INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

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

APPLICABLE LINES OF BUSINESS/PRODUCTS

This policy applies to Oxford Commercial plan membership.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.
Virtual upper gastrointestinal endoscopy is unproven and not medically necessary for detecting and evaluating upper gastrointestinal lesions due to insufficient clinical data from the peer-reviewed published medical literature to conclude that virtual upper gastrointestinal endoscopy is effective.

A limited number of studies of virtual upper gastrointestinal endoscopy have been published. Most studies involve a small number of patients and lack definitive patient selection criteria. Many of the studies have a serious shortcoming in that they assessed patients who were known or strongly suspected to have cancer or other upper gastrointestinal (GI) lesions. As a result, these studies may have overestimated the sensitivity of virtual endoscopy for gastric cancer detection. Randomized controlled studies comparing virtual upper GI endoscopy to conventional upper GI endoscopy are needed.

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 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 may apply.

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<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>76497</td>
<td>Unlisted computed tomography procedure (e.g., diagnostic, interventional)</td>
</tr>
<tr>
<td>76498</td>
<td>Unlisted magnetic resonance procedure (e.g., diagnostic, interventional)</td>
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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 thought by some to be useful in determining the cause of symptoms such as nausea, gastric reflux, abdominal pain, unexplained weight loss, and identifying inflammation, ulcers, precancerous conditions, and hernias.

Patients undergoing a virtual upper gastrointestinal endoscopy usually do not need anesthesia or sedation. Another advantage is that upon procedure completion, 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 biopsy during the procedure. (If a lesion is found, conventional upper GI endoscopy is necessary for excision or biopsy.

Okten et al. (2012) assessed the role of multidetector computed tomography (MDCT) with multiplanar 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.

Hwang et al. (2010) determined the accuracy of endoscopic ultrasonography (EUS) and multidetector-row computed tomography (MDCT) for the locoregional staging of gastric cancer. Among the 277 patients, the overall accuracy of EUS and MDCT for T staging was 74.7% and 76.9%, respectively. Among the 141 patients with visualized primary lesions on MDCT, the overall accuracy of EUS and MDCT for T staging was 61.7% and 63.8%, respectively. The overall accuracy for N staging was 66% and 62.8%, respectively. The performance of EUS and MDCT for large lesions and lesions at the cardia and angle had significantly lower accuracy than that of other groups. The authors concluded that for the preoperative assessment of individual T and N staging in patients with gastric cancer, the accuracy of MDCT was close to that of EUS. Both EUS and MDCT are useful complementary modalities for the locoregional staging of
gastric cancer. However, this study was not randomized or case controlled, limiting the significance of these conclusions.

Qumseya et al. (2013) conducted a meta-analysis and systematic review to prospectively compare the use of both virtual chromoendoscopy and chromoendoscopy with white-light endoscopy (WLE) and collection of random biopsies for surveillance of patients with Barrett’s esophagus (BE) to detect dysplasia. Fourteen studies with a total of 843 patients were included in the final analysis. It was noted that though white-light endoscopy (WLE) and collection of random biopsies is the recommended mode of surveillance, this approach does not definitively or consistently detect areas of dysplasia. It was surmised that advanced imaging technologies can increase detection of dysplasia and cancer. Results showed overall, that the advanced imaging techniques increased the diagnostic yield for detection of dysplasia or cancer by 34%. There was no noted significant difference between virtual chromoendoscopy and chromoendoscopy, based on Student t test analysis. Though the virtual chromoendoscopy compared favorable to the conventional chromoendoscopy, there was no evidence to show that virtual imaging was superior to the conventional study in any way. Additional randomized controlled studies comparing virtual upper GI endoscopy to conventional upper GI endoscopy are needed.

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.

Chen et al. (2007) prospectively evaluated the accuracy of multi-detector row computed tomographic (CT) images for preoperative staging of gastric cancer by using surgical and histopathologic results as reference standards. Fifty-five consecutive patients with gastric cancer underwent preoperative multi-detector row CT. Detection rates of primary tumors with transverse images, MPRs, and combinations of MPR and virtual gastroscopy images were 91%, 96%, and 98%, respectively. Overall accuracy in assessment of tumor invasion of the gastric wall (T stage) was significantly better with MPR images (89%) than with transverse images (73%). The authors concluded that multi-detector row CT with combined water and air distention can improve the accuracy of preoperative staging of gastric cancer. MPRs yield significantly better overall accuracy than transverse images for tumor staging but not for lymph node staging. However, this was a small study population, limiting the significance of this conclusion.

Kim et al. (2009) evaluated the usefulness of CT gastrography in preoperative localization of gastric cancer. CT gastrographic images of 213 patients with gastric cancer were evaluated for localization of tumor. A software module was developed to measure the shortest distances from tumor to the esophagogastric junction and to the pylorus on the images. After gastrectomy, these were compared with the shortest distances on surgical specimen. The localization rates of advanced and early gastric cancer were 100.0% and 88.8%, respectively. There were significantly linear relationship between the shortest distances measured on CT gastrographic images and those on surgical specimen. The authors concluded that CT gastrography could be a useful preoperative localization tool. Further research is needed that confirm this finding.

Kim et al. (2007) evaluated the use of multidetector computed tomographic (CT) esophagography to grade esophageal varices and differentiate between varices at low risk and those at high risk for bleeding, with endoscopy as the reference standard. Ninety patients with cirrhosis were prospectively enrolled and underwent endoscopy and CT esophagography. Sixty patients were determined to be in a low-risk group and 30 in a high-risk group for variceal bleeding at endoscopy. There was almost perfect agreement in grading esophageal varices between endoscopists. There was close correlation and substantial agreement between endoscopic and CT esophagographic grades. The authors concluded that the use of CT esophagography allows grading of esophageal varices and differentiation between low- and high-risk varices and shows better patient acceptance than endoscopy. The study did not obtain long-term follow-up data regarding whether the patients evaluated with CT esophagography eventually had esophageal variceal bleeding.

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
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 interobserver 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% (70 of 76) and 88.2% (67 of 76), respectively, for overall diagnosis of malignant gastric ulcers, and specificities of 91.9% (34 of 37) and 89.5% (34 of 38), respectively, for overall diagnosis of malignant gastric ulcers. Endoscopy was more sensitive in depicting malignancy according to ulcer base (85.5% [65 of 76] vs 68.4% [52 of 76]), and VG was more specific in depicting malignancy according to ulcer margin (78.4% [29 of 37] vs 63.2% [24 of 38]). 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.

The reviewed studies all have a serious shortcoming in that they assessed patients who were known or strongly suspected to have cancer or other gastric lesions. As a result, these studies may have overestimated the sensitivity of virtual endoscopy for gastric cancer detection. For the detection of early gastric carcinoma, the lower sensitivity of virtual endoscopy relative to conventional imaging techniques has significant clinical implications. Randomized controlled studies comparing it to conventional upper GI endoscopy are needed to determine its clinical value.

The American Cancer Society (2015) considers virtual endoscopy a fairly new procedure of which the best use has not yet been determined.

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 Web site by product and/or manufacturer name:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmncf/

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...
REFERENCES

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. [2016T0400K]


POLICY HISTORY/REVISION INFORMATION

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<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tr>
<td>11/01/2016</td>
<td>• Reformatted and reorganized policy; transferred content to new template</td>
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<tr>
<td></td>
<td>• Updated benefit considerations; added instruction to check the member specific</td>
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<tr>
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<td>benefit plan document and any federal or state mandates, if applicable, before</td>
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<td>• Updated supporting information to reflect the most current clinical evidence and</td>
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<td>references; no change to coverage rationale or list of applicable codes</td>
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