VIRTUAL UPPER GASTROINTESTINAL ENDOSCOPY

Policy Number: CS130.H   **Effective Date**: September 1, 2019

Instructions for Use ⓘ

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Related Community Plan Policy
- Computed Tomographic Colonography

Commercial Policy
- Virtual Upper Gastrointestinal Endoscopy

APPLICATION

This policy does not apply to the state of Tennessee; refer to the Medical Policy titled Virtual Upper Gastrointestinal Endoscopy (for Tennessee Only).

COVERAGE RATIONALE

Virtual upper gastrointestinal endoscopy using 3-D computed tomography (CT) or 3-D 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 Coverage Determination 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, and identifying inflammation, ulcers, precancerous conditions, and hernias.

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.

Almeida et al. (2018) evaluated the accuracy of multidetector computed tomography used in conjunction with virtual gastroscopy in staging of gastric cancer. The study included 14 patients 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, who had extensive experience in abdominal cancer imaging. The sensitivity, specificity, and accuracy of the method were calculated by comparing it with the pathology result. All patients underwent partial or total gastrectomy. The mean age was 61.5 years, and 53.8% of the patients 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 patients (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 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.

Okten et al. (2012) assessed the role of multidetector computed tomography (MDCT) with multiplanar (3-D) reconstruction (MPR) and virtual gastroscopy (VG) for detection and differentiation of gastric subepithelial masses (SEMs) by comparison with endoscopic ultrasonography (EUS). Forty-one patients with a suspected SEM were evaluated using EUS and MDCT. MDCT findings were analyzed based on the consensus of two radiologists who were 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 patients, 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 the evaluation of SEMs. The authors stated that specific MDCT criteria for various SEMs may be helpful in making an accurate diagnosis. These findings require confirmation in a larger study.

Moschetta et al. (2012) assessed the diagnostic accuracy of virtual gastroscopy obtained by 320-row computed tomography (CT) examination in differentiating benign from malignant gastric ulcers (GUs). Forty-nine patients with endoscopic and histological diagnosis 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 patients (71%) were affected by malignant ulcers, while in the remaining 14 cases diagnosis of benign GU was made. Virtual gastroscopy 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 CT virtual gastroscopy improves the identification of GUs and allows differentiating 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 in 50 patients with diagnosis of esophageal neoplasm. A 14 French Foley catheter was used trans-orally in all patients. 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 by using multiplanar 3D reconstructions and virtual endoscopy. Wall infiltration and presence of adenopathies were analyzed. In 44/50 patients, wall thickening was observed, and in 34/50 regional adenopathies were found. In 29/50 patients the lesion was found in the lower third and in the gastroesophageal junction. The surgical correlation for wall infiltration was 85.7%. The investigators concluded that PnCT64 is useful and safe for identification of esophageal wall thickening and presurgical characterization. Optimal distension allowed definition of both upper and lower borders of the tumors located in the gastroesophageal junction, of utmost importance to determine the surgical approach. These findings need confirmation in a larger investigation.

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 patients with gastric cancer and in a control group composed of 35 patients without gastric disease. All gastric cancer was pathologically proven by endoscopy and surgery. Among 104 patients with gastric cancer, 63 patients 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 retrospective design of the study and a relatively small patient population.

Kim et al. (2015) note limitations and diagnostic pitfalls of 3D MDCT gastrography to include lack of color detection as compared to conventional endoscopy, and that gastric secretion or residual food can mask a gastric cancer and may be confused with a true lesion. In addition, they commented that this diagnostic tool can be time consuming to learn and to prepare and interpret the images.

Chen et al. (2009) retrospectively compared the use of computed tomographic virtual gastroscopy (VG) to conventional optical gastroendoscopy when determining differences between benign and malignant gastric ulcers. Gastric ulcers in 115 patients (mean age, 64.7 years; range, 31-86 years; 61 men, 54 women) were evaluated by using endoscopy and VG. At histopathologic examination, 39 gastric ulcers were benign, while 76 were malignant. VG and endoscopy had sensitivities of 92.1% and 88.2%, respectively, for overall diagnosis of malignant gastric ulcers, and specificities of 91.9% and 89.5%, respectively, for 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.

Professional practice guidelines related to virtual upper gastrointestinal endoscopy were not identified.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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 specifically indicated 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 June 28, 2019)

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] and the CT Colonography/Navigator 2 package [GE Medical Systems, Buc Cedex, France. 510k (K012313) approval received on August 7, 2001] for use with the HiSpeed Advantage CT Scanner [GE Medical Systems, Milwaukee, WI. 510k (K940606) approval received on August 23, 1994].

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for virtual upper gastrointestinal endoscopy using 3-D computed tomography (CT) or 3-D magnetic resonance imaging (MRI). Local Coverage Determinations (LCDs) do not exist at this time.
(Accessed July 9, 2019)

REFERENCES

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
09/01/2019	**Application** • Added language to indicate this policy does not apply to the state of Tennessee; refer to the Medical Policy titled Virtual Upper Gastrointestinal Endoscopy (for Tennessee Only) **Supporting Information** • Updated *Clinical Evidence*, *CMS*, and *References* sections to reflect the most current information; no change to *Coverage Rationale* or *Applicable Codes* • Archived previous policy version CS130.G

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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