timely colonoscopy (qualified recommendation). The recommendation for regular screening in adults aged 50 years and older is a *strong recommendation*. CTC is an acceptable structural examination which is recommended every 5 years if the initial CTC is negative for significant polyps. However, if current studies detect polyps of a significant size, the patient should be referred for colonoscopy (Wolf et al., 2018).

American College of Gastroenterology (ACG)

In a 2021 update to the 2009 CRC screening guidelines, the ACG states that CTC is a screening option for individuals unable to undergo colonoscopy or fecal immunochemical test (FIT), and a follow up diagnostic colonoscopy is required if the result is positive (Shaukat et al.).

In its 2018 clinical guideline on management of Crohn's Disease in Adults, the ACG does not cite CTC in the imaging studies that should be performed as part of the initial diagnostic workup or for disease management (Lichtenstein et al.).

American College of Radiology (ACR)

ACR Appropriateness Criteria for CRC screening cites the following regarding CTC:

- For average-risk individuals, aged 50 or older, CTC is usually appropriate for CRC screening, then follow up every 5 years after initial negative result
- For moderate-risk individuals (e.g., first-degree family history of cancer or adenoma), CTC is usually appropriate for CRC screening, then follow up every 5 years after initial negative result.
- For moderate-risk individuals after positive fecal occult blood test (FOBT) or positive fecal immunochemical test, CTC is usually appropriate for CRC detection.

- For high-risk individuals (e.g., hereditary nonpolyposis CRC, UC, or Crohn colitis), CTC is usually not appropriate, and colonoscopy is preferred because of its ability to obtain biopsies to look for dysplasia.
- For CRC screening after incomplete colonoscopy, CTC is usually appropriate for individuals at average, moderate, or high risk for CRC (Moreno et al., 2018).

The 2019 revision of the ACR Practice Parameters for the Performance of CTC in Adults lists the following indications and contraindications for a CTC examination which include, but are not limited to:

- Indications:
 - Screening examination in individuals who are at average or moderate risk for developing CRC. Screening of individuals who are at moderate risk for CRC may be managed individually based on clinical context or local practice patterns.
 - Surveillance examination in patients with a history of previous colonic neoplasm, depending on the appropriate clinical context.
 - Diagnostic examination in symptomatic patients, particularly in the setting of incomplete colonoscopy, including, but not limited to, those with the following:
 - Abdominal pain
 - Diarrhea
 - Constipation
 - Gastrointestinal bleeding
 - Anemia
 - Intestinal obstruction
 - Weight loss
 - Following incomplete screening, surveillance, or diagnostic colonoscopy and for characterization of colorectal lesions indeterminate on OC
 - Patients who may be at increased risk for complications during OC (e.g., advanced age, anticoagulant therapy, sedation risk, prior incomplete colonoscopy)
 - 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.
 - Prior to laparoscopic surgery for CRC in order to accurately localize the tumor or search for synchronous lesions
- Contraindications:
 - The relative contraindications or conditions that require caution in performing a CTC examination include, but are not limited to, the following:
 - Symptomatic acute colitis
 - Acute diarrhea
 - Recent acute diverticulitis
 - Recent colorectal surgery
 - Symptomatic colon-containing abdominal wall hernia
 - Recent deep endoscopic biopsy or polypectomy/mucosectomy
 - Known or suspected colonic perforation
 - Symptomatic or high-grade small bowel obstruction
 - CTC is not indicated for the following:
 - Routine follow-up of inflammatory bowel disease
 - Hereditary polyposis or nonpolyposis cancer syndromes
 - Evaluation of anal canal disease
 - 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)

National Comprehensive Cancer Network (NCCN)

In its 2021 (updated April 2023) Colorectal Cancer (CRC) Screening guidelines, the NCCN stated the following:

- Computed tomographic colonography (CTC) is evolving as a promising technique and is considered a primary CRC screening modality
- Available data indicate that CTC may be useful for the detection of larger polyps
- Data on optimal frequency, polyp size leading to referral for colonoscopy, and protocol for evaluating extra-colonic lesions are evolving
- If more than three polyps are 6 to 9 mm in size, or lesions greater than or equal to 10cm are detected, colonoscopic surveillance is recommended

Computed Tomographic Colonography

UnitedHealthcare Commercial and Individual Exchange Medical Policy

Proprietary Information of UnitedHealthcare. Copyright 2024 United HealthCare Services, Inc.

• The American College of Radiology has recommended that the reporting of polyps < 5mm in size is not necessary. However, if polyps of this size are reported, the decision to refer for colonoscopy with polypectomy versus surveillance colonoscopy should be individualized.

National Institute for Health and Clinical Excellence (NICE)

In its 2011 guidelines (updated 2022) addressing colonoscopic surveillance for prevention of CRC in individuals with UC, CD, or adenomas, the use of CTC is no longer addressed. This guideline now refers out to their interventional procedures' guidance on CTC (virtual colonoscopy).

NICE's 2005 interventional procedures guidance on CTC states that current evidence on the safety and efficacy of CTC appears adequate to support the use of this procedure to examine the colon and rectum to detect abnormalities such as polyps and cancer. The guideline also stated that the risks of missing small or flat lesions and of complications (such as bowel perforation and reaction to contrast medium) were similar to those of other diagnostic techniques.

The U.S. Multisociety Task Force on Colorectal Cancer

This society represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy, and recommends that clinicians offer CRC screening beginning at age 45 with adjustments recommended based on race and family history. They also rank CRC screening tests in 3 tiers based on performance features, costs, and practical considerations. While colonoscopy is the preferred method, the MSTF suggests clinicians explore other screening options using this approach (Rex et al., 2017; updated Patel et al., 2022):

- Tier 1: Colonoscopy every 10 years and annual FIT
- Tier 2: CTC every 5 years, FIT-fecal DNA test every 3 years, and FS every 5 to 10 years
- Tier 3: Capsule colonoscopy every 5 years

US Preventive Services Task Force (USPSTF)

In the 2021 final recommendation for colorectal cancer screening, the USPSTF recommends screening all adults aged 45 to 75 years old for colon cancer. Recommended screening strategies include computed tomography colonography every 5 years.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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. Additional information can be found using product code JAK on the following website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMN.cfm. (Accessed August 1, 2023)

References

American College of Radiology (ACR). Practice Parameter for the Performance of Computed Tomography (CT) Colonography in Adults. 2019. <u>https://www.acr.org/-/media/ACR/Files/Practice-Parameters/ct-colonog.pdf</u>. Accessed August 1, 2023.

Bai W, Yu D, Zhu B, et al. Diagnostic accuracy of computed tomography colonography in patients at high risk for colorectal cancer: a meta-analysis. Colorectal Dis. 2020 Nov;22(11):1528-1537.

Bhatia A, Saxena AK, Kalra N, et al. Intravenous contrast enhanced computed tomography colonoscopy in children with suspected colonic polyps. Eur J Radiol. 2013 Jun;82(6):905-12.

Biancone L, Fiori R, Tosti C, et al. Virtual colonoscopy compared with conventional colonoscopy for structuring postoperative recurrence in Crohn's disease. Inflammatory Bowel Diseases. 9(6):343-50, 2003 Nov.

Chabok A, Smedh K, Nilsson S, et al. CT-colonography in the follow-up of acute diverticulitis: patient acceptance and diagnostic accuracy. Scand J Gastroenterol. 2013 Aug;48(8):979-86.

Chini A, Manigrasso M, Cantore G, et al. Can computed tomography colonography replace optical colonoscopy in detecting colorectal lesions?: State of the art. Clin Endosc. 2022 Mar;55(2):183-190.

ECRI Institute. Clinical Evidence Assessment. Computed Tomography Colonography for Colorectal Cancer Screening. May 8, 2012. Updated May 20, 2021.

Gao Y, Wang J, Lv H, et al. Diagnostic value of magnetic resonance and computed tomography colonography for the diagnosis of colorectal cancer: A systematic review and meta-analysis. Medicine (Baltimore). 2019 Sep;98(39):e17187.

Hjern F, Jonas E, Holmstrom B, et al. CT colonography versus colonoscopy in the follow-up of patients after diverticulitis - a prospective, comparative study. Clinical Radiology. 62(7):645-50, 2007 Jul.

Ichikawa T, Kawada S, Hirata S, et al. Initial experience with computed tomographic colonography applied for noncolorectal cancerous conditions. Jpn J Radiol. 2011 Jul;29(6):386-93.

Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018 Apr;113(4):481-517. Accessed August 1, 2023.

Mäntymäki LM, Grönroos J, Riskumäki M, et al. Risk for colorectal cancer after computed tomography verified acute diverticulitis: A retrospective cohort study with long-term follow-up. Scand J Surg. 2023 Jun 22:14574969231175567.

Moreno C, Kim DH, Bartel TB, et al. ACR Appropriateness Criteria(^{*}) Colorectal Cancer Screening. J Am Coll Radiol. 2018 May;15(5S):S56-S68.

National Comprehensive Cancer Network[®]. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]). Colorectal Cancer Screening. v1 2023. May 17, 2023.

National Institute for Health and Care Excellence (NICE). Colonoscopic surveillance for prevention of colorectal cancer in people with ulcerative colitis, Crohn's disease or adenomas. London (UK). CG118. March 2011; Updated September 20, 2022. Accessed August 1, 2023.

National Institute for Health and Care Excellence (NICE). Computed tomographic colonography (virtual colonoscopy). London (UK). IPG129. June 2005. Accessed August 1, 2023.

Njølstad T, Young VS, Drolsum A, et al. Is there need for routine CT colonography after CT-verified uncomplicated diverticulitis of the sigmoid colon? Eur J Radiol Open. 2021 Mar 31;8:100341.

Obana T, Fujita N, Sugita R, et al. Prospective evaluation of contrast-enhanced computed tomography for the detection of colonic diverticular bleeding. Dig Dis Sci. 2013 Jul;58(7):1985-90.

Patel SG, May FP, Anderson JC, et al. Updates on age to start and stop colorectal cancer screening: Recommendations from the U.S. Multi-Society Task Force on Colorectal Cancer. Am J Gastroenterol. 2022 Jan 1;117(1):57-69.

Pickhardt PJ, Correale L, Hassan C. PPV and detection rate of mt-sDNA testing, FIT, and CT colonography for advanced neoplasia: a hierarchic Bayesian meta-analysis of the noninvasive colorectal screening tests. AJR Am J Roentgenol. 2021 Oct;217(4):817-830.

Prabhakar N, Kalra N, Bhasin DK, et al. Comparison of CT colonography with conventional colonoscopy in patients with ulcerative colitis. Acad Radiol. 2015 Mar;22(3):296-302.

Regge D, Iussich G, Segnan N, et al. Comparing CT colonography and flexible sigmoidoscopy: a randomized trial within a population-based screening program. Gut. 2017 Aug;66(8):1434-1440.

Rex DK, Boland CR, Dominitz JA, et al. Colorectal Cancer Screening: Recommendations for Physicians and Patients From the U.S. Multi-Society Task Force on Colorectal Cancer. Gastroenterology. 2017 Jun 2. pii: S0016-5085(17)35599-3.

Sali L, Mascalchi M, Falchini M, et al. Reduced and full-preparation CT colonography, fecal immunochemical test, and colonoscopy for population screening of colorectal cancer: A randomized trial. J Natl Cancer Inst. 2015 Dec 30;108(2). pii: djv319.

Shaukat A, Kahi CJ, Burke CA, et al. ACG Clinical Guidelines: Colorectal Cancer Screening 2021. Am J Gastroenterol. 2021 Mar 1;116(3):458-479.

Stoop EM, de Haan MC, de Wijkerslooth TR, et al. Participation and yield of colonoscopy versus non-cathartic CT colonography in population-based screening for colorectal cancer: a randomized controlled trial. Lancet Oncol. 2012 Jan;13(1):55-64.

Sun S, Yang C, Huang Z, et al. Diagnostic value of magnetic resonance versus computed tomography colonography for colorectal cancer: A PRISMA-compliant systematic review and meta-analysis. Medicine (Baltimore). 2018 Jun;97(22):e10883.

United States Preventive Services Task Force (USPSTF). Final Recommendation Statement: Screening for Colorectal Cancer. U.S. Preventive Services Task Force. August 2021.

https://uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening. Accessed August 1, 2023.

Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. CA Cancer J Clin. 2018 Jul;68(4):250-281.

Policy History/Revision Information

Date	Summary of Changes			
01/01/2024	Benefit Considerations (new to policy)			
	Added language to indicate:			
	 Most benefit plans include coverage for proven and medically necessary diagnostic computed tomographic colonography with member cost-sharing 			
	 In certain circumstances, screening computed tomographic colonography may be covered as a preventive care services benefit without member cost-sharing 			
	 Refer to the member specific benefit plan document for details and the Medical Policy titled <i>Preventive Care Services</i> 			
	Supporting Information			
	• Updated Clinical Evidence and References sections to reflect the most current information			
	Archived previous policy version 2023T0320Y			

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual[®] criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies 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.