United Healthcare® Community Plan

UnitedHealthcare® Community Plan
Medical Policy

Virtual Upper Gastrointestinal Endoscopy
(for Louisiana Only)

Policy Number: CS130LA.~~HI~~**I**
Effective Date: ~~December 1, 2020~~**TBD**

➲ Instructions for Use

Application

This Medical Policy only applies to the state of Louisiana.

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 Guidelines may apply.

CPT Code	Description
76497	Unlisted computed tomography procedure (e.g., diagnostic, interventional)
76498	Unlisted magnetic resonance procedure (e.g., diagnostic, interventional)

CPT® is a registered trademark of the American Medical Association

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 3-D computed tomography (CT) or 3-D magnetic resonance imaging (MRI) is mainly **constituted of** ~~studied in clinical trials~~ **observational studies** and case reports. There were no ~~systematic reviews or~~ randomized controlled trials (RCTs) available **to assess clinical utility.** ~~Virtual upper GI endoscopy using CT is a hopeful method for the detection and evaluation of upper GI lesions.~~ Randomized controlled studies comparing it to conventional upper GI endoscopy are needed to determine its clinical value as well as safety and efficacy.

Wani et al. (2021) in an observational study ~~looked~~ **assessed** ~~at~~ **the diagnostic accuracy of multi-detector computed tomography (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 patients with endoscopically diagnosed and biopsy-proven gastric cancer were subjected to MDCT after adequate gaseous and hydro-distention of stomach. Multi-planar reformatted (MPR) as well as 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. General diagnostic accuracy of T staging in our study 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** ~~our~~ **the study was 93.75% with high specificity of 96% but low sensitivity of 66.7%. The authors concluded that** ~~Using~~ **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** ~~use~~ **clinical utility of virtual gastroscopy in the staging of gastric cancer.**

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.

~~Kim et al. (2015) updated the below Kim et al. (2012) to include 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 interpretinterpet the images~~.

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.

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~~ **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.

Chen et al. (2009) retrospectively compared the use of computed tomographic virtual gastroscopy (VG) to conventional optical **gastro endoscopy** ~~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.~~

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) prior to 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 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 August 3, 2022)http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October 9, 2020)

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 **Hi-Speed** HiSpeed Advantage CT Scanner [GE Medical Systems, Milwaukee, WI. 510k (K940606) approval received on August 23, 1994].

References

Almeida MFA, Verza L, Bitencourt AGV, et al. Computed tomography with a stomach protocol and virtual gastroscopy in the staging of gastric cancer: an initial experience. Radiol Bras. 2018 Jul-Aug;51(4):211-217.

Chen CY, Hsu JS, Wu DC, et al. Gastric cancer: preoperative local staging with 3D multi-detector row CT—correlation with surgical and histopathologic results. Radiology. 2007 Feb;242(2):472-82.

Kim JH, Eun HW, Hong SS, et al. Gastric cancer detection using MDCT compared with 2D axial CT: diagnostic accuracy of three different reconstruction techniques. Abdom Imaging. 2012 Aug;37(4):541-8.

Moschetta M, Scardapane A, Telegrafo M, et al. Differential diagnosis between benign and malignant ulcers: 320-row CT virtual gastroscopy. Abdom Imaging. 2012 Dec;37(6):1066-73.

Okten RS, Kacar S, Kucukay F, et al. Gastric subepithelial masses: evaluation of multidetector CT (multiplanar reconstruction and virtual gastroscopy) versus endoscopic ultrasonography. Abdom Imaging. 2012 Aug;37(4):519-30.

Pimentel-Nunes P, Libânio D, Bastiaansen BAJ, et al. Endoscopic submucosal dissection for superficial gastrointestinal lesions: European Society of Gastrointestinal Endoscopy (ESGE) Guideline – Update 2022. Endoscopy. 2022 Jun;54(6):591-622.

Ulla M, Cavadas D, Muñoz I, et al. Esophageal cancer: pneumo-64-MDCT. Abdom Imaging. 2010 Aug;35(4):383-9.

Wani AH, Parry AH, Feroz I, et al. Preoperative staging of gastric cancer using computed tomography and its correlation with histopathology with emphasis on multi-planar reformations and virtual gastroscopy. J Gastrointest Cancer. 2021 Jun;52(2):606-615.

Policy History/Revision Information

Date	Summary of Changes
TBD	**Supporting Information** • **Updated *Clinical Evidence* and *References* sections to reflect the most current information** • **Archived previous policy version CS130LA.H**

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.

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