

Cohere Medicare Advantage Policy -Esophagogastroduodenoscopy (EGD) Clinical Guidelines for Medical Necessity Review

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Important Notices

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(Version 2)

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Medical Necessity Criteria

Service: Esophagogastroduodenoscopy (EGD)

Benefit Category

Diagnostic Tests (other)
Physicians' Services

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the <u>CMS Medicare Coverage Database</u> for the most current applicable CMS National Coverage. 54-59

- National Coverage Determination (NCD) Endoscopy (100.2)
- <u>Local Coverage Determination (LCD)</u>. <u>Diagnostic and Therapeutic Esophagogastroduodenoscopy (L33583)</u>
- Billing and Coding: Diagnostic and Therapeutic Esophagogastroduodenoscopy (A57063)
- <u>Local Coverage Determination (LCD)</u>. <u>Upper Gastrointestinal Endoscopy</u> (<u>Diagnostic and Therapeutic</u>) (<u>L35350</u>)
- Billing and Coding: Upper Gastrointestinal Endoscopy (Diagnostic and Therapeutic) (A57414)
- <u>Local Coverage Determination (LCD)</u>. <u>Upper Gastrointestinal Endoscopy and Visualization</u>. (<u>L34434</u>)

Recommended Clinical Approach

Esophagogastroduodenoscopy (EGD) is an upper intestinal endoscopy technique used to examine, obtain samples, or treat pathological conditions of the upper intestinal tract. EGD is performed with a lighted, flexible, fiberoptic instrument, usually less than 12 mm in diameter, passed through the cricopharynx. The patient receives conscious sedation, and a topical anesthetic may be applied to the posterior pharynx. The entire esophagus, stomach, and duodenum can be visualized with EGD. Endoscopic ultrasound (EUS) or transendoscopic ultrasound uses a transducer at the end of an

endoscope to obtain high-resolution images that improve visualization of the gastrointestinal tract and allow evaluation of adjacent structures, including the pancreas and biliary tree.

Diagnostic EGD is used to visualize the oropharynx, esophagus, stomach, and proximal duodenum and is useful for detecting conditions such as focal benign or malignant lesions, diffuse mucosal changes, luminal obstruction, abnormal motility, and extrinsic compression by contiguous structures. A diagnostic EGD allows the examiner to visualize abnormalities detectable by the technique and to photograph and collect a biopsy sample as appropriate. An endoscopic Doppler probe can be used as an adjunct diagnostic modality to assess local blood supply and efficacy of treatment and to stratify patients at higher risk of repeat upper gastrointestinal bleeding (UGIB). Pulsatile Doppler signals can indicate the presence and path of bleeding vessels. The probe can also determine if vessels were appropriately coagulated following endoscopic hemostasis. The absence of a Doppler signal is consistent with successful hemostasis of a bleeding lesion. Lesions with a persistent dopplerable signal have a higher risk for rebleeding.

EGD is generally considered a safe procedure, although bleeding, perforation, infection, acute pancreatitis, and sedation-related complications following the procedure have been reported in rare instances.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of esophagogastroduodenoscopy. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Cardiopulmonary-related adverse events account for over 60% of unplanned events during endoscopy.¹⁰
- Sore throat¹⁰
- Bleeding¹⁰
- Perforation (less than 1 in 2,500 cases)

- Infection due to translocation of endogenous bacterial flora (including Escherichia coli, Klebsiella, other Enterobacteriaceae, and enterococci) from one patient to another¹¹
- Acute pancreatitis⁷
- Sedation-related complications^{8,10}
- Dental trauma¹⁰
- To decrease GI peristalsis, the anti-cholinergic agent hyoscine-N-butyl bromide (HBB) is used in gastrointestinal (GI) endoscopy. Side effects of HBB may include sleepiness, vision changes, dry mouth, rapid heart rate, triggering of glaucoma, and severe allergies.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Fast and accurate visualization of inflammation, growths, ulcers, bleeding, and other abnormalities of the upper gastrointestinal (GI) tract.⁵
- Alternative EGD technique, such as nasal EGD, has been considered to reduce patients' discomfort and anxiety and avoid sedation-related adverse effects relative to peroral EGD.¹²
- Early detection, diagnosis, and surveillance of upper gastrointestinal malignancies.

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- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- → Esophagogastroduodenoscopy (EGD) is considered appropriate if ANY of the following is TRUE^{55,57,59}:
 - ◆ Gastroesophageal reflux disease (GERD) symptoms (e.g., heartburn, regurgitation, or chest pain) that persist despite treatment⁵⁻⁶; **OR**
 - ◆ A single screening exam for GERD with AT LEAST THREE of the following risk factors for concurrent Barrett's esophagus^{1.5}:
 - Prolonged GERD for more than 5 years; OR
 - The age of the patient is greater than 50 years; OR
 - Male gender; OR
 - Hiatal hernia⁷⁻⁸; **OR**
 - Current or past tobacco use; OR
 - Obesity; OR
 - Family history of Barrett's esophagus in a first-degree relative; OR
 - Family history of esophageal adenocarcinoma in a first-degree relative; OR
 - Planning for anti-reflux surgery⁹; OR
 - Nausea that is persistent and unexplained⁶; OR
 - Vomiting that is persistent and unexplained⁵⁻⁶; OR
 - ◆ Atypical chest pain after cardiac disease has been ruled out⁶; **OR**
 - Heartburn with alarm symptoms (e.g., anemia, GI bleeding, unexplained weight loss)^{8,10}; OR
 - ◆ Prolonged anorexia⁵; **OR**
 - Unexplained weight loss⁵; OR
 - ◆ Effects of nonsteroidal anti-inflammatory drug (NSAID) use¹¹; **OR**
 - Barrett's esophagus is present, and the patient requires ALL of the following¹²:
 - Routine surveillance of non-dysplastic disease every 1 to 5 years^{1,13}; AND
 - Reassessment during treatment to eliminate dysplasia (e.g., ablation, mucosal resection, mucosal dissection) every 3 to 6 months¹²; AND
 - Surveillance after completion of treatment for dysplasia when **ANY** of the following is **TRUE**¹:

- For low-grade dysplasia initially at 2-3 months after diagnosis, and then, if persistent, every 6 months for 1 year, then annually thereafter^{55,57,59}; OR
- For high-grade dysplasia every 3 months for 1 year, then every 6 months for 1 year, then annually thereafter; OR
- Swallowing symptoms including, but not limited to, ANY of the following 55,57,59:
 - Difficulty swallowing (e.g., dysphagia); OR
 - Pain while swallowing (odynophagia); OR
- Esophageal dysmotility based on barium radiography or esophageal manometry, when suggestive of achalasia¹⁴; OR
- ◆ Confirmation and specific histologic diagnosis of radiologically demonstrated lesions, including, but not limited to, **ANY** of the following 14-17:
 - Protrusions/growths from, within, or extrinsic to the mucosal wall; OR
 - Excavated lesions, such as erosions, ulcers, or diverticula;
 OR
 - Other mucosal abnormalities, including thickened fold(s) or asymmetric/symmetric narrowing(s) (stenoses/strictures);
 OR
 - Any lesion that requires biopsy for diagnosis^{55,57,59}; OR
- Clarification of location or pathology of a lesion during surgery¹⁸;
 OR
- Evaluation for possible gastric or duodenal polyps in patients with familial adenomatous polyposis or other at-risk hereditary syndromes (e.g., Lynch syndrome, juvenile polyposis syndrome, Peutz-Jegher's syndrome, MUTYH-Associated Polyposis [MAP], Li-Fraumeni syndrome, Cowden syndrome, hereditary gastric cancer syndrome)¹⁹; OR
- The patient is less than 60 years of age and has dyspepsia with ANY of the following:
 - Negative Helicobacter pylori test and no response to proton pump inhibitor (PPI) therapy^{5,20-21}; OR
 - Equivocal results from non-invasive *Helicobacter pylori* testing and need for gastric biopsy²¹⁻²²; **OR**

- A one-time screening in a patient with a family history of upper GI malignancy in a first-degree relative; OR
- Lymphadenopathy (e.g., supraclavicular, periumbilical); OR
- Palpable abdominal mass; OR
- Alarm symptoms (e.g., anemia, GI bleeding, unexplained weight loss, dysphagia/odynophagia); OR
- The patient is 60 years of age or older and has dyspepsia; OR
- ◆ Peptic ulcer disease with ANY of the following²³⁻²⁴:
 - Persistent or recurrent symptoms despite treatment; OR
 - For follow-up of esophageal, gastric or stomal ulcers to demonstrate healing (frequency of follow-up EGDs is variable, but every two to four months until healing is demonstrated is reasonable)^{55,57,59}; OR
 - Follow-up of duodenal ulcer or other lesions of the upper gastrointestinal tract that have resulted in serious consequences (e.g., hemorrhage)^{55,57,59}; OR
- Erosive reflux esophagitis with ANY of the following^{2,23}:
 - Persistent or recurrent symptoms despite appropriate GERD treatment; OR
 - To document healing after treatment of LA grade C or D esophagitis and to exclude the development of Barrett's esophagus; OR
- Surveillance as determined by the endoscopist for or suspected recurrence of prior upper GI cancer or pre-cancer, including ANY of the following²³:
 - Squamous cell carcinoma of the esophagus; OR
 - Adenocarcinoma of the esophagus; OR
 - Adenocarcinoma or mucosa-associated lymphoma (MALT) of the stomach; OR
 - Adenocarcinoma of duodenum or ampulla; OR
 - Stromal/neuroendocrine tumor of the esophagus, stomach, or duodenum; OR
 - Other subepithelial pre-malignant lesion of the esophagus, stomach, or duodenum; OR
 - Adenomatous polyp of stomach, duodenum, or ampulla;
 OR
 - Dysplasia (low or high grade) in patients with gastric intestinal metaplasia or chronic atrophic gastritis; OR

- Confirmed or suspected eosinophilic esophagitis (EoE) for ANY of the following²⁵:
 - Initial exam for suspected EoE for evaluation of dysphagia, GERD symptoms refractory to PPI therapy, or history of esophageal food bolus impaction; OR
 - Follow-up exam to reassess esophageal histology for confirmed EoE, after treatment (e.g., food allergen restriction, PPI therapy, steroid therapy, anti-interleukin therapy); OR
 - Follow-up exam to reassess esophagus when symptoms recur on previously effective therapy; OR
- ◆ Evaluation of chronic diarrhea to identify an upper GI etiology when small bowel disease is suspected (55,57,59); **OR**
- Suspected celiac disease based on ANY of the following²⁶:
 - Typical signs or symptoms (e.g., abdominal pain, diarrhea, constipation, weight loss without intent, iron deficiency anemia); OR
 - Abnormal celiac serology including ANY of the following:
 - Elevated tissue transglutaminase immunoglobulin A (TTG IgA) with normal total IgA; OR
 - Elevated endomysial IgA with normal total IgA; OR
 - Elevated deamidated anti-gliadin IgG with IgA deficiency; OR
 - The patient is at a high-risk based on celiac human leucocyte antigen (HLA) analysis; OR
- Known celiac disease with ANY of the following²⁶:
 - The patient has been on a gluten-free diet for at least 1 year and requires histologic confirmation of remission; **OR**
 - Symptoms persist despite adherence to a gluten-free diet for at least 6 months; OR
- ◆ Acute injury including, but not limited to, ANY of the following:
 - Caustic agent ingested 55,57,59; **OR**
 - Foreign object ingested²⁷; OR
- ◆ Evaluation for esophagogastric varices (swollen veins [varices] in the esophageal or gastric wall) due to suspicion for or confirmation of liver cirrhosis or portal hypertension²⁸; **OR**
- Routine screening (every 3 years) or surveillance (every 1-2 years) of non-bleeding esophagogastric varices²⁸⁻²⁹; OR

- ◆ Evaluation of GI bleeding and **ANY** of the following 55,57,59:
 - Upper GI symptoms; OR
 - Presumed chronic blood loss (iron deficiency anemia, positive fecal occult blood test, or both) when investigation of colon is negative³⁰; OR
 - Active bleeding is present (hematemesis, melena, or hematochezia); OR
 - Recent active bleeding; OR
 - Suspected aorto-enteric fistula; OR
 - Suspected portal hypertension; OR
 - Rebleeding occurs after acute self-limited blood loss; OR
 - Rebleeding occurs after recent endoscopic therapy; OR
 - Surgery is being considered; OR
- Suspected inflammation of the upper gastrointestinal (GI) tract from etiologies including, but not limited to, inflammatory myositis, Crohn's disease, ulcerative colitis, inflammatory bowel disease (IBD), and acute graft versus host disease³¹⁻³²; OR
- Conditions in which upper GI pathology might modify other planned management, such as patients with ANY of the following⁵:
 - Organ transplantation is planned; OR
 - Long-term anticoagulation therapy; OR
 - Long-term nonsteroidal anti-inflammatory drug therapy for arthritis; OR
 - Cancer of the head and neck; OR
 - Bariatric surgery is planned; OR³³
- When sampling of duodenal or jejunal tissue or fluid is indicated^{55,57,59}; OR
- ◆ Therapeutic treatment of **ANY** of the following ^{55,57,59}:
 - Treatment of bleeding from lesions; OR
 - Sclerotherapy and/or band ligation for bleeding from esophageal or gastric varices; OR
 - Removal of selected polypoid lesions; OR
 - Dilatation of strictures in the upper intestinal tract; OR
 - Palliative therapy of stenosing neoplasms; OR
 - Endoscopic therapy of intestinal metaplasia; OR

- Management of operative complications (e.g., dilatation of anastomotic strictures, stenting of anastomotic disruption, fistula, or leak in selected circumstances); OR
- ◆ Serial follow-up of **ANY** of the following^{55,57,59}:
 - Follow-up and treatment of patients with esophageal varices or bleeding lesions requiring recurrent therapy; OR
 - Follow-up and treatment of esophageal strictures requiring guidewire dilation; OR
 - Follow-up for removal of percutaneous gastrostomy tube (PEG); OR
- ◆ **EGD with endoscopic ultrasound** is considered appropriate for **ANY** of the following ^{55,57,59}:
 - Staging tumors of the GI tract, pancreas, and bile ducts; OR
 - Evaluating abnormalities of the GI tract wall or adjacent structures; OR
 - Tissue sampling of lesions within, or adjacent to, the wall of the GI tract; OR
 - Evaluation of abnormalities of the pancreas, including masses, pseudocysts and chronic pancreatitis; OR
 - Evaluation of abnormalities of the biliary tree; OR
 - Providing endoscopic therapy of the GI tract under ultrasonographic guidance; OR
 - Staging of tumors shown to be metastatic only when the results are the basis for therapeutic decision; OR
 - Providing access into the bile ducts or pancreatic duct, either independently or as an adjunct to ERCP; OR
 - For transmural injection of therapeutic agents (e.g., ethanol, phenol) including ANY of the following:
 - Neurolytic agent (e.g., botulinum toxin, ethanol, phenol) into the celiac plexus for ANY of the following:
 - Palliate chronic pain related to upper abdominal cancer (including pancreatic cancer); OR
 - Relieve chronic pain related to chronic pancreatitis that is unresponsive to medical therapy; OR

- Identify/predict surgical success in patients with median arcuate ligament syndrome (MALS); OR
- Botulinum toxin into the esophageal muscularis for treatment of achalasia; OR
- For transmural delivery of targeted cancer treatment (eg radiofrequency ablation, chemotherapy); OR
- For transmural placement of fiducial markers in tumors for surveillance or presurgical marking.

Non-Indications

- → Diagnostic esophagogastroduodenoscopy (EGD) is not considered appropriate if ANY of the following is TRUE^{55,57,59}:
 - Blockage in the esophagus, stomach, or duodenum is previously established; OR
 - Surveillance of healed, benign disease, such as gastric or duodenal ulcer or benign esophageal strictures¹; OR
 - ◆ Confirming Helicobacter pylori eradication; OR
 - Cancer surveillance in patients with pernicious anemia, treated achalasia, or prior gastric resection¹; OR
 - ◆ Patients with significant cardiac arrhythmia or recent (within the last 3-6 months) myocardial infarction¹; **OR**
 - Perforated bowel; OR
 - ◆ Peritonitis; OR
 - ◆ Toxic megacolon in an unstable patient; OR
 - Perforated viscus is known or suspected; OR
 - ◆ Before bariatric surgery in asymptomatic individuals; **OR**
 - ◆ Confirming placement of gastric band; OR
 - Diagnosing laryngopharyngeal reflux; OR
 - Optical endomicroscopy is requested.

*Note: Patients undergoing dilations, percutaneous endoscopic gastrostomy [PEG], polypectomy, endoscopic sphincterotomy, endoscopic ultrasound-guided fine-needle aspiration [FNA], laser ablation, and coagulation are at higher risk for bleeding, and adjustment of anticoagulation may be necessary.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

| CPT/HCPCS Code | Code Description | |
|----------------|--|--|
| 43239 | Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple | |
| 43235 | Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure) | |
| 43237 | Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures | |
| 43238 | Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures) | |
| 43242 | Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis) | |
| 43252 | Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy | |
| 43253 | Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where | |

| the jejunum is examined distal to the anastomosis) |
|---|
| Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis. |

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Sengupta et al. (2024) documented the recommendations of a panel of experts from the American College of Gastroenterology and the Society of Abdominal Radiology, comparing the advantages and limitations of endoscopic versus radiologic diagnostic examinations in patients with gastrointestinal bleeding. The authors noted that unless contraindicated, the evaluation of non-variceal upper gastrointestinal bleeding begins with EGD, with the ideal timing for the procedure being within 24 hours of presentation due to the increased risk of mortality when performed greater than 24-36 hours.³⁷

The European Society of Gastrointestinal Endoscopy (ESGE) published a technical review of endoscopic ultrasound in 2022. The authors discussed several scenarios wherein endoscopic ultrasound is the optimal diagnostic or therapeutic modality, such as the drainage of fluid collections, biopsy of suspicious lesions, and surveillance and staging of neoplasms.³⁸

A 2022 American Society of Gastrointestinal Endoscopy (ASGE) standards of practice review of adverse events associated with EGD found this procedure to be well-tolerated and safe, with more than 7 million esophagogastroduodenoscopies taking place each year in the United States. The overall incidence of the most insidious complications, including perforation, cardiopulmonary sequelae, and bleeding, remains extraordinarily low. Rates of perforation, for example, have been estimated at 1 in 25,000. Bleeding requiring emergency department care or inpatient stay for resolution has been evaluated at 80 in 100,000 patients within 30 days of the EGD.⁵

The American College of Gastroenterologists (ACG) and the American Gastroenterological Association (AGA) have published several recent guidelines pertaining to the use of EGD in high-volume clinical scenarios, such as peptic disease, Barrett's esophagus, and celiac disease. This robust guidance has been utilized where appropriate to synthesize this policy. 16,24,26

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Clinical Guideline Revision History/Information

| Original Date: February 6, 2025 | | | | |
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| Review History | | | | |
| Version 2 | 3/13/2025 | Added previously missing CMS guidance (NCD 100.2, LCD L34434). Modified criteria so as not to be perceived as more stringent than CMS (i.e., loosed surveillance timeframe of non-dysplastic Barrett's to 1-3 years, utilized CMS language around peptic ulcer disease, simplified, added CMS indication for need for tissue/fluid sampling, simplified definition of "recent bleeding", utilized CMS indications for therapeutic EGD use, serial follow-up, and esophageal ultrasound). Rewrote medical evidence section for relevance. Added references | | |