Virtual Upper Gastrointestinal Endoscopy

Policy Number: DIAGNOSTIC 045.17
Effective Date: November 1, 2024

➲ Instructions for Use

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Related Policies
None

Coverage Rationale

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

Applicable Codes

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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 (GI) 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 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, and unexplained weight loss; in identifying esophageal varices, inflammation, ulcers, precancerous conditions, and hernias; and in gastric cancer preoperative staging.

Individuals undergoing virtual upper GI 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 GI 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 biopsy.

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Clinical Evidence

The body of published, peer reviewed, scientific evidence evaluating virtual upper gastrointestinal (GI) endoscopy using three dimensional (3-D) computed tomography (CT) or 3-D magnetic resonance imaging (MRI) primarily consists of observational studies and case reports. There are no randomized controlled trials (RCTs) available to assess clinical utility. Studies are limited with small number of participants, lack of comparison, standard methods, and lack of studies designed to establish the clinical utility on long term patient and oncologic outcomes. RCTs comparing virtual upper GI endoscopy to conventional upper GI endoscopy are needed to determine clinical value as well as safety and efficacy.

Kumar et al. (2023) conducted a cross-sectional study to determine how effective multi-detector computed tomography (MDCT) virtual esophagography was at detecting and grading esophageal varices (EV) in individuals with chronic cirrhotic liver disease (CLD). The study included 62 individuals with CLD who underwent CT scan followed by endoscopic examination of the esophagus. CT scans were obtained after esophageal distention and processed using two-dimensional (2-D) and 3-D software that allowed processing of multiplanar reconstructions and volume renderings by using surface-shaded transparent and virtual endoscopy modes. EVs were graded at MDCT and at endoscopic examination using a standardized classification system. The study results revealed CT virtual esophagography had a sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of 86%, 90%, 98%, 56%, and 87%, respectively. Substantial agreement between endoscopic examination and CT virtual esophagography was determined to be statistically significant ($k = 0.616$; $p \leq 0.001$). However, agreement for the detection of grade I esophageal varices was poor ($k = 0.102$), possibly due to these lesions being less conspicuous on CT. The authors concluded the study results have the potential to change the way CLD is managed and encourage further research. A multicenter study with a large number of individuals is needed to support these findings. The authors noted several study limitations including small sample size and single center design. The study also included a small number of individuals with grade 0 and grade I EVs.

In a 2022 retrospective study of individuals admitted to the emergency department, Kim et al. aimed to investigate the diagnostic value of MDCT for individuals with suspected upper GI bleeding (UGIB). The study included 386 individuals and compared contrast-enhanced abdominopelvic MDCT to endoscopy. 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 study results revealed 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, respectively ($p = 0.4028$). Additionally, the accuracy in differentiating ulcerative, cancerous, and variceal bleeding was 58.3%, 65.9%, and 56.6%, respectively ($p = 0.6193$). The authors concluded MDCT has limited use as a supportive screening method to identify the presence of UGIB. Limitations of the study noted by the authors included the retrospective nature of the research design. Unidentified confounders and selection bias may have been introduced. Non-blinded data interpretation carried out by different radiologists may have also generated variation in the reported findings. The study was conducted at a single-tertiary hospital. Multi-center studies are needed. False positive and false negative results could have been produced due to the widely diverse characteristics of UGIB.

Wani et al. (2021) evaluated the diagnostic accuracy of MDCT in tumor (T) and nodal (N) staging of gastric cancer with an attempt to differentiate between early and advanced gastric carcinomas. In this observational study, 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 (VG) 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. The study results revealed the 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 was 93.75%, with high specificity of 96%, but low sensitivity of 66.7%. The authors concluded MDCT after gaseous and hydro-distension 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 VG and MPR images helps in better detection of early gastric cancer. Larger more robust studies are needed to support the clinical utility of VG in staging gastric cancer.

Almeida et al. (2018) evaluated the accuracy of MDCT with a stomach protocol in staging gastric cancer. The study included 14 participants who underwent preoperative staging of gastric adenocarcinoma in a 16-channel CT scanner. The stomach protocol included a period of fasting, followed by an intravenous antispasmodic agent, and ingestion of two effervescent salt envelopes diluted in water just prior to CT. All participants were then treated with a total or partial gastrectomy. Biopsies were taken during surgery and submitted for histopathological analysis. Sensitivity, specificity, and accuracy were calculated by comparing MDCT with the pathology result. The gastric lesions were classified as T1/T2 in

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35.7% of the cases, as T3 in 28.5% of the cases, and as T4 in 35.7% of the cases. Eleven participants (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 MDCT with a stomach protocol, used in conjunction with VG, showed good accuracy in the tumor and lymph node staging of gastric adenocarcinoma. This study was 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 2-D axial CT. CT examinations were performed in 104 consecutive individuals with gastric cancer and a control group composed of 35 individuals without gastric disease. All gastric cancer was pathologically proven by endoscopy and surgery. Among the 104 individuals with gastric cancer, 63 had early gastric cancer. Two radiologists , using a commercially available, 3-D workstation, retrospectively and independently interpreted the axial CT and different reconstruction techniques. The techniques included multiplanar reformation (MPR), transparent imaging (TI), and VG. Overall, VG had significantly better performance than 2-D axial CT ($p = 0.016$). Sensitivity and specificity were 76.7% and 82.9% for axial CT, 79.6% and 85.7% for MPR, 91.3% and 80% for T, and 95.1% and 74.3% for VG. For early gastric cancer, VG had significantly better performance than both 2-D axial CT ($p = 0.006$) and MRP ($p = 0.038$). Sensitivity and specificity were 62.9% and 82.9% for axial CT, 67.7% and 85.7% for MPR, 85.5% and 80% for TI, and 91.9% and 74.3% for VG. There was substantial inter-observer 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 2-D axial CT. Interpretation of these findings is limited due to the study's single institution, retrospective design, and relatively small patient sample size.

Okten et al. (2012) assessed the role of MDCT with MPR and VG for the detection and differentiation of gastric subepithelial masses (SEMs) 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. The study results revealed among the 41 individuals, 34 SEMs were detected using EUS. For the detection of SEMs 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 SEMs was 85.3% and 78.8%, respectively. The authors concluded that MDCT with MPR and VG is a valuable method for evaluating SEMs. Specific MDCT criteria for various SEMs may help in making an accurate diagnosis. The authors noted several study limitations including small sample size. Additionally, MDCT was performed in individuals with a high probability of having a gastric SEM. This may have led to high accuracy rates for the detection of lesions.

Moschetta et al. (2012) assessed the diagnostic accuracy of VG obtained by 320-row CT examination in differentiating benign from malignant gastric ulcers. Forty-nine individuals with endoscopic and histological diagnoses of gastric ulcers underwent CT examination. Based on morphological features, gastric ulcers 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. The study results revealed 35 out of 49 participants (71%) were affected by malignant ulcers, while in the remaining 14 cases, a diagnosis of benign gastric ulcers was made. VG showed diagnostic accuracy, sensitivity, and specificity values of 94%, 91%, and 100%, respectively, in differentiating benign from malignant gastric ulcers. Almost perfect agreement between the two readers was found. The authors concluded that CT VG improves gastric ulcer identification and allows the differentiation of benign from malignant forms. The authors noted several study limitations including small sample size. Additionally, only individuals with endoscopically diagnosed lesions were included in the study. Thus, results for the detection of gastric cancer may be biased. The value of VG in the screening of gastric cancer cannot be provided. Furthermore, a direct comparison with optical gastroscopy was not performed.

Ulla et al. (2010) evaluated the usefulness of the Pneumo-64-MDCT (PnCT64) technique in the presurgical characterization of esophageal neoplasms in correlation with surgical findings. The prospective study included 50 individuals with an endoscopically confirmed esophageal neoplasm diagnosis. In order to optimize tumor visualization in the esophageal wall and in the gastroesophageal (GE) junction, individuals underwent insertion of a transoral Foley catheter. Air was then instilled through the catheter to achieve esophageal distension. A 64-row MDCT scan was then performed, and the tumor was characterized according to scope, shape and anatomic location using multiplanar 3-D reconstructions and virtual endoscopy. Wall infiltration and the presence of adenopathies were analyzed. Adequate GE distension was achieved in all individuals. The study results revealed that PnCT64 showed wall thickening in 44/50 (84%) individuals and regional adenopathies in 34/50 (68%) individuals. In 29/50 individuals, the lesion was found in the lower third and the GE junction. The surgical correlation for wall infiltration was 85.7%. Surgery was performed in 35/50 individuals. A comparison of PnCT64 with histopathological findings showed a surgical correlation for wall infiltration in

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30/35 (85.7%) individuals. In 5/35 individuals who underwent surgery, PnCT64 did not show evidence of wall infiltration. Of these, 3 were T1 tumors, and the other 2 were T2 tumors.

Surgical correlation for the detection of adenopathies reached 75%. The authors 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 GE junction, which is of utmost importance to determine the surgical approach. The authors noted study limitations including the lack of comparison between PnCT64 and other imaging modalities. There may have also been bias introduced in the analysis, as the radiologists were not masked to the endoscopically confirmed esophageal neoplasm diagnosis.

Chen et al. (2009) retrospectively compared CT VG to conventional optical gastroendoscopy when determining differences between benign and malignant gastric ulcers. The study included 115 individuals with gastric ulcers who were evaluated using endoscopy and VG. Histopathologic examination revealed 39 gastric ulcers were benign, and 76 gastric ulcers were malignant. For the overall diagnosis of malignant gastric ulcers, VG and endoscopy had a sensitivity of 92.1% and 88.2%, respectively. Specificity was 91.9% and 89.5%, respectively. Endoscopy was more sensitive in depicting malignancy according to ulcer base (85.5% vs. 68.4%) ($p = .034$), and VG was more specific in depicting malignancy according to ulcer margin (78.4% vs 63.2%) ($p = .034$). The authors concluded VG and endoscopy were almost equally useful in distinguishing between malignant and benign gastric ulcers. The authors noted some study limitations including selection bias. There was also great variation noted in the elapsed time between the endoscopic and VG examinations. Additional prospective, RCTs comparing VG and optical endoscopy are needed to investigate the overall efficacy of VG.

Chen et al. (2007) prospectively evaluated the accuracy of MDCT for the preoperative staging of gastric cancer by using surgical and histopathologic results as reference standards. The study included 55 consecutive individuals who were diagnosed with gastric cancer. Prior to MDCT, individuals underwent endoscopic biopsy that provided histologic confirmation of gastric cancer. MDCT included acquisition of VG images after air distention and contrast material-enhanced dynamic transverse and MPR images after water distention. All individuals underwent partial or complete gastrectomy. CT findings were compared with surgical and histopathologic results. The study results revealed detection rates of primary tumors with transverse images, MPRs, and combinations of MPR and virtual gastroscopy images were 91% (50 of 55), 96% (53 of 55), and 98% (54 of 55), respectively. The overall accuracy in assessment of tumor invasion into the gastric wall (T stage) was significantly better with MPR images (89%) (49 of 55) than with transverse images (73%) (40 of 55) ($p < .01$). Additionally, the overall accuracy for lymph node (N) staging was 78% (43 of 55) with MPR images and 71% (39 of 55) with transverse images. This difference was not significant ($p = .103$). The authors concluded MDCT with combined water and air distention can improve the accuracy of preoperative staging of gastric cancer. MPRs also yield significantly better overall accuracy than transverse images for tumor staging, but not for lymph node staging. The authors noted some study limitations including small sample size. Studies with a larger number of individuals are needed.

Clinical Practice Guidelines

European Society of Gastrointestinal Endoscopy (ESGE)

The updated 2022 ESGE guideline for superficial GI lesions recommends that the evaluation of superficial GI 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 EUS, CT, 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: JAK, LLZ, or LNH. Note that the devices listed under these codes may not be indicated explicitly for virtual upper gastrointestinal endoscopy. Refer to the FDA's 510(k) Premarket Notification website for information regarding marketing clearance for a specific device or manufacturer: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 1, 2024)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2024T0400V]

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Policy History/Revision Information

Date	Summary of Changes
11/01/2024	**Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version DIAGNOSTIC 045.16

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford 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 Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

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