Local Coverage Determination (LCD):
Noncovered Procedures - Endoscopic Treatment of Gastroesophageal Reflux Disease (GERD) (L33296)

Contractor Information

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction</th>
<th>State(s)</th>
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<tr>
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<td>A and B MAC</td>
<td>09101 - MAC A</td>
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<td>Florida</td>
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LCD Information

Document Information

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<th>LCD ID</th>
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<td>L33296</td>
<td>For services performed on or after 10/01/2015</td>
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<th>Source Proposed LCD</th>
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<tr>
<td>Noncovered Procedures - Endoscopic Treatment of Gastroesophageal Reflux Disease (GERD)</td>
<td>N/A</td>
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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/alginic 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 esophagogastrectomy fundoplasty 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.

Esophagogastrectomy 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, fixing 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 PolymethyImethacrylate (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.

**Summary of Evidence**
N/A

**Analysis of Evidence (Rationale for Determination)**
N/A

**Coding Information**

**Bill Type Codes:**
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

- 013x Hospital Outpatient
- 085x Critical Access Hospital

**Revenue Codes:**
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

- 0360 Operating Room Services - General Classification
- 0361 Operating Room Services - Minor Surgery
- 0750 Gastro-Intestinal (GI) Services - General Classification

**CPT/HCPCS Codes**

**Group 1 Paragraph:** 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.

**Group 1 Codes:**

<table>
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<th>Description</th>
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<tr>
<td>43201</td>
<td>ESOPHAGOSCOPY, FLEXIBLE, TRANSORAL; WITH DIRECTED SUBMUCOSAL INJECTION(S), ANY SUBSTANCE</td>
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<tr>
<td>43236</td>
<td>ESOPHAGOGASTRODUODENOSCOPY, FLEXIBLE, TRANSORAL; WITH DIRECTED SUBMUCOSAL INJECTION(S), ANY SUBSTANCE</td>
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<tr>
<td>43241</td>
<td>ESOPHAGOGASTRODUODENOSCOPY, FLEXIBLE, TRANSORAL; WITH INSERTION OF INTRALUMINAL TUBE OR CATHETER</td>
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<td>43257</td>
<td>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</td>
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<td>43499</td>
<td>UNLISTED PROCEDURE, ESOPHAGUS</td>
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**ICD-10 Codes that Support Medical Necessity**
ICD-10 Codes that DO NOT Support Medical Necessity

Additional ICD-10 Information

N/A

General Information

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

FCSO reference LCD number(s): L32485


Other Contractor’s LCDs.


Bibliography

N/A

Revision History Information

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<tr>
<td>01/25/2018</td>
<td>R2</td>
<td>Revision Number: 2</td>
<td>• Reconsideration</td>
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<tr>
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<td>Publication: January 2018</td>
<td>Request</td>
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<td>Connection LCR A/B2018-002</td>
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<td><strong>Explanation of Revision:</strong> 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. 01/11/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the</td>
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coverage determination and therefore not all the fields included on the LCD are applicable as noted in this policy.

<table>
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<th>Date</th>
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<td>01/01/2016</td>
<td>R1</td>
<td>Revision Number: 1 Publication: December 2015 Connection LCR A/B2016-016</td>
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**Associated Documents**

**Attachments**

N/A

**Related Local Coverage Documents**

Article(s)
A54815 - Noncovered Procedures - Endoscopic Treatment of Gastroesophageal Reflux Disease (GERD) coding guidelines
A55869 - Noncovered procedures - endoscopic treatment of gastroesophageal reflux disease (GERD) revision to the Part A and Part B LCD

**Related National Coverage Documents**

N/A

**Public Version(s)**

Updated on 01/11/2018 with effective dates 01/25/2018 - N/A
Updated on 12/28/2015 with effective dates 01/01/2016 - 01/24/2018
Updated on 07/01/2014 with effective dates 10/01/2015 - N/A
Updated on 03/26/2014 with effective dates 10/01/2015 - N/A

**Keywords**

N/A