

# Upper Gastrointestinal Endoscopy and Visualization

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***L34434***

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# Upper Gastrointestinal Endoscopy and Visualization

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## Coverage Indications

A. Indications which support EGD(s) for diagnostic purposes:

1. upper abdominal distress which persists despite an appropriate trial of therapy;
2. upper abdominal distress associated with symptoms and/or signs suggesting serious organic disease (e.g., anorexia and weight loss);
3. dysphagia or odynophagia;
4. esophageal reflux symptoms which are persistent or recurrent despite appropriate therapy;
5. persistent vomiting of unknown cause;
6. cirrhosis;
7. other symptoms of disease in which the presence of upper GI pathology might modify other planned management. Examples include patients with a history of GI bleeding who are scheduled for organ transplantation; long-term anticoagulation; and chronic non-steroidal therapy for arthritis. Other examples include patients with cirrhosis being considered for liver transplantation and those with cancer of the neck.
8. Radiologic findings of:
  - a. a suspected neoplastic lesion, for confirmation and specific histologic diagnosis;
  - b. gastric or esophageal ulcer; or
  - c. evidence of upper GI tract stricture or obstruction.
9. The presence of GI bleeding:
  - a. in most actively bleeding patients; when surgical therapy is contemplated;
  - b. when rebleeding occurs after acute self-limited blood loss or after endoscopic therapy;
  - c. when portal hypertension (HTN) or aorto-enteric fistula (AEF) is suspected; or
  - d. for presumed chronic blood loss and for iron deficiency anemia when colonoscopy is negative.<sup>10</sup>

- e. when sampling of duodenal or jejunal tissue or fluid is indicated;
- f. to assess acute injury after caustic agent ingestion;
- g. to assess diarrhea in patients suspected of having small-bowel disease (e.g., celiac disease);
- h. intraoperative EGD when necessary to clarify the location or pathology of a lesion.

B. Indications which support EGD(s) for therapeutic purposes:

1. treatment of bleeding from lesions such as ulcers, tumors, vascular malformations (e.g., electrocoagulation, heater probe, laser photocoagulation or injection therapy);
2. sclerotherapy and/or band ligation for bleeding from esophageal or proximal gastric varices or banding of varices;
3. foreign body removal;
4. removal of selected polypoid lesions;
5. dilation of stenotic lesions (e.g., with transendoscopic balloon dilators or dilating systems employing guide wires);
6. palliative therapy of stenosing neoplasms (e.g., laser,
7. bipolar electrocoagulation, stent placement);
8. management of achalasia (e.g., botulinum toxin, balloon dilatation);
9. endoscopic therapy of intestinal metaplasia;
10. management of operative complications (e.g., dilation of anastomotic strictures, stenting of anastomotic disruption, fistula, or leak in selected circumstances).

C. Covered Transesophageal Endoscopic Procedure for the Treatment of GERD

- I. Transoral incisionless fundoplication (TIF) is a transesophageal endoscopic procedure for the treatment of GERD that is covered under this Local Coverage Determination (LCD).<sup>4</sup> Current published peer reviewed literature supports the safety and efficacy of the *EsophyX*® device used in this procedure.
  - ®*EsophyX* is a device used in a TIF procedure to repair the natural antireflux barrier and is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia  $\leq 2$  cm in size. *EsophyX*® includes SerosaFuse® Fasteners and consists of a flexible fastener delivery system comprised of 3 elements: a stylet, a pusher rod, and a delivery tube. The *EsophyX*® procedure is designed for use in transoral tissue approximation, full thickness serosa to

serosa plications and to construct valves in the GI tract which are used. The procedure is performed with the patient under general anesthesia.

- D. Sequential or periodic diagnostic EGD may be indicated for an appropriate number of procedures for active or symptomatic conditions:
1. follow-up of selected esophageal, gastric or stomal ulcers to demonstrate healing (frequency of follow-up EGD is variable, but every 2 to 4 months until healing is demonstrated is reasonable);
  2. follow-up in patients with prior adenomatous gastric polyps (approximate frequency of follow-up EGD's would be every 1 to 4 years depending on the clinical circumstances, with occasional patients with sessile polyps requiring every 6-month surveillance initially);
  3. follow-up for adequacy of prior sclerotherapy and/or band ligation of esophageal varices (approximate frequency of follow-up EGD's is variable depending on the state of the patient but every 6 to 24 months is reasonable after the initial sclerotherapy/banding sessions are completed);
  4. follow-up of Barrett's esophagus (approximate frequency of follow-up EGD's is 1 to 2 years with biopsies, unless dysplasia or atypia is demonstrated, in which case a repeat biopsy in 2 to 3 months might be indicated); or
  5. follow-up in patients with familial adenomatous polyposis (FAP) (approximate frequency of follow-up EGD's would be every 2 to 4 years, but might be more frequent, such as every 6 to 12 months if gastric adenomas or adenomas of the duodenum were demonstrated).
- E. Endoscopic retrograde cholangiopancreatography (ERCP) is generally indicated for the following biliary and pancreatic conditions:
1. Traumatic pancreatitis to accurately localize the injury and provide endoscopic drainage;
  2. pancreatic duct stricture evaluation
  3. bile duct stones extraction in severe gallstone induced pancreatitis;
  4. Detecting pancreatic ductal changes in chronic pancreatitis and also the presence of calcified stones in the ductal system. A pancreatogram may be performed and is likely to be abnormal in chronic alcoholic pancreatitis but less so in non-alcoholic induced types;
  5. Detecting gallstones in symptomatic patients whose oral cholecystogram and gall-bladder ultrasonograms are normal; and

6. Radiologic imaging suggestive of common bile duct stones or other potential hepatobiliary pathology.
- F. Indications for endoscopic ultrasound:
1. staging tumors of the GI tract, pancreas, and bile ducts; evaluating abnormalities of the GI tract wall or adjacent structures;
  2. tissue sampling of lesions within, or adjacent to, the wall of the GI tract;
  3. evaluation of abnormalities of the pancreas, including masses, pseudocysts and chronic pancreatitis;
  4. evaluation of abnormalities of the biliary tree;
  5. providing endoscopic therapy of the GI tract under ultrasonographic guidance;
  6. staging of tumors shown to be metastatic only when the results are the basis for therapeutic decision;
  7. providing access into the bile ducts or pancreatic duct, either independently or as an adjunct to ERCP.

## Limitations

- A. Noncovered Transesophageal Endoscopic Procedures for the Treatment of Gastroesophageal Reflux Disease (GERD)
1. Some transesophageal endoscopic procedures for the treatment of GERD are not currently covered as the safety and efficacy of these procedures cannot be established by review of the available published peer reviewed literature.
  2. Several endoscopic or endoluminal procedures have been designed for the treatment of GERD. There are currently 3 transesophageal endoscopic approaches used to treat GERD including endoscopic plication or suturing devices; radiofrequency energy; and submucosal injection or implantation of biocompatible bulking agents or polymer prosthetics to treat GERD without surgery.
  3. Endoscopic plication or suturing devices that have received 510(k) marketing clearance from the Food and Drug Administration (FDA) for the treatment of GERD are all performed as outpatient procedures and include the following:
    - a. *EndoCinch*®, also titled Bard Endoscopic Suturing System (BESS), is a plication procedure using a flexible endoscope which has a device similar to a miniature sewing machine attached inside the tip of the scope. The scope is passed through the throat of the patient while they are under mild sedation. Sutures are placed on both sides of the esophagus at the junction of

the esophagus and the stomach. The ends of the suture material are tied together to form pleats or folds which are used to prevent acid from flowing back up into the esophagus.

- b. *Plicator*® is a device that uses an endoscope passed into the stomach in conjunction with a flexible gastroscope. The *Plicator*® is used to grasp and fold the gastric cardia, fixating it with a pre-tied suture at the junction of the stomach and esophagus. This tightens the valve that provides a natural barrier to gastric reflux. The full thickness tissue plication restructures the gastroesophageal flap valve enabling serosa to serosa tissue healing to prevent reflux. The procedure is performed using conscious sedation.
4. Submucosal injection or implantation of biocompatible bulking agents or polymer prosthetics are not FDA approved for the treatment of GERD. Some of the products/procedures are currently under investigation and may be FDA approved for the treatment of GERD in the future.
- a. Enteryx is a biocompatible nonbiodegradable liquid polymer which is implanted via injections during endoscopy into the inside muscle wall of the esophagus close to the lower esophageal sphincter (LES). The liquid thickens into a sponge-like substance within the muscle enabling the sphincter to act as a barrier to reflux of the stomach acids. Enteryx received pre-market approval from FDA in 2003, however, Boston Scientific Corporation issued a recall of the product in 2005 due to serious adverse events prior to receiving final FDA approval. Once implanted, Enteryx cannot be removed.
  - b. Gatekeeper Reflux Repair System endoscopically introduces an expandable hydrogen prosthesis into the submucosa of the LES zone. The biocompatible material is made of a substance similar to the substance used to make contact lenses and upon insertion the prosthesis is dry but expands when it comes into contact with moisture. Gatekeeper can be removed if complications occur. This product is not FDA approved and is not currently available in the United States.
  - c. Plexiglas Polymethylmethacrylate (PMMA) implantation is an endoscopic procedure which involves injection of gelatinous inert polymer material in the form of beads into the submucosa of the proximal LES zone to provide bulking support to the sphincter and decrease transient relaxation of the LES. This product is not FDA approved and is not currently available in the United States.
  - d. Durasphere is a bulking agent made of pyrolytic carbon-coated zirconium oxide spheres which received FDA approval in 1999 for the treatment of

stress urinary incontinence in women. It is currently also approved for the treatment of fecal incontinence. Durasphere GR is a product listed as an investigational device by the manufacturer which is in clinical trial for use in the treatment of GERD.

5. All of the ancillary procedures and services associated with the treatment procedures described above, such as EGD, are also noncovered when performed in conjunction with any of the procedures listed above, and should be billed and documented on the same claim as the non-covered procedure.
- B. Endoscopic retrograde cholangiopancreatography (ERCP) is generally **NOT** indicated for the following conditions:
  1. Diagnosis of pancreatitis except for gallstone pancreatitis; or
  2. Early stages or in acute pancreatitis and could possibly exacerbate this condition.

## Procedure Code Table

**Table 1. LCD L34434 Upper Gastrointestinal Endoscopy and Visualization Associated Procedure Codes**

Code	Description
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)
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple
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)
43259	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



## Coverage and Tracking Information

**Table 1. LCD L34434 Upper Gastrointestinal Endoscopy and Visualization Coverage Areas**

Service Level	Covered States
Inpatient	AL, GA, TN, SC, VA, WV, NC
Outpatient	AL, GA, TN, SC, VA, WV, NC

**Table 2. LCD L34434 Upper Gastrointestinal Endoscopy and Visualization Tracking Information**

Information	Description
Revision Effective Date	For services performed on or after 08/14/2022
Original Effective Date	For services performed on or after 10/01/2015

## References

- [1] Centers for Medicare and Medicaid Services. (2022). Local Coverage Determination (LCD) Upper Gastrointestinal Endoscopy and Visualization L34434 . Retrieved: January 2023.  
<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=34434&ver=63>

## Definitions

**Achalasia** is a condition in which the muscles of the lower part of the esophagus fail to relax, preventing food and liquid from passing into the stomach.

**Adenomatous polyp** is a polyp that consists of benign neoplastic tissue derived from the glandular epithelium.

**Aortoenteric fistula (AEF)** are abnormal connections between the aorta or its major arterial branches and the GI tract and can occur with or without previous aortic surgery.

**Band ligation** is a procedure that uses elastic bands to treat enlarged veins, or varices, in the esophagus.

**Barrett's esophagus:** is a metaplastic change of the esophageal epithelium from normal stratified squamous to columnar with goblet cells, resulting from chronic inflammation and repair. The presence of metaplastic epithelium increases risk for esophageal dysplasia and cancer.

**Cholecystogram** is an x-ray procedure used to look for gallstones in the gallbladder or bile duct.

**Cirrhosis** is widespread disruption of normal liver structure by fibrosis and the formation of regenerative nodules caused by any of various chronic progressive conditions affecting the liver.

**Dysphagia** refers to any difficulty with swallowing, including occult or asymptomatic impairments. Dysphagia is classified according to the location of the problem as oropharyngeal (localized to

the oral cavity or pharynx, not just the oropharynx) or esophageal. It may also be classified as mechanical (due to a structural lesion of the foodway) or functional (caused by a physiologic abnormality of foodway function).

**Endoscopic retrograde cholangiopancreatography (ERCP)** is a procedure that uses an endoscope to examine and x-ray the pancreatic duct, hepatic duct, common bile duct, duodenal papilla, and gallbladder.

**Esophagogastroduodenoscopy (EGD)** is a procedure to examine the inside of the esophagus, stomach, and duodenum.

**Familial Adenomatous Polyposis (FAP)** is an inherited disease of the large intestine marked by the formation especially in the colon and rectum of numerous glandular polyps which typically become malignant if left untreated.

**Gastroesophageal reflux disease (GERD)** is a condition, in which stomach contents, including gastric acid, refluxes into the esophagus, which causes troublesome symptoms, complications, or both. GERD may lead to esophagitis. Erosive esophagitis also called reflux esophagitis, is inflammation of the lining of the esophagus, caused by irritation of the esophagus and inflammation of the lining of the esophagus from stomach acid. Mild erosive esophagitis is classified as Los Angeles grade A/B, while severe erosive esophagitis is classified as Los Angeles grade C/D. Esophagitis is classified in severity by the Los Angeles Classification

**Odynophagia:** is pain while swallowing.

**Pancreatitis** is inflammation of the pancreas.

**Portal hypertension** is elevated blood pressure in the portal vein and the smaller veins that branch off from it. The portal venous system drains blood from the stomach, intestines, pancreas and spleen into the liver through the portal vein.

**Transoral incisionless fundoplication** is a minimally invasive procedure to treat acid reflux and other symptoms associated with chronic gastroesophageal reflux disease (GERD).

## Disclaimer & Legal Notice

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The purpose of the HealthHelp's clinical guidelines is to assist healthcare professionals in selecting the medical service that may be appropriate and supported by evidence to safely improve outcomes. Medical information is constantly evolving, and HealthHelp reserves the right to review and update these clinical guidelines periodically. HealthHelp reserves the right to include in these guidelines the clinical indications as appropriate for the organization's program objectives. Therefore the guidelines are not a list of all the clinical indications for a stated procedure, and associated Procedure Code Tables may not represent all codes available for that state procedure or that are managed by a specific client-organization.



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## Clinician Review

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