LCD Database ID Number
L33296

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09101 – Florida
09102 – Florida
09201 – Puerto Rico/Virgin Islands
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC – Part A and B

LCD Title
Noncovered Procedures - Endoscopic Treatment of Gastroesophageal Reflux Disease (GERD)

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CMS National Coverage Policy

Language quoted from CMS National Coverage Determination (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.
Indications and Limitations of Coverage and/or Medical Necessity

The intent of this local coverage determination (LCD) is to communicate the non-coverage for certain procedures used for the endoscopic treatment of gastroesophageal reflux disease (GERD).

Currently, the published available evidence based on peer-reviewed literature and other pertinent sources is not sufficient to establish the long-term safety and efficacy of transesophageal endoscopic anti-reflux procedures as treatment for GERD. Therefore, this LCD finds the transesophageal endoscopic treatment methods not reasonable and necessary and not eligible for reimbursement at this time.

GERD is a condition caused by reflux of the gastric content into the esophagus which can lead to esophageal damage or serious conditions including esophagitis, strictures, Barrett’s metaplasia, and adenocarcinoma of the esophagus. The two main factors involved in esophageal reflux are the gastric contents and the anti-reflux mechanism, which includes the lower esophageal sphincter (LES) and the anatomic configuration of the gastroesophageal junction.

The goal of treatment for GERD is to reduce gastroesophageal reflux. Current treatment options of GERD include lifestyle modification, and medical treatment with pharmacotherapy, and surgery.

Lifestyle modification includes:

- Dietary change
- Elevation of the head of the bed
- Smoking cessation
- Sitting upright for at least 30 minutes after eating

Pharmacologic acid suppression using proton pump inhibitor (PPI) therapy is widely used for patients with GERD without untoward effects and with a high level of effectiveness.
Pharmacotherapies include:

- histamine type-2 receptor antagonists (H2RAs)
- proton pump inhibitors (PPIs)
- supplemental acid-neutralizing agents
- over-the-counter (OTC) remedies (antacids, combined antacid/alginate acids, H2RAs)

When the initial treatments are not effective or not tolerated, anti-reflux surgery can be used to treat GERD. The current standard surgical therapy for GERD is esophagogastric fundoplication which include procedures such as Nissen, Belsey, or Dor fundoplication, all of which are performed as laparoscopic or open inpatient surgical procedures. The surgical procedures reconstruct the weakened flap valve at the junction of the stomach and the esophagus.

Esophagogastric fundoplasty is performed either as a complete (360°) or partial encircling of the gastroesophageal junction. The fundoplication procedure involves pulling the fundus of the stomach around the lower end of the esophagus by pushing it from left to right behind the gastroesophageal junction.

Surgical treatment includes:

- Nissen fundoplication is a complete wrapping procedure in which the gastric fundus is sutured to itself.
- Belsey, Dor, and Toupet fundoplications are partial wrapping procedures in which the gastric fundus is sutured to the adjacent esophagus.

Limitations of Coverage

Transesophageal Endoscopic Procedures

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.

Several endoscopic or endoluminal procedures have been designed for the treatment of GERD. There are currently three 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.

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:

- **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.

- **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 value enabling serosa to serosa tissue healing to prevent reflux. The procedure is performed using conscious sedation.

Radiofrequency (RF) energy is delivered through an endoscope as an outpatient procedure with the patient under conscious sedation. The FDA approved one endoscopic RF procedure in 2000.

- **The Stretta® procedure** uses a flexible endoscope to advance a radiofrequency (RF) delivery balloon-tipped catheter. The Stretta® catheter includes four sharp probes on the outside of the balloon which discharge controlled
levels of RF energy into the LES muscle and the gastric cardia thereby creating thermal lesions on the targeted areas. The lesions heal and tighten the LES muscles decreasing the possibility of stomach acid refluxing into the stomach.

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.

- **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 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 premarket 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.

- **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.

- **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.

- **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.

**Type of Bill Code**

13x Hospital Outpatient

85x Critical Access Hospital

**Revenue Codes**

0360 Operating Room Services - General Classification

0361 Operating Room Services - Minor Surgery

0750 Gastro-Intestinal (GI) Services - General Classification

**CPT/HCPCS Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>43201</td>
<td>Esophagoscopy flexible, transoral; with directed submucosal injection(s), any substance</td>
</tr>
<tr>
<td>43236</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance</td>
</tr>
<tr>
<td>43241</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube or catheter</td>
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</tbody>
</table>
Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease

Unlisted procedure, esophagus

All of the services associated with these treatment procedures, such as esophagogastroduodenoscopy (EGD), are also noncovered, and should be billed and documented on the same claim. All unlisted procedure codes billed for services are subject to development and medical review.

ICD-10 Codes that Support Medical Necessity

N/A

Diagnoses that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Associated Information

Documentation Requirements

In order for a noncovered service/procedure listed in this LCD to be evaluated for coverage, a reconsideration request to remove the service/procedure from the list must be submitted in writing to First Coast Service Options, Inc. Medical Policy Department. Copies of published evidence (e.g., peer-reviewed medical literature, published studies, etc.) must also be included with the reconsideration request.

Utilization Guidelines

N/A

Sources of Information and Basis for Decision

FCSO reference LCD number(s): L32485


EndoGastric Solutions, Inc., Effective Solution for Chronic Acid Reflux. EsophyX ® TIF® Package Insert for the Device. Retrieved From EndoGastric Solutions, Inc. Web site at [www.EndoGastricSolutions.com](http://www.EndoGastricSolutions.com)

Food and Drug Administration (FDA). (N.D.) Advice for patients with Enteryx® for gastroesophageal reflux disease (1st advisory). Retrieved from [http: www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PatientAlerts/ucm064748.htm](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PatientAlerts/ucm064748.htm)


Other Contractor’s LCDs.


**Start Date of Comment Period**

N/A

**End Date of Comment Period**

N/A
Start Date of Notice Period
N/A

Revision History

Revision History Number: R2

Revision Number: 2
Publication: January 2018 Connection
LCR A/B2018-002

Explanation of Revision: Based on a reconsideration request, a decision was made to revise this LCD to remove CPT code 43210. Also, the paragraph that describes EsophyX® is removed from the “Limitations of Coverage” section of the LCD. In addition, the “Sources of Information and Basis for Decision” section of the LCD was updated with eight full text published sources from this reconsideration request for CPT code 43210 for the Esophyx® system for the treatment of GERD. The effective date of this revision is based on date of service.

Revision History Number: R1

Revision Number: 1
Publication: December 2015 Connection
LCR A/B2016-016

Explanation of Revision: Annual 2016 HCPCS Update. HCPCS code C9724 was deleted and replaced with CPT code 43210. The effective date of this revision is based on date of service

Revision Number: Original

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.

Related Documents

A54815 - Noncovered Procedures - Endoscopic Treatment of Gastroesophageal Reflux Disease (GERD) Codeguide

LCD Attachments

N/A