Subject: Minimally Invasive Procedures for the Treatment of Gastroesophageal Reflux Disease (GERD) and Dysphagia

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DESCRIPTION:

Gastroesophageal reflux disease (GERD) is a common disorder characterized by heartburn and other symptoms related to reflux of stomach acid into the esophagus. The pathophysiology of GERD involves excessive exposure to stomach acid, which occurs for several reasons. There can be an incompetent barrier between the esophagus and stomach, either due to dysfunction of the lower esophageal sphincter or incompetence of the diaphragm. Another mechanism is an abnormally slow clearance of stomach acid. In this situation, delayed clearance leads to an increased reservoir of stomach acid and a greater tendency to reflux. Treatment options for GERD include weight loss, smoking cessation, head of the bed elevation, elimination of food triggers, and proton pump inhibitors.

Esophageal achalasia is characterized by reduced numbers of neurons in the esophageal myenteric plexuses and reduced peristaltic activity, making it difficult to swallow food and possibly leading to complications such as regurgitation, coughing, choking, aspiration pneumonia, esophagitis, ulceration, and weight loss. Treatment options for esophageal achalasia include pharmacotherapy (eg, injections with botulinum toxin), pneumatic dilation, and laparoscopic Heller myotomy.

Surgical options investigated for treating GERD and dysphagia caused by achalasia include transesophageal endoscopic gastroplasty, transoral incisionless fundoplication ITIF), transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction, endoscopic submucosal implantation of a biocompatible polymer, endoscopic submucosal implantation of a prosthesis or injection of a bulking agent, magnetic sphincter augmentation, and peroral endoscopic myotomy (POEM).
POSITION STATEMENT:
Transesophageal endoscopic gastroplasty for the treatment of GERD is considered experimental or investigational.

Transoral incisionless fundoplication (TIF) (e.g., Esophyx) for the treatment GERD is considered experimental or investigational.

Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (e.g., the Stretta procedure) for the treatment of GERD is considered experimental or investigational.

Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., polymethylmethacrylate beads, zirconium oxide spheres) for the treatment of GERD is considered experimental or investigational.

Magnetic sphincter augmentation (e.g., LINX™ Reflux Management System) for the treatment of GERD is considered experimental or investigational.

Peroral endoscopic myotomy (POEM) for the treatment for pediatric and adult esophageal achalasia is considered experimental or investigational.

There is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on safety and net health outcomes associated with the procedures listed above.

BILLING/CODING INFORMATION:

CPT Coding:

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<th>Code</th>
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<tr>
<td>43210</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed (Investigational)</td>
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<tr>
<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 [Stretta] (Investigational)</td>
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<tr>
<td>43284</td>
<td>Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed (Investigational)</td>
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<tr>
<td>43285</td>
<td>Removal of esophageal sphincter augmentation device (Investigational)</td>
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REIMBURSEMENT INFORMATION:
Refer to section entitled POSITION STATEMENT.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

Achalasia: a disorder of the esophagus characterized by reduced numbers of neurons in the esophageal myenteric plexuses and reduced peristaltic activity, making it difficult to swallow food and
possibly leading to complications such as regurgitation, coughing, choking, aspiration pneumonia, esophagitis, ulceration, and weight loss.

**Dysphagia**: Difficulty in swallowing.

**Gastroesophageal junction**: The lower part of the esophagus that connects to the stomach

**Myotomy** (i.e., Heller myotomy): a surgical procedure in which the muscles of the lower esophageal sphincter (LES) are cut, allowing food and liquids to pass to the stomach; used to treat achalasia.

**Nissen fundoplication**: A surgical procedure in which the upper portion of the stomach is wrapped around the lower end of the esophagus and sutured in place as a treatment for GERD.

**Odynophagia**: Pain produced by swallowing

**Proton pump inhibitor (PPI)**: Any of a group of drugs (e.g., omeprazole) that inhibit the activity of proton pumps and are used to inhibit gastric acid secretion in the treatment of ulcers and gastroesophageal reflux disease.

**RELATED GUIDELINES**:

*Endoscopic Radiofrequency Ablation or Cryosurgical Ablation for Barrett’s Esophagus, 01-91000-10*

**OTHER**:

**NOTE**: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Other names used to report minimally invasive procedures for treating gastroesophageal reflux disease:

- Angelchik anti-reflux prosthesis
- ARD Plicator
- Bard Endoscopic Suturing System (BESS)
- Durasphere®
- EndoLuminal gastroplication
- Endoscopic gastroplasty or gastroplication
- Endoscopic Plicator™ System
- EsophyX™ System
- Gatekeeper™ Reflux Repair System
- Implantable magnetic esophageal ring
- LINX™ Reflux Management System
- Magnetic sphincter augmentation (MSA)
- Mechanical sphincter augmentation (MSA)
- MUSE™ System
- OverStitch Endoscopic Suturing System
- Plexiglas polymethylmethacrylate (PMMA) microspheres
- SRS™ Endoscopic Stapling System
- StomaphyX™ System
- Stretta® System

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29. Blue Cross Blue Shield Association Evidence Positioning System®, 7.01.137, Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease, 12/19.

30. Blue Cross Blue Shield Association Evidence Positioning System® 2.01.91 Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia, 12/19.


38. California Bankruptcy Blog. Curon Medical Inc. of Fremont California shuts down and files for Chapter 7 Bankruptcy (11/17/06).


43. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Implantation of Anti-Gastroesophageal Reflux Device (100.9) (06/22/87).


49. LINX Reflux Management System (NCT01624506).

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52. ClinicalTrials.gov. Randomized EsophyX Versus Sham / Placebo Controlled TIF Trial: The RESPECT Study (RESPECT). March 2019.


63. ECRI Custom Hotline Response. Endoluminal Gastroplication (Endocinch) for Gastroesophageal Reflux Disease. Plymouth Meeting, PA: ECRI. Updated 04/18/08.

64. ECRI Emerging Technology Report. Magnetic Sphincter Augmentation (Linx Reflux Management System) for Treating Gastroesophageal Reflux Disease (09/13/13).


66. ECRI Forecast. Boston Scientific recalls Enteryx for acid reflux (10/07/05).

67. ECRI Stretta System (Mederi Therapeutics, Inc.) for Treating Gastroesophageal Reflux Disease; Hotline Article (06/05/2012).


71. ECRI Health Technology Forecast - PerOral Endoscopic Myotomy (POEM) for Treating Esophageal Achalasia (8/12/13)


73. EndoGastric Solutions® Clinical Dossier: Transoral Incisionless Fundoplication (TIF®) for the Treatment of Gastroesophageal Reflux Disease Disease (GERD).
74. EndoGastric Solutions® Executive Summary: Endoscopic Treatment of Reflux Disease.

75. EndoGastric Solutions®: Transoral Incisionless Fundoplication (TIF® 2.0) w/ the EsophyX® Device For Gastroesophageal Reflux Disease (GERD) (June 2019).

76. Endogastric Solutions press release. “10,000th Patient in the United States Treated with Transoral Incisionless Fundoplication (TIF®) Using EsophyX® Technology from EndoGastric Solutions”, Redwood City, CA, September 6, 2012.

77. Endogastric Solutions press release. “EndoGastric Solutions Completes Patient Enrollment in Clinical Trial Comparing TIF Procedure to PPI Therapy for the Treatment of GERD”, Redwood City, CA, October 2, 2012.


81. First Coast Service Options (FCSO). Local Medicare Coverage Determination Noncovered Procedures - Endoscopic Treatment of Gastroesophageal Reflux Disease (GERD) (L32485) (01/01/13). (Retired 09/30/15).


91. Hakansson B, Et al. Randomised clinical trial: transoral incisionless fundoplication vs. sham intervention to control chronic GERD. Aliment Pharmacol Ther 2015. John Wiley & Sons Ltd.


95. Heidelbaugh J, Nostrand T. Medical and surgical management of gastroesophageal reflux disease. Clin Fam Pract. 2004 Sep;6(3);547.


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181. U. S. Food and Drug Administration (FDA), Center for Devices and Radiologic Health. Summary of Safety and Effectiveness Data, Enteryx™ Procedure Kit. PMA # P020006. 04/22/03.


**COMMITTEE APPROVAL:**

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 10/22/20.
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