Computed Tomographic Colonography

Guideline Number: MMG024.J
Effective Date: January 1, 2021

Instructions for Use

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Related Medical Management Guideline
• Preventive Care Services

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 are unable to 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.

Required Clinical Information
Computed Tomographic Colonography

• Provider should call the number on the member's ID card when referring for radiology services
• Medical notes documenting all of the following:
  ○ Recent history and physical
  ○ Co-morbid medical condition(s)
  ○ Documentation to support medical necessity
  ○ Applicable CPT code

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 guideline 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 post processing; without contrast material
74262	Computed tomographic (CT) colonography, diagnostic, including image post processing; with contrast material(s) including non-contrast images, if performed
74263	Computed tomographic (CT) colonography, screening, including image post processing

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 perceived by some persons to be 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 believed by some to be less invasive than CC and does not require sedation, individuals may find it more acceptable, thereby improving compliance with colorectal cancer (CRC) screening recommendations.

CTC may not detect lesions <6mm in size which could result in delay in treatment and/or conversion to colonoscopy.

Clinical Evidence

Colorectal Cancer

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 magnetic resonance colonography (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 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).

Weinberg et al. (2018) conducted a multicenter comparative study of 231 patients with resected stage 0-III CRC to determine whether CTC, concurrent with CT, could substitute for standard colonoscopy in CRC surveillance. Approximately 1 year after surgery, participants underwent outpatient CTC plus CT, followed by same-day colonoscopy. CTC results were revealed after

endoscopic visualization of sequential colonic segments, which were re-examined for discordant findings. The primary outcome was performance of CTC in the detection of colorectal adenomas and cancers using endoscopy as the reference standard. Results showed that 50% of participants had polyps of any size or histology identified by colonoscopy, and 15.6% had conventional adenomas and/or serrated polyps ≥ 6 mm. No intra-luminal cancers were detected. CTC detected polyps of ≥ 6 mm with 44% sensitivity and 93.4% specificity. CTC detected polyps ≥ 10 mm with 76.9% and 89% sensitivity and specificity, respectively. Similar values were found when only adenomatous polyps were considered. The negative predictive value of CTC for adenomas ≥ 6 mm was 90.7% and 98.6% for adenomas ≥ 10 mm. The authors concluded that in this patient population, CTC was inferior to colonoscopy for detecting patients with polyps ≥ 6 mm (NCT02143115).
(Accessed November 6, 2020)

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 advanced adenomas or CRC [advanced neoplasia (AN)]. Individuals with polyps ≥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 (NCT01739608). (Accessed November 6, 2020)

The USPSTF (2017) found that evidence for assessing the effectiveness of CTC is limited to studies of its test characteristics. They stated that CTC can result in unnecessary diagnostic testing or treatment of incidental extracolonic findings that are of no importance or would never have threatened the patient's health or become apparent without screening (i.e., overdiagnosis and overtreatment). They noted that extracolonic findings are not uncommon, occurring in about 40-70% of screening examinations with between 5-37% of these findings resulting in diagnostic follow-up, and about 3% requiring definitive treatment. As with other screening strategies, indirect harms from CTC can also occur from follow-up colonoscopy for positive findings.

The U.S. Multi-Society Task Force of Colorectal Cancer (MSTF), which represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy, recommends that clinicians offer CRC screening beginning at age 50 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):

- 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

In a systematic review and meta-analysis for the United States Preventive Services Task Force (USPSTF), 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 = 5,328), the per-person sensitivity to detect adenomas ≥10 mm 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 1,169) 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).

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 ≥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.

Pickhardt et al. (2011) performed a systematic review and meta-analysis of studies assessing the sensitivity of CTC and 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.

Bhatia et al. 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 CTCs and 31 CCs 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 (2013).

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 CC. 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 CC or surgery for removal.

Regge et al. (2009) conducted a multicenter, cross-sectional study to assess the accuracy of CTC in detecting advanced 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) $\geq$6 mm 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 is potentially as effective as colonoscopy for screening persons at increased risk.

A prospective study by Graser et al. (2008) compared the performance characteristics of 5 different screening tests for the detection of advanced colon cancer: CTC, colonoscopy, FS, FIT (n= 285) and fecal occult blood testing (FOBT) (n=276). Participants completing the study totaled 307. Each participant collected stool samples for FOBT and FIT prior to endoscopy. After CTC, patients had a colonoscopy and FS. 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 FS. 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 (n= 3,120 consecutive adults) to primary OC screening (n=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. zero CTC group). The authors therefore concluded that these findings support the use of CTC as a primary screening test before therapeutic OC.

In its 2020 CRC Screening guidelines, the National Comprehensive Cancer Network (NCCN) stated the following:

- CT 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.
- 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.

Other Intestinal Disorders

There is insufficient evidence regarding the effectiveness for CT colonography 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 study conducted by Obana et al. (2013), enrolled a total of 52 patients with the aim of evaluating the ability of contrast-enhanced 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. The detection rate for the total colonoscopy was 38.5%. 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 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

In a retrospective single center study, Ohgo et al. evaluated the morphology of the colon in patients with IBS by using CTC. Twelve patients with diarrhea type IBS (IBS-D), 13 patients with constipation type IBS (IBS-C), 12 patients with functional constipation (FC) and 14 control patients underwent colonoscopy following CTC. The lengths and diameters of various areas of the colon were measured. After analyzing the data, it is supposed that IBS-C and FC are both characterized by a longer and thicker colon. The authors concluded that CTC might contribute to the clarification of subtypes of IBS according to the different morphological findings. A larger prospective study with multiple centers is necessary to accumulate more clinical data (2016).

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.

In a review of CTC techniques and indications, Laghi stated that acute abdominal conditions, like diverticulitis or the acute phase of IBDs, are contraindications to CTC because of the high risk of complications (i.e., perforations). CTC should be also avoided as a surveillance test in patients with a long-standing history of UC or CD, citing colonoscopy as the preferred diagnostic option (2014).

In a review on the role of radiological imaging in the evaluation and management of UC, Deepak and Bruining state that while colonoscopy remains the ‘gold standard’, CTC is noted to be one of the emerging techniques with potential applications in UC in both diagnostic and management algorithms (2014).

Ichikawa, et al. retrospectively examined the performance of CTC for noncolorectal 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), noncolorectal 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 noncolorectal cancerous conditions (2011).

In its 2013 guidelines addressing colonoscopic surveillance for prevention of CRC in individuals with UC, CD or adenomas, the National Institute for Health and Clinical Excellence (NICE) stated the following:

- Consider 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)

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

- For average-risk individuals, CTC is usually appropriate for CRC screening.
- For moderate-risk individuals (e.g., first-degree family history of cancer or adenoma), CTC is usually appropriate for CRC screening.
- For moderate-risk individuals after positive 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), colonoscopy is preferred over imaging tests 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.)

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 noncolonoscopy 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 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.)

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. 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.

Additional information (product code JAK) is available at:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMN.cfm (Accessed November 10, 2020)

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Guideline History/Revision Information

Date	Summary of Changes
01/01/2021	**Template Update** • Reformatted policy; transferred content to new template **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version MMG024.I

Instructions for Use

This Medical Management Guideline 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 guideline, 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 Management Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare West Medical Management 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.

Member benefit coverage and limitations may vary based on the member's benefit plan Health Plan coverage provided by or through UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare Benefits of Texas, Inc., or UnitedHealthcare of Washington, Inc.