Virtual Upper Gastrointestinal Endoscopy

Policy Number: CS130.M
Effective Date: November 1, 2023

➲ Instructions for Use

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Related Community Plan Policy

- Computed Tomographic Colonography

Commercial Policy

- Virtual Upper Gastrointestinal Endoscopy

Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Indiana	Virtual Upper Gastrointestinal Endoscopy (for Indiana Only)
Kentucky	Virtual Upper Gastrointestinal Endoscopy (for Kentucky Only)
Louisiana	Virtual Upper Gastrointestinal Endoscopy (for Louisiana Only)
New Jersey	Virtual Upper Gastrointestinal Endoscopy (for New Jersey Only)
New Mexico	Virtual Upper Gastrointestinal Endoscopy (for New Mexico Only)
Ohio	Virtual Upper Gastrointestinal Endoscopy (for Ohio Only)
Pennsylvania	Virtual Upper Gastrointestinal Endoscopy (for Pennsylvania Only)
Tennessee	Virtual Upper Gastrointestinal Endoscopy (for Tennessee Only)

Coverage Rationale

Virtual upper gastrointestinal endoscopy using 3D computed tomography (CT), or 3D magnetic resonance imaging (MRI) is unproven and not medically necessary for detecting and evaluating upper gastrointestinal lesions due to insufficient evidence of efficacy.

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 federal, state, or contractual requirements 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
76497	Unlisted computed tomography procedure (e.g., diagnostic, interventional)
76498	Unlisted magnetic resonance procedure (e.g., diagnostic, interventional)

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Description of Services

Virtual upper gastrointestinal endoscopy is a noninvasive procedure that uses three-dimensional imaging and computed tomography (CT) to capture detailed pictures of the inside surfaces of organs [e.g., organs of the gastrointestinal (GI) tract]. Magnetic resonance imaging (MRI) can also be used to perform virtual upper GI endoscopy. Virtual endoscopy is proposed as a means to determine the cause of symptoms such as nausea, gastric reflux, abdominal pain, unexplained weight loss; in identifying inflammation, ulcers, precancerous conditions, and hernias; and in gastric cancer preoperative staging.

Individuals undergoing virtual upper gastrointestinal endoscopy usually do not need anesthesia or sedation. As this is an imaging procedure, physicians have the capability to modify the captured pictures by magnifying the images or altering the image angles. Disadvantages of virtual upper gastrointestinal endoscopy include the difficulty in showing fine detail compared to a standard endoscopy procedure; exposure to CT scan radiation, and the inability to perform a biopsy during the procedure. If a lesion is found, conventional upper GI endoscopy is necessary for excision or biopsy.

Clinical Evidence

The body of evidence in the published peer reviewed scientific literature evaluating virtual upper gastrointestinal endoscopy using 3D computed tomography (CT) or 3D magnetic resonance imaging (MRI) is mainly constituted of observational studies and case reports. There were no randomized controlled trials (RCTs) available to assess clinical utility. Randomized controlled studies comparing it to conventional upper GI endoscopy are needed to determine its clinical value as well as safety and efficacy.

In a 2022 retrospective study of individuals admitted to the emergency department, Kim et al. aimed to investigate the diagnostic value of multi-detector computed tomography (MDCT) for individuals with suspected upper gastrointestinal bleeding (UGIB). In total, 386 individuals were compared between contract enhanced abdominopelvic MCT to endoscopy, and the performance of MDCT in identifying the status, location of origin, and etiology of UGIB was analyzed. The outcomes measured were sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy. The MDCT was able to accurately identify 32.9% [21.9–43.9, 95% confidence interval (CI)] for individuals with active bleeding, 27.4% (18.9–35.9, 95% CI) for individuals with recent bleeding, and 94.8% (91.8–97.8, 95% CI) for individuals without bleeding evidence ($p < 0.001$). MDCT showed an accuracy of 60.9%, 60.6%, and 50.9% in identifying bleeding in the esophagus, stomach, and duodenum in that order ($p = 0.4028$). The accuracy in differentiating ulcerative, cancerous, and variceal bleeding was 58.3%, 65.9%, and 56.6%, respectively ($p = 0.6193$). The authors concluded that the MDCT has limited use as a supportive screening method to identify the presence of gastrointestinal bleeding.

Wani et al. (2021) in an observational study assessed the diagnostic accuracy of MDCT using hydro- and gaseous-distension of stomach superseding endoscopic ultrasound in tumor (T) and nodal (N) staging of gastric cancer with an attempt to differentiate between early and advanced gastric carcinomas. A total of 160 individuals with endoscopically diagnosed and biopsy-proven gastric cancer were subjected to MDCT after adequate gaseous- and hydro-distention of stomach. Multi-planar reformatted (MPR) and virtual gastroscopy images were also obtained. Gastric lesions were categorized into T1 to T4 stages with N staging from N0 to N3. Preoperative CT findings were correlated with histopathological findings. In the study, general diagnostic accuracy of T staging was 82.5% (132/160) with an accuracy of 75% (120/160) for N staging. The diagnostic accuracy of CT for early gastric carcinoma in the study was 93.75% with high specificity of 96% but low sensitivity of 66.7%. The authors concluded that gaseous and hydro-distension in MDCT of the stomach is an excellent method for near accurate preoperative T staging of gastric cancer. Nevertheless, CT has a limited role in the N staging of gastric cancer. This study also suggested that the use of virtual gastroscopy and MPR images helps in better detection of early gastric cancers. Larger more robust studies are needed to support the clinical utility of virtual gastroscopy in staging gastric cancer.

Almeida et al. (2018) evaluated the accuracy of multidetector computed tomography used in conjunction with virtual gastroscopy in staging gastric cancer. The study included 14 participants who underwent computed tomography in a 16-channel scanner for preoperative staging of gastric adenocarcinoma between September 2015 and December 2016. All images were analyzed by the same radiologist with extensive abdominal cancer imaging experience. The method sensitivity, specificity, and accuracy were calculated by comparing it with the pathology result. All participants underwent partial or total gastrectomy. The mean age was 61.5 years, and 53.8% were male. The gastric lesions were classified as T1/T2 in 35.7% of the cases, as T3 in 28.5%, and as T4 in 35.7%. Eleven people (68.7%) had suspicious (N-positive) lymph nodes. The accuracy of the T1/T2, T3, T4, and lymph node staging tests was 85%, 78%, 90%, and 78%, respectively. The respective sensitivity and specificity values were 71% and 100% for T1/T2, 66% and 81% for T3, 100% and 90% for T4, and 88% and 60% for lymph nodes. The authors concluded that the multidetector computed tomography

with a stomach protocol, used in conjunction with virtual gastroscopy, shows good accuracy in the tumor and lymph node staging of gastric adenocarcinoma. This study is limited by a small sample size.

Kim et al. (2012) assessed the diagnostic accuracy of different reconstruction techniques using MDCT for gastric cancer detection compared with 2D axial CT. The authors performed CT examinations in 104 consecutive individuals with gastric cancer, and the control group was composed of 35 individuals without gastric disease. All gastric cancer was pathologically proven by endoscopy and surgery. Among 104 of those with gastric cancer, 63 had early gastric cancer (EGC). Two radiologists retrospectively and independently interpreted the axial CT and three different reconstruction techniques, including multiplanar reformation (MPR), transparent imaging (TI), and virtual gastroscopy (VG). VG had significantly better performance than 2D axial CT. The sensitivity and specificity were as follows: 76.7% and 82.9% in axial CT; 79.6% and 85.7% in MPR; 91.3% and 80% in TI; and 95.1% and 74.3% in VG. VG had significantly better performance than both 2D axial CT and MRP. The sensitivity and specificity were as follows: 62.9% and 82.9% in axial CT; 67.7% and 85.7% in MPR; 85.5% and 80% in TI; and 91.9% and 74.3% in VG. The inter-observer agreement showed substantial agreement. The authors concluded that among the different reconstruction techniques, VG is a promising method for accurately detecting gastric cancer and is especially useful for early gastric cancer compared with 2D axial CT. Interpretation of these findings is limited due to the study's retrospective design and relatively small patient sample size.

Okten et al. (2012) assessed the role of MDCT with multiplanar (3D) reconstruction (MPR) and VG for the detection and differentiation of gastric subepithelial masses (SEM) by comparison with endoscopic ultrasonography (EUS). Forty-one individuals with a suspected SEM were evaluated using EUS and MDCT. MDCT findings were analyzed based on the consensus of two radiologists blinded to the EUS findings. EUS and MDCT results were compared with histopathology for the pathologically proven lesions. For the non-pathologically proven lesions, MDCT results were compared with EUS. Among the 41 participants, 34 SEM were detected using EUS. For the detection of SEM with MDCT, a sensitivity of 85.3%, a specificity of 85.7%, a positive predictive value of 96.7%, and a negative predictive value of 54.5% were calculated. The overall accuracy of MDCT for detecting and classifying the SEM was 85.3% and 78.8%, respectively. The authors concluded that MDCT with MPR and VG is a valuable method for evaluating SEMs. The authors stated that specific MDCT criteria for various SEMs may help make an accurate diagnosis. These findings require confirmation in a larger study.

Moschetta et al. (2012) assessed the diagnostic accuracy of VG obtained by 320-row computed tomography (CT) examination in differentiating benign from malignant gastric ulcers (GUs). Forty-nine individuals with endoscopic and histological diagnoses of GU underwent CT examination. Based on morphological features, GUs were subdivided into benign or malignant forms by two blinded radiologists. CT results were then compared with endoscopic and histological findings, having the latter as the reference standard. Thirty-five out of 49 participants (71%) were affected by malignant ulcers, while in the remaining 14 cases, a diagnosis of benign GU was made. VG showed diagnostic accuracy, sensitivity, and specificity values of 94%, 91%, and 100%, respectively, in differentiating benign from malignant ulcers. Almost perfect agreement between the two readers was found. The authors concluded that the CT VG improves the identification of GUs and allows the differentiation of benign from malignant forms. The significance of this study is limited by a small sample size.

In a prospective trial, Ulla et al. (2010) evaluated the usefulness of Pneumo-64-MDCT (PnCT64) in the presurgical characterization of esophageal neoplasms in correlation with surgical findings for 50 individuals with a diagnosis of esophageal neoplasm. A 14 French Foley catheter was used trans-orally in all participants. Air was instilled through the catheter to achieve esophageal distension. A 64-row MDCT scan was performed, and the tumor was characterized according to scope, shape, and anatomic location using multiplanar 3D reconstructions and virtual endoscopy. Wall infiltration and the presence of adenopathies were analyzed. In 44/50 people, wall thickening was observed, and 34/50, regional adenopathies were found. In 29/50 individuals, the lesion was found in the lower third and the gastroesophageal junction. The surgical correlation for wall infiltration was 85.7%. The investigators concluded that PnCT64 is useful and safe for identifying esophageal wall thickening and presurgical characterization. Optimal distension allows the definition of both upper and lower borders of the tumors located in the gastroesophageal junction, which is of utmost importance to determine the surgical approach. These findings need confirmation in a larger investigation.

Chen et al. (2009) retrospectively compared CT VG to conventional optical gastro endoscopy when determining differences between benign and malignant gastric ulcers. Gastric ulcers in 115 individuals (mean age, 64.7 years; range, 31-86 years; 61 men, 54 women) were evaluated by using endoscopy and VG. At the histopathologic examination, 39 gastric ulcers were benign, while 76 were malignant. VG and endoscopy had 92.1% and 88.2% sensitivities, respectively, for the overall diagnosis of malignant gastric ulcers and specificities of 91.9% and 89.5%, respectively, for the overall diagnosis of malignant gastric ulcers. Endoscopy was more sensitive in depicting malignancy according to ulcer base (85.5% vs. 68.4%), and VG was more specific in depicting malignancy according to ulcer margin (78.4% vs. 63.2%). The

authors concluded that VG and endoscopy were almost equally useful in distinguishing between malignant and benign gastric ulcers. These findings need confirmation in a larger study.

Clinical Practice Guidelines

European Society of Gastrointestinal Endoscopy (ESGE)

The updated 2022 ESGE guideline for endoscopic submucosal dissection (ESD) for superficial gastrointestinal lesions recommends that the evaluation of superficial gastrointestinal lesions should be made by an experienced endoscopist using high-definition white-light and chromoendoscopy (virtual or dye-based), and validated classifications when available. Strong recommendation, high-quality evidence. ESGE does not recommend routine performance of endoscopic ultrasonography (EUS), computed tomography (CT), magnetic resonance imaging (MRI), or positron emission tomography CT (PET-CT) before endoscopic resection (ER). Strong recommendation, moderate quality evidence.

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.

Imaging devices used to create virtual endoscopy images are classified under the following product codes: LLZ (system, image processing, radiological); JAK (system, x-ray, tomography, computed); and LNH (system, nuclear magnetic resonance imaging). Note that devices listed under these codes are general imaging devices and may not be indicated explicitly for virtual upper gastrointestinal endoscopy. To locate marketing clearance information for a specific device or manufacturer, search the following website by product and/or manufacturer name: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 14, 2023)

Two software packages that can be used to convert two-dimensional helical computed tomography (CT) images into three-dimensional images are the Magic View package for use with the Somatom Plus 4 scanner [Siemens Medical Solutions, Erlangen, Germany, 510k (K964747) approval received on February 10, 1997] additional information at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K964747. (Accessed July 14, 2023), and the CT Colonography/Navigator 2 package [GE Medical Systems, Buc Cedex, France. 510k (K012313) approval received on August 7, 2001] additional information at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K012313. (Accessed July 14, 2023), and for use with the Hi-Speed Advantage CT Scanner [GE Medical Systems, Milwaukee, WI. 510k (K940606) approval received on August 23, 1994] additional information at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K940606. (Accessed July 14, 2023)

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Policy History/Revision Information

Date	Summary of Changes
07/01/2024	**Application** ***New Mexico*** • Added language to indicate this policy does not apply to the state of New Mexico; refer to the state-specific policy version
11/01/2023	**Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version CS130.L

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. 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.

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