

01-91000-03

Original Effective Date: 06/15/01

Reviewed: 08/25/22

Revised: 09/15/22

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

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

<a href="#">Position Statement</a>	<a href="#">Billing/Coding</a>	<a href="#">Reimbursement</a>	<a href="#">Program Exceptions</a>	<a href="#">Definitions</a>	<a href="#">Related Guidelines</a>
<a href="#">Other</a>	<a href="#">References</a>	<a href="#">Updates</a>			

### 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 (TIF), 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). Variations of peroral endoscopic myotomy (POEM) include diverticular peroral

endoscopic myotomy (D-POEM), gastric peroral endoscopic myotomy (G-POEM), and zenker peroral endoscopic myotomy (Z-POEM).

**POSITION STATEMENT:**

Peroral endoscopic myotomy (POEM) **meets the definition of medical necessity** when **ALL** of the following are met:

- Age 18 or older
- Primary idiopathic achalasia confirmed by esophageal manometry
- Eckardt symptom score is greater than 3
- No previous history of open surgery of the stomach or esophagus

The following procedures are considered **experimental or investigational**:

- Diverticular peroral endoscopic myotomy (D-POEM)
- Gastric peroral endoscopic myotomy (G-POEM)
- Zenker peroral endoscopic myotomy (Z-POEM)
- Transesophageal endoscopic gastroplasty
- Transoral incisionless fundoplication (TIF) (e.g., Esophyx)
- Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (e.g., the Stretta procedure)
- Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., polymethylmethacrylate beads, zirconium oxide spheres)
- Magnetic sphincter augmentation (e.g., LINX™ Reflux Management System) for the treatment of GERD

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:**

43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed <b>(Investigational)</b>
43257	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] <b>(Investigational)</b>
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed <b>(Investigational)</b>
43285	Removal of esophageal sphincter augmentation device <b>(Investigational)</b>
43497	Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])

## 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.

**Eckardt symptom score:** a grading system most frequently used for the evaluation of symptoms, stages and efficacy of achalasia treatment. It attributes points (0 to 3 points) for four symptoms of the disease (dysphagia, regurgitation, chest pain and weight loss), ranging from 0 to 12.

**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

## REFERENCES:

1. Agency for Healthcare, Research and Quality(AHRQ) (2011). Comparative Effectiveness Review #29. Management Strategies for Gastroesophageal Reflux Disease: An Update. Executive Summary (Updated 09/23/11).
2. Aiolfi A, Asti E, et al. Early results of magnetic sphincter augmentation versus fundoplication for gastroesophageal reflux disease: Systematic review and meta-analysis. *Int J Surg.* 2018 Apr;52:82-88. doi: 10.1016/j.jisu.2018.02.041. Epub 2018 Feb 20.
3. Alicuben ET, Bell RCW, Jobe BA, et al. Worldwide Experience with Erosion of the Magnetic Sphincter Augmentation Device. *Journal of Gastrointestinal Surgery* (2018). <https://doi.org/10.1007/s11605-018-3775-0>.
4. American College of Gastroenterology. Practice Guidelines: Updated guidelines for the diagnosis and treatment of gastroesophageal reflux disease (01/05)
5. American College of Gastroenterology, Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol* advance online publication (02/19/13).
6. American College of Gastroenterology. ACG Clinical Guidelines: Diagnosis and Management of Achalasia. *The American Journal of Gastroenterology*: September 2020 - Volume 115 - Issue 9 - p 1393-1411. doi: 10.14309/ajg.0000000000000731.

7. American Foregut Society. Letter to Insurance Carriers Regarding: Insurance coverage for the LINX® Reflux Management System procedure for gastroesophageal reflux disease. Accessed at <https://www.americanforegutsociety.org>.
8. American Gastroenterological Association Position Statement on the Management of Gastroesophageal Reflux Disease. *Gastroenterology* 2008;135:1383-1391. (updated 07/26/10)
9. American Gastroenterological Association Medical Position Statement on the Management of Gastroesophageal Reflux Disease (10/2008).
10. American Gastroenterological Association Position Statement on the use of Endoscopic Therapy for Gastroesophageal Reflux Disease. *Gastroenterology* 2006; 131:1313-1314.
11. American Gastroenterological Association Technology Coverage Statement on Minimally Invasive Surgical Options for Gastroesophageal Reflux Disease (April 2016).
12. American Society for Gastrointestinal Endoscopy (ASGE) Technology Assessment Committee. Endoscopic anti-reflux procedures. Updated 03/01/09.
13. American Society for Gastrointestinal Endoscopy (ASGE). Role of endoscopy in the management of GERD. *Gastrointest Endosc* 2007 Aug;66(2):219-24 (reaffirmed 2011).
14. American Society for Gastrointestinal Endoscopy (ASGE). Role of endoscopy in the management of GERD. *Gastrointestinal Endoscopy* Vol. 81 No. 6: 2015.
15. American Society of General Surgeons (ASGS). Position statement: Transoral fundoplication. 2011; <http://www.theasgs.org/aboutus/ASGS-Transoral-Fundoplication.pdf>.
16. American Society of General Surgeons (ASGS) Position Statement Transoral Fundoplication. Accessed at <https://theasgs.org/position-statements/american-society-of-general-surgeons-asgs-position-statement-transoral-fundoplication/>.
17. American Society of General Surgeons (ASGS). LINX Statement of Support from ASGS (2014). Accessed at <https://theasgs.org/>.
18. Arts J, Bisschops R, Blondeau K, Farré R, Vos R, Holvoet L, Caenepeel P, Lerut A, Tack J. A double-blind sham-controlled study of the effect of radiofrequency energy on symptoms and distensibility of the gastro-esophageal junction in GERD. *The American journal of gastroenterology*. 2012 Feb;107(2):222. PMID: 22108449.
19. Ayazi, S., Zaidi, A.H., Zheng, P. et al. Comparison of surgical payer costs and implication on the healthcare expenses between laparoscopic magnetic sphincter augmentation (MSA) and laparoscopic Nissen fundoplication (LNF) in a large healthcare system. *Surg Endosc* 34, 2279–2286 (2020). <https://doi.org/10.1007/s00464-019-07021-4>.
20. Ayazi S, Zheng P, Zaidi AH, et al. Magnetic Sphincter Augmentation and Postoperative Dysphagia: Characterization, Clinical Risk Factors, and Management. *J Gastrointest Surg*. 2020;24(1):39–49. doi:10.1007/s11605-019-04331-9.
21. Aziz AM, El-Khayat HR, Sadek A, Mattar SG, McNulty G, Kongkam P, Guda MF, Lehman GA. A prospective randomized trial of sham, single-dose Stretta, and double-dose Stretta for the treatment of gastroesophageal reflux disease. *Surgical endoscopy*. 2010 Apr;24(4):818.
22. Bell RC, Freeman KD. Clinical and pH-metric outcomes of transoral esophagogastric fundoplication for the treatment of gastroesophageal reflux disease. *Surg Endosc* 2011; 25(6):1975-84.
23. Bell RC, et al. A Prospective Multicenter Registry of Chronic Gastroesophageal Disease Receiving Transoral Incisionless Fundoplication. *J Am Coll Surg*. 2012 August 2012.
24. Bell RC, et al. Univariate and multivariate analyses of preoperative factors influencing symptomatic outcomes of transoral fundoplication. *Surg Endosc*. 2014 May 31.
25. Bell RC, Hufford RJ, Fearon J, Freeman KD. Revision of failed traditional fundoplication using EsophyX transoral fundoplication. *Surg Endosc*. 2013 Mar;27(3):761-7.

26. Bell RCW, Barnes WE, Carter BJ, Sewell RW, Mavrelis PG, Ihde GM, Hoddinott KM, Fox MA, Freeman KD, Gunsberger T, Hausmann MG, Dargis D, Gill BD, Wilson EB, Trad KS. Transoral Incisionless Fundoplication: 2 year results from the prospective multicenter U.S. study. *Am Surg*. 2014 Nov; 80(11):1093-1105.
27. Bell RCW, Freeman K, Heidrick R, Ayazi S. Transoral incisionless fundoplication demonstrates durability at up to 9 years. *Therap Adv Gastroenterol*. 2021 Apr 16;14:17562848211004827. doi: 10.1177/17562848211004827.
28. Bell R, Lipham J, Louie B, et al. Laparoscopic magnetic sphincter augmentation versus double-dose proton pump inhibitors for management of moderate-to-severe regurgitation in GERD: a randomized controlled trial. *Gastrointest Endosc*. 2019 Jan;89(1):14-22.e1. doi: 10.1016/j.gie.2018.07.007. Epub 2018 Jul 18.
29. Bell R, Lipham J, Louie BE, et al. Magnetic Sphincter Augmentation Superior to Proton Pump Inhibitors for Regurgitation in a 1-Year Randomized Trial. Published:September 10, 2019 DOI:<https://doi.org/10.1016/j.cgh.2019.08.056>.
30. Blue Cross Blue Shield Association Evidence Positioning System®. 2.01.38, Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease, 01/22.
31. Blue Cross Blue Shield Association. Technology Evaluation Center (TEC). Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease. TEC Assessments 2003, Volume 18, No. 20.
32. Blue Cross Blue Shield Association Evidence Positioning System®, 7.01.137, Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease, 12/21.
33. Blue Cross Blue Shield Association Evidence Positioning System® 2.01.91 Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia, 12/21.
34. Bona D, Saino G, Mini E, Lombardo F, Panizzo V, Cavalli M, Bonitta G, Campanelli G, Aiolfi A. Magnetic sphincter augmentation device removal: surgical technique and results at medium-term follow-up. *Langenbecks Arch Surg*. 2021 Nov;406(7):2545-2551. doi: 10.1007/s00423-021-02294-7. Epub 2021 Aug 30.
35. Bonavina L, et al. Laparoscopic sphincter augmentation device eliminates reflux symptoms and normalizes esophageal acid exposure: one- and 2-year results of a feasibility trial. *Ann Surg*. 2010 Nov;252(5):857-62.
36. Bonavina L, et al. LINX(®) Reflux Management System in chronic gastroesophageal reflux: A novel effective technology for restoring the natural barrier to reflux. *Therap Adv Gastroenterol*. 2013a; 6(4):261-268.
37. Bonavina L, et al. Magnetic augmentation of the lower esophageal sphincter: results of a feasibility clinical trial. *J Gastrointest Surg*. 2008 Dec;12(12):2133-40.
38. Bonavina L, Saino G, et al. One Hundred Consecutive Patients Treated with Magnetic Sphincter Augmentation for Gastroesophageal Reflux Disease: 6 Years of Clinical Experience from a Single Center. *J Am Coll Surg* 2013.
39. Bonavina L, Horbach T, Schoppmann SF, et al. Three-year clinical experience with magnetic sphincter augmentation and laparoscopic fundoplication. *Surg Endosc* (2020). <https://doi.org/10.1007/s00464-020-07792-1>.
40. Bortolotti M. Magnetic challenge against gastroesophageal reflux. *World J Gastroenterol*. 2021 Dec 28;27(48):8227-8241. doi: 10.3748/wjg.v27.i48.8227.
41. Buckley FP, Havemann B, Chawla A. Magnetic sphincter augmentation: Optimal patient selection and referral care pathways. *World J Gastrointest Endosc*. 2019;11(8):472–476. doi:10.4253/wjge.v11.i8.472.

42. Buckley III FP, Bell RCW, et al. Favorable results from a prospective evaluation of 200 patients with large hiatal hernias undergoing LINX magnetic sphincter augmentation. *Surg Endosc.* 2018; 32(4): 1762–1768.
43. Cadiere GB, Buset M, Muls V et al. Antireflux transoral incisionless fundoplication using EsophyX: 12-month results of a prospective multicenter study. *World J Surg* 2008; 32(8):1676-88.
44. California Bankruptcy Blog. Curon Medical Inc. of Fremont California shuts down and files for Chapter 7 Bankruptcy (11/17/06).
45. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD): Endoscopic Treatment of GERD (L34659) (10/01/15) (Revised 02/14/21).
46. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination: Noncovered Procedures - Endoscopic Treatment of Gastroesophageal Reflux Disease (GERD) (L33296) (10/01/15) (Retired 02/14/20).
47. Centers for Medicare and Medicaid (CMS). Local Coverage Determination (LCD): Noncovered Services (L33777) (10/01/15) (Retired 07/01/20).
48. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD): Select Minimally Invasive GERD Procedures (L35080) (IL, MN, WI, CT, NY, ME, MA, NH, RI, VT) (10/01/15) (Revised 04/15/21).
49. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Implantation of Anti-Gastroesophageal Reflux Device (100.9) (01/01/21).
50. Chang KJ, Bell R. Transoral Incisionless Fundoplication. *Gastrointest Endosc Clin N Am.* 2020 Apr;30(2):267-289. doi: 10.1016/j.giec.2019.12.008. Epub 2020 Feb 13.
51. Chen KY, et al. Seasonal Variation in the Incidence of Gastroesophageal Reflux Disease. *The American Journal of the Medical Sciences* • Volume 338, Number 6, December 2009.
52. Chen NY, Huang DY, et al. Efficacy of Magnetic Sphincter Augmentation versus Nissen Fundoplication for Gastroesophageal Reflux Disease in Short Term: A Meta-Analysis. *Can J Gastroenterol Hepatol.* 2017;2017:9596342. doi: 10.1155/2017/9596342. Epub 2017 Mar 30.
53. Chen YK, Raijman I, Ben-Menachem T, Starpoli AA, Liu J, Pazwash H, Weiland S, Shahrier M, Fortajada E, Saltzman JR, Carr-Locke DL. Long-term outcomes of endoluminal gastroplication: a U.S. multicenter trial. *Gastrointest Endosc.* 2005 May; 61(6): 659-67.
54. Chen YK. Endoscopic suturing devices for treatment of GERD: too little, too late? *Gastrointest Endosc.* 2005 Jul; 62(1): 44-7.
55. ClinicalTrials.gov. NCT04695171: LINX Reflux Management System or Fundoplication Clinical Study in Patients With Hiatal Hernia >3 cm. Foregut Research Foundation (January 2021).
56. ClinicalTrials.gov. NCT04253392: RETHINK REFLUX Registry. LINX Reflux Management System. Ethicon Endo-Surgery (May 2021).
57. Ferrari D, Asti E, Lazzari V, et al. Six to 12-year outcomes of magnetic sphincter augmentation for gastroesophageal reflux disease. *Sci Rep* 10, 13753 (2020). <https://doi.org/10.1038/s41598-020-70742-3>.
58. LINX Reflux Management System (NCT01624506).
59. LINX Reflux Management System Clinical Study Protocol (NCT00776997).
60. ClinicalTrials.gov. "Evaluation of the Efficacy of Radiofrequency in the Treatment of Gastroesophageal Reflux Disease"; Identifier # NCT00200642 (05/20/08).
61. ClinicalTrials.gov. Randomized EsophyX Versus Sham / Placebo Controlled TIF Trial: The RESPECT Study (RESPECT). March 2019.

62. ClinicalTrials.gov. NCT01940185: A Post-Approval Study of the LINX® Reflux Management System (Torax Medical) (September 2016).
63. ClinicalTrials.gov. NCT00776997: LINX Reflux Management System Clinical Study Protocol (Torax Medical) (November 2013).
64. ClinicalTrials.gov. NCT02935881: STRETTA ,Radio Frequency Ablation (RFA) v/s Sham Therapy for the Treatment of Refractory GERD (STRETTAGERD) (October 2016).
65. ClinicalTrials.gov. NCT01512719: POEM- Peroral Endoscopic Myotomy for Esophageal Motility Disorders (POEM) (April 2016).
66. Comay D, Adam V, da Silveira EB, Kennedy W, Mayrand S, Barkun AN. The Stretta procedure versus proton pump inhibitors and laparoscopic Nissen fundoplication in the management of gastroesophageal reflux disease: a cost-effectiveness analysis. *Can J Gastroenterol*. 2008 Jun;22(6):552-8.
67. Corley DA, Katz P, Wo JM, Stefan A, Patti M, Rothstein R, Edmundowicz S, Kline M, Mason R, Wolfe MM. Improvement of gastroesophageal reflux symptoms after radiofrequency energy: a randomized, sham-controlled trial. *Gastroenterology*. 2003 Sep; 125 (3): 668-76.
68. Coron E, Sebillé V, Cadiot G, Zerbib F, Ducrotte P, Ducrot F, Poudroux P, Arts J, Le Rhun M, Piche T, Bruley DV. Clinical trial: Radiofrequency energy delivery in proton pump inhibitor-dependent gastro-oesophageal reflux disease patients. *Alimentary pharmacology & therapeutics*. 2008 Nov 1;28(9):1147.
69. Delshad SD, Almario CV, Chey WD, Spiegel BMR. Prevalence of Gastroesophageal Reflux Disease and Proton Pump Inhibitor-Refractory Symptoms. *Gastroenterology*. 2020 Apr;158(5):1250-1261.e2. doi: 10.1053/j.gastro.2019.12.014. Epub 2019 Dec 19.
70. DeMarchi J, Schwiers M, Soberman M, Tokarski A. Evolution of a novel technology for gastroesophageal reflux disease: a safety perspective of magnetic sphincter augmentation. *Dis Esophagus*. 2021 Nov 11;34(11):doab036. doi: 10.1093/dote/doab036.
71. DeVault KR, Castell DO; American College of Gastroenterology. Updated guidelines for the diagnosis and treatment of gastroesophageal reflux disease. *Am J Gastroenterol*. 2005 Jan; 100(1): 190-200.
72. Dughera L, et al. Durability of Stretta Radiofrequency Treatment for GERD: Results of an 8-Year Follow-Up. *Gastroenterol Res Pract*. 2014;2014:531907.
73. Dunn C, Bildzukewicz N, Lipham J. Magnetic Sphincter Augmentation for Gastroesophageal Reflux Disease. *Gastrointest Endosc Clin N Am*. 2020;30(2):325–342. doi:10.1016/j.giec.2019.12.010. PMID: 32146949.
74. ECRI Clinical Evidence Assessment. EsophyX (EndoGastric Solutions, Inc.) for Treating Gastroesophageal Reflux Disease. (August 2021).
75. ECRI Custom Hotline Response. Endoluminal Gastroplication (Endocinch) for Gastroesophageal Reflux Disease. Plymouth Meeting, PA: ECRI. Updated 04/18/08.
76. ECRI Emerging Technology Report. Magnetic Sphincter Augmentation (Linx Reflux Management System) for Treating Gastroesophageal Reflux Disease (09/13/13).
77. ECRI Endoluminal gastroplication [EndoCinch (TM)] for gastroesophageal reflux disease (GERD). Plymouth Meeting, PA: ECRI, 2003:17, (updated 04/18/08).
78. ECRI Forecast. Boston Scientific recalls Enteryx for acid reflux (10/07/05).
79. ECRI Stretta System (Mederi Therapeutics, Inc.) for Treating Gastroesophageal Reflux Disease; Hotline Article (06/05/2012).
80. ECRI The Stretta™ procedure for gastroesophageal reflux disease [GERD]. Plymouth Meeting, PA: ECRI, 2003:32, (updated 04/18/08).



81. ECRI Product Brief. Stretta System (Mederi Therapeutics, Inc.) for Treating Gastroesophageal Reflux Disease (March, 2014).
82. ECRI Product Brief. OverStitch Endoscopic Suturing System (Apollo Endosurgery, Inc.) for Placing Full-thickness Surgical Sutures (Dec, 2013).
83. ECRI Health Technology Forecast - PerOral Endoscopic Myotomy (POEM) for Treating Esophageal Achalasia (8/12/13)
84. Edriss H, El-Bakush A, Nugent K. Esophageal Perforation and Bilateral Empyema Following Endoscopic EsophyX Transoral Incisionless Fundoplication. *Clin Endosc.* 2014 Nov;47(6):560-3.
85. EndoGastric Solutions® Clinical Dossier: Transoral Incisionless Fundoplication (TIF®) for the Treatment of Gastroesophageal Reflux Disease (GERD).
86. EndoGastric Solutions® Executive Summary: Endoscopic Treatment of Reflux Disease.
87. EndoGastric Solutions®: Transoral Incisionless Fundoplication (TIF® 2.0) w/ the EsophyX® Device For Gastroesophageal Reflux Disease (GERD) (June 2019).
88. 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.
89. 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.
90. Falk GW, Fennerty MB, Rothstein RI. AGA Institute medical position statement on the use of endoscopic therapy for gastroesophageal reflux disease. *Gastroenterology.* 2006 Oct; 131(4): 1313-4.
91. Fass R, Cahn F, et al.. Systematic review and meta-analysis of controlled and prospective cohort efficacy studies of endoscopic radiofrequency for treatment of gastroesophageal reflux disease. (2017).
92. Feng J, Ali RW, Hao JY, Kong GX, Yang LH, Huang XJ. Peroral endoscopic myotomy for esophageal motility disorders. *Esophagus.* 2020 Jan;17(1):11-18. doi: 10.1007/s10388-019-00693-w. Epub 2019 Oct 12.
93. Ferrari D, Siboni S, Riva CG, Guerrazzi G, Lovece A, Bonavina L. Magnetic Sphincter Augmentation Outcomes in Severe Gastroesophageal Reflux Disease. *Front Med (Lausanne).* 2021 Nov 2;8:645592. doi: 10.3389/fmed.2021.645592.
94. 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).
95. Franciosa M, et al. Stretta Radiofrequency Treatment for GERD: A Safe and Effective Modality. *Gastroenterol Res Pract.* 2013;2013:783815.
96. Funk LM, Zhang JY, Drosdeck JM, Melvin WS, Walker JP, Perry KA. Long-term cost-effectiveness of medical, endoscopic and surgical management of gastroesophageal reflux disease. *Surgery.* 2015 Jan 1;157(1):126-36. PMID: 25262216.
97. Galmiche JP, et al. Laparoscopic Antireflux Surgery vs Esomeprazole Treatment for Chronic GERD. The LOTUS Randomized Clinical Trial. *JAMA,* May 18, 2011—Vol 305, No. 19.
98. Ganz RA, Peters JH, Horgan S, et al. Esophageal sphincter device for gastroesophageal reflux disease. *N Engl J Med;* 368(8):719-27. (2013)
99. Ganz RA, Edmundowicz SA, et al. Long-term Outcomes of Patients Receiving a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux. *Clinical Gastroenterology and Hepatology* 2016;14:671–677.

100. Gawron AJ, Bell R, Abu Dayyeh BK, et al. Surgical and endoscopic management options for patients with GERD based on proton pump inhibitor symptom response: recommendations from an expert U.S. panel. *Gastrointest Endosc.* 2020 Jul;92(1):78-87.e2. doi: 10.1016/j.gie.2020.01.037. Epub 2020 Jan 31.
101. Gerson L, Stouch B, Lobonțiu A. Transoral Incisionless Fundoplication (TIF 2.0): A Meta-Analysis of Three Randomized, Controlled Clinical Trials. *Chirurgia (Bucur).* 2018;113(2):173–184. doi:10.21614/chirurgia.113.2.173. PMID: 29733015.
102. Gisi C, Wang K, Khan F, Reicher S, Hou L, Fuller C, Sattler J, Eysselein V. Efficacy and patient satisfaction of single-session transoral incisionless fundoplication and laparoscopic hernia repair. *Surg Endosc.* 2020 Jul 20. doi: 10.1007/s00464-020-07796-x. Epub ahead of print. PMID: 32691205.
103. Gregory D, Scotti DJ, Buck D, Triadafilopoulos G. Budget Impact Analysis to Estimate the Cost Dynamics of Treating Refractory Gastroesophageal Reflux Disease With Radiofrequency Energy: a Payer Perspective. *Managed care (Langhorne, Pa.).* 2016 May;25(5):42.
104. Guidozi N, Wiggins T, et al.. Laparoscopic magnetic sphincter augmentation versus fundoplication for gastroesophageal reflux disease: systematic review and pooled analysis. *Dis Esophagus.* 2019 Nov 13;32(9):doz031. doi: 10.1093/dote/doz031. PMID: 31069388.
105. Hailey D. Endoscope-based treatments for gastroesophageal reflux disease. Ottawa: Canadian Coordinating Office for Health Technology Assessment (CCOHTA), 2004.
106. 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.
107. Hawasli A, et al. Laparoscopic management of severe reflux after sleeve gastrectomy using the LINX® system: Technique and one year follow up case report. *Int J Surg Case Rep.* 2016 Nov 29;30:148-151.
108. Hayes, Inc. HAYES Medical Technology Directory. Endoscopic Therapy for Gastroesophageal Reflux Disease. Lansdale, PA: Hayes, Inc. October 2007.
109. He S, Xu F, Xiong X, Wang H, Cao L, Liang N, Wang H, Jing X, Liu T. Stretta procedure versus proton pump inhibitors for the treatment of nonerosive reflux disease: A 6-month follow-up. *Medicine (Baltimore).* 2020 Jan;99(3):e18610. doi: 10.1097/MD.00000000000018610.
110. Heidelbaugh J, Nostrant T. Medical and surgical management of gastroesophageal reflux disease. *Clin Fam Pract.* 2004 Sep; 6(3); 547.
111. Herman RM, Berho M, Murawski M, Nowakowski M, Ryś J, Schwarz T, Wojtysiak D, Wexner SD. Defining the histopathological changes induced by nonablative radiofrequency treatment of faecal incontinence--a blinded assessment in an animal model. *Colorectal disease: the official journal of the Association of Coloproctology of Great Britain and Ireland.* 2015 May;17(5):433.
112. Hopkins J, Switzer NJ, Karmali S. Update on novel endoscopic therapies to treat gastroesophageal reflux disease: A review. *World J Gastrointest Endosc.* 2015 Aug 25;7(11):1039-44.
113. Hunter JG, Kahrilas PJ, Bell RCW, Wilson EB, Trad KS, Dolan JP, Perry KA, Oelschlager BK, Soper NJ, Snyder BA, Burch MA, Melvin WS, Reavis K, Turgeon DG, Hungness ES, Diggs BS. Efficacy of transoral fundoplication vs. omeprazole for treatment of regurgitation in a randomized controlled trial. *Gastroenterology.* 2015 Feb;148(2):324-333.
114. Ihde GM. The evolution of TIF: transoral incisionless fundoplication. *Therap Adv Gastroenterol.* 2020 May 21;13:1756284820924206. doi: 10.1177/1756284820924206.
115. Ip S, Bonis P, Tatsioni A, Raman G, Chew P, Kupelnick B, Fu L, DeVine D, Lau J. Comparative Effectiveness Strategies for Gastroesophageal Reflux Disease. Evidence Report/Technology Assessment No. 1. (Prepared by Tufts-New England Medical Center Evidence-based Practice Center under Contract No. 290-02-0022) Rockville, MD: Agency for Healthcare Research and Quality. AHRQ Publication No. 06-EHC003-EF. December 2005.

116. Ip S, Chung M, Moorthy D, Yu WW, Lee J, Chan JA, Bonis PA, Lau J. Comparative Effectiveness of Management Strategies for Gastroesophageal Reflux Disease: Update. Comparative Effectiveness Review No. 29. (Prepared by Tufts Medical Center Evidence-based Practice Center under Contract No. HHS 290-2007-10055-I.) AHRQ Publication No. 11-EHC049-EF. Rockville, MD: Agency for Healthcare Research and Quality. September 2011.
117. Janu P, Shughoury AB, et al. Laparoscopic Hiatal Hernia Repair Followed by Transoral Incisionless Fundoplication With EsophyX Device (HH + TIF): Efficacy and Safety in Two Community Hospitals. *Surg Innov*. 2019 Dec;26(6):675-686. doi: 10.1177/1553350619869449. Epub 2019 Aug 20.
118. Kahn F, et al. Utilisation of surgical fundoplication for patients with gastro-oesophageal reflux disease in the USA has declined rapidly between 2009 and 2013. *Aliment Pharmacol Ther* © 2016 John Wiley & Sons Ltd.
119. Kalapala R, Shah H, Nabi Z, Darisetty S, Talukdar R, Nageshwar RD. Treatment of gastroesophageal reflux disease using radiofrequency ablation (Stretta procedure): An interim analysis of a randomized trial. *Indian journal of gastroenterology: official journal of the Indian Society of Gastroenterology*. 2017 Sep;36(5):337. PMID: 29030802.
120. Katz PO, Dunbar KB, Schnoll-Sussman FH, et al. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol*. 2022 Jan 1;117(1):27-56. doi: 10.14309/ajg.0000000000001538.
121. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. *Am J Gastroenterol*. 2013 Mar;108(3):308-28.
122. Kahrilas EJ, Katzka D, Richter JE. AGA CLINICAL PRACTICE UPDATE: EXPERT REVIEW. Clinical Practice Update: The Use of Per-Oral Endoscopic Myotomy in Achalasia: Expert Review and Best Practice Advice From the AGA Institute. *Gastroenterology* 2017;153:1205–1211.
123. Khashab MA, Sanaei O, et al. Peroral endoscopic myotomy: anterior versus posterior approach: a randomized single-blinded clinical trial. *Gastrointest Endosc*. 2020 Feb;91(2):288-297.e7. doi: 10.1016/j.gie.2019.07.034. Epub 2019 Aug 10. PMID: 31408652.
124. Kirkham EN, Main BG, Jones KJB, Blazeby JM, Blencowe NS. Systematic review of the introduction and evaluation of magnetic augmentation of the lower oesophageal sphincter for gastro-oesophageal reflux disease. *Br J Surg*. 2020;107(1):44–55. doi:10.1002/bjs.11391.
125. Laurino-Neto RM, Herbella F, Schlottmann F, Patti M. EVALUATION OF ESOPHAGEAL ACHALASIA: FROM SYMPTOMS TO THE CHICAGO CLASSIFICATION. *Arq Bras Cir Dig*. 2018;31(2):e1376. doi: 10.1590/0102-672020180001e1376. Epub 2018 Jul 2.
126. Liang WT, et al. Long-term outcomes of patients with refractory gastroesophageal reflux disease following a minimally invasive endoscopic procedure: a prospective observational study. *BMC Gastroenterol*. 2014 Oct 10;14:178.
127. Lipham, JC, Demeester, TR, Ganz, RA, et al. The LINX reflux management system: confirmed safety and efficacy now at 4 years. *Surg Endosc*; 26: 2944-9. (2012).
128. Lipham JC, et al. Safety analysis of first 1000 patients treated with magnetic sphincter augmentation for gastroesophageal reflux disease. *Diseases of the Esophagus*, March 2014.
129. Liu HF, et al. Improvement of clinical parameters in patients with gastroesophageal reflux disease after radiofrequency energy delivery. *World J Gastroenterol*. 2011 Oct 21;17(39):4429-33.
130. Lo WK, Mashimo H. Critical Assessment of Endoscopic Techniques for Gastroesophageal Reflux Disease. *J Clin Gastroenterol*. 2015 Oct;49(9):720-4.
131. Loh Y, et al. Is the LINX reflux management system an effective treatment for gastro-oesophageal reflux disease? *Int J Surg*. 2014;12(9):994-7.
132. Louie BE, et al. Short-term outcomes using magnetic sphincter augmentation versus Nissen fundoplication for medically resistant gastroesophageal reflux disease. *Ann Thorac Surg*. 2014 Aug;98(2):498-504; discussion 504-5.

133. Ma L, Li T, Liu G, Wang J, Yin Z, Kang J. Stretta radiofrequency treatment vs Toupet fundoplication for gastroesophageal reflux disease: a comparative study. *BMC Gastroenterol.* 2020 May 27;20(1):162. doi: 10.1186/s12876-020-01310-2.
134. Madan AK, Ternovits CA, Tichansky DS. Emerging endoluminal therapies for gastroesophageal reflux disease: adverse events. *Am J Surg.* 2006 Jul; 192(1): 72-5.
135. Mahmoud T, Jaruvongvanich V, Ghazi R, Abusaleh R, Abu Dayyeh BK. Complete endoscopic removal of an eroded magnetic sphincter augmentation device. *VideoGIE.* 2021 Sep 21;6(10):450-453. doi: 10.1016/j.vgie.2021.05.023.
136. Marano L, et al. Surgery or Peroral Esophageal Myotomy for Achalasia: A Systematic Review and Meta-Analysis. *Medicine (Baltimore).* 2016 Mar;95(10):e3001.
137. McCarty TR, Itidiare M, Njei B, Rustagi T. Efficacy of transoral incisionless fundoplication for refractory gastroesophageal reflux disease: a systematic review and meta-analysis. *Endoscopy.* 2018;50(7):708–725. doi:10.1055/a-0576-6589.
138. Meier PN. Efficacy of endoscopic antireflux procedures: at least durability for radiofrequency energy delivery. *Gastrointest Endosc.* 2007 Mar; 65(3): 375-6.
139. Moayyedi P, Eikelboom JW, Bosch J, et al. COMPASS Investigators. Safety of Proton Pump Inhibitors Based on a Large, Multi-Year, Randomized Trial of Patients Receiving Rivaroxaban or Aspirin. *Gastroenterology.* 2019 Sep;157(3):682-691.e2. doi: 10.1053/j.gastro.2019.05.056. Epub 2019 May 29.
140. Nabi Z, Reddy DN. Endoscopic management of gastroesophageal reflux disease: revisited. *Clinical endoscopy.* 2016 Sep;49(5):408.
141. National Digestive Diseases Information Clearinghouse. NIH Publication No. 07–0882, Heartburn, Gastroesophageal Reflux (GER), and Gastroesophageal Reflux Disease (GERD) (05/07).
142. National Guideline Clearinghouse. Guideline Summary 008578: SAGES guidelines for the surgical treatment of esophageal achalasia (May 2011).
143. National Guideline Clearinghouse. Gastroesophageal reflux disease (GERD) (2002; revised 01/07).
144. National Guideline Clearinghouse. Guideline synthesis: Diagnosis and management of gastroesophageal reflux disease (GERD). Agency for Healthcare Research and Quality (AHRQ); 2008 May (revised 2012 Nov).
145. National Institute for Clinical Excellence (NICE). Endoscopic gastroplication for gastro-oesophageal reflux disease. London, UK: NICE; Feb 2005.
146. National Institute for Clinical Excellence (NICE). Gastroelectrical stimulation for gastroparesis. London, UK: NICE; February 2005.
147. National Institute for Health and Care Excellence (NICE). CG184: Gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management (November 2014). Accessed at <https://www.nice.org.uk/guidance/cg184/>.
148. Noar M, et al. Long-term maintenance effect of radiofrequency energy delivery for refractory GERD: a decade later. *Surg Endosc.* 2014 Aug;28(8):2323-33.
149. Noar MD, Lotfi-Emran S. Sustained improvement in symptoms of GERD and antisecretory drug use: 4-year follow-up of the Stretta procedure. *Gastrointestinal endoscopy.* 2007 Mar;65(3):367.
150. Parker M, et al. Comparing Effectiveness of Endoscopic Full Thickness Plication and Endoscopic Radiofrequency Treatments for Patients with GERD. *Expert Review of Gastroenterology & Hepatology* August 2010, Vol 4, No 4, Pages 387-390.
151. Perry K, Banerjee A, Melvin S. Radiofrequency Energy Delivery To The Lower Esophageal Sphincter Reduces Esophageal Acid Exposure And Improves GERD Symptoms: A Systematic

- Review and Meta-Analysis. Surgical Laparoscopy Endoscopy and Percutaneous Techniques, August 2012; 22(4) 283-288.
152. Pleskow D, Rothstein R, Lo S, Hawes R, Kozarek R, Haber G, Gostout C, Lembo A. Endoscopic full-thickness publication for the treatment of GERD: 12-month follow-up for the North American open-label trial. *Gastrointest Endosc.* 2005 May; 61(6): 643-9.
  153. Rabach L, Saad AR, Velanovich V. How to choose among fundoplication, magnetic sphincter augmentation or transoral incisionless fundoplication [published online ahead of print, 2019 Apr 24]. *Curr Opin Gastroenterol.* 2019;10.1097/MOG.0000000000000550.
  154. Reavis KM, Perry KA. Transoral incisionless fundoplication for the treatment of gastroesophageal reflux disease. *Expert Rev Med Devices.* 2014 Jul;11(4):341-50.
  155. Rettura F, Bronzini F, Campigotto M, Lambiase C, Pancetti A, Berti G, Marchi S, de Bortoli N, Zerbib F, Savarino E, Bellini M. Refractory Gastroesophageal Reflux Disease: A Management Update. *Front Med (Lausanne).* 2021 Nov 1;8:765061. doi: 10.3389/fmed.2021.765061.
  156. Reymunde A, Santiago N. Long-term results of radiofrequency energy delivery for the treatment of GERD: sustained improvements in symptoms, quality of life, and drug use at 4-year follow-up. *Gastrointest Endosc.* 2007 Mar; 65(3): 361-6.
  157. Reynolds J, et al. Magnetic Sphincter Augmentation with the LINX Device for Gastroesophageal Reflux Disease after U.S. Food and Drug Administration Approval. *The American Surgeon*, October 2014.
  158. Reynolds JL, et al. Laparoscopic Magnetic Sphincter Augmentation vs Laparoscopic Nissen Fundoplication: A Matched-Pair Analysis of 100 Patients. *J Am Coll Surg.* 2015 Jul;221(1):123-8.
  159. Richards WO, Houston HL, Torquati A, Khaitan L, Holzman MD, Sharp KW. Paradigm shift in the management of gastroesophageal reflux disease. *Ann Surg.* 2003 May; 237(5): 638-47; discussion 648-9.
  160. Riegler M, Schoppman SF, et al. Magnetic sphincter augmentation and fundoplication for GERD in clinical practice: one-year results of a multicenter, prospective observational study. *Surg Endosc.* 2015 May;29(5):1123-9.
  161. Rodríguez de Santiago E, Albéniz E, Estremera-Arevalo F, Teruel Sanchez-Vegazo C, Lorenzo-Zúñiga V. Endoscopic anti-reflux therapy for gastroesophageal reflux disease. *World J Gastroenterol.* 2021 Oct 21;27(39):6601-6614. doi: 10.3748/wjg.v27.i39.6601.
  162. SAGES: Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). TAVAC Category: Safety and Effectiveness. LINX Reflux Management System. 2017; <https://www.sages.org/publications/tavac/tavac-safety-and-effectiveness-analysis-linx-reflux-management-system/>.
  163. Sanaka MR, et al. Efficacy of peroral endoscopic myotomy vs other achalasia treatments in improving esophageal function. *World J Gastroenterol.* 2016 May 28;22(20):4918-25.
  164. Schilling D, Kiesslich R, Galle PR, Riemann JF. Endoluminal therapy of GERD with a new endoscopic suturing device. *Gastrointest Endosc.* 2005 Jul; 62(1): 37-43.
  165. Schizas D, Mastoraki A, et al. LINX® reflux management system to bridge the "treatment gap" in gastroesophageal reflux disease: A systematic review of 35 studies. *World J Clin Cases.* 2020 Jan 26;8(2):294-305. doi: 10.12998/wjcc.v8.i2.294.
  166. Schwameis K, et al. Modern GERD treatment: feasibility of minimally invasive esophageal sphincter augmentation. *Anticancer Res.* 2014 May;34(5):2341-8.
  167. Schwartz MP, Wellink H, Gooszen HG, Conchillo JM, Samsom M, Smout AJ. Endoscopic gastroplication for the treatment of gastro-oesophageal reflux disease: a randomised, sham-controlled trial. *Gut.* 2007 Jan; 56(1): 20-8.

168. Shaheen NJ. The rise and fall (and rise?) of endoscopic anti-reflux procedures. *Gastroenterology*. 2006 Sep; 131(3): 952-4.
169. Skubleny D, Switzer NJ, et al. LINX® magnetic esophageal sphincter augmentation versus Nissen fundoplication for gastroesophageal reflux disease: a systematic review and meta-analysis. *Surg Endosc*. 2017 Aug;31(8):3078-3084. doi: 10.1007/s00464-016-5370-3. Epub 2016 Dec 15.
170. Smith CD, DeVault KR, Buchanan M, Introduction of Mechanical Sphincter Augmentation for Gastroesophageal Reflux Disease into Practice: Early Clinical Outcomes and Keys to Successful Adoption. *Journal of the American College of Surgeons* (2014), doi:10.1016/j.jamcollsurg.2013.12.034.
171. Smith MR, Ayazi S, Grubic AD, Shen X, Jobe BA. Swallow-induced syncope after magnetic sphincter augmentation: a case report and physiologic explanation. *Clin J Gastroenterol*. 2021 Oct;14(5):1318-1323. doi: 10.1007/s12328-021-01448-w. Epub 2021 May 29. PMID: 34053004.
172. Snow GE, Dbouk M, Akst LM, et al. Response of Laryngopharyngeal Symptoms to Transoral Incisionless Fundoplication in Patients with Refractory Proven Gastroesophageal Reflux. *Ann Otol Rhinol Laryngol*. 2022 Jun;131(6):662-670. doi: 10.1177/00034894211037414. Epub 2021 Aug 11.
173. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Clinical Spotlight Review: Endoluminal Treatments for Gastroesophageal Reflux Disease (GERD) (May 2017).
174. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Position Statement on Endoluminal Therapies for Gastrointestinal Diseases (11/09).
175. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Sages Clinical Spotlight. Clinical Spotlight Review (02/2013).
176. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). TAVAC Safety and Effectiveness Analysis: LINX® Reflux Management System (March 2017). Accessed at <https://www.sages.org/>.
177. Society of American Gastrointestinal Endoscopic Surgeons (SAGES). Endoluminal treatments for gastroesophageal reflux disease (GERD). Los Angeles (CA): Society of American Gastrointestinal Endoscopic Surgeons (SAGES); 2013 Feb. 22.
178. Society of American Gastrointestinal and Endoscopic Surgeons. Clinical Spotlight Review: Endoluminal Treatments for Gastroesophageal Reflux Disease (GERD) (2017).
179. Souza TF, Grecco E, Quadros LG, Albuquerque YD, Azôr FO, Galvão NM. SHORT-TERM RESULTS OF MINIMALLY INVASIVE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE BY RADIOFREQUENCY (STRETTA): FIRST BRAZILIAN SERIES OF CASES. *Arquivos de gastroenterologia*. 2018 Nov;55(Suppl 1):52.
180. Sriratanaviriyakul N, et al. LINX®, a novel treatment for patients with refractory asthma complicated by gastroesophageal reflux disease: a case report. *J Med Case Rep*. 2016; 10: 124.
181. Stefanidis G, Viazis N, Kotsikoros N, et al. Long-term benefit of transoral incisionless fundoplication using the esophyx device for the management of gastroesophageal reflux disease responsive to medical therapy. *Dis Esophagus*. 2017;30(3):1–8. doi:10.1111/dote.12525. PMID: 27868281.
182. Subramanian CR, Triadafilopoulos G. Refractory gastroesophageal reflux disease. *Gastroenterol Rep (Oxf)*. 2015 Feb;3(1):41-53.
183. ui X, Gao X, Zhang L, Zhang B, Zhong C, Chen Y, Wang X, Li D, Wu W, Li L. Clinical efficacy of endoscopic antireflux mucosectomy vs. Stretta radiofrequency in the treatment of gastroesophageal reflux disease: a retrospective, single-center cohort study. *Ann Transl Med*. 2022 Jun;10(12):660. doi: 10.21037/atm-22-2071.
184. Tam WC, Schoeman MN, Zhang Q, Dent J, Rigda R, Utley D, Holloway RH. Delivery of radiofrequency energy to the lower oesophageal sphincter and gastric cardia inhibits transient lower oesophageal sphincter relaxations and gastro-oesophageal reflux in patients with reflux disease. *Gut*. 2003 Apr; 52(4): 479-85.

185. Testoni S, Hassan C, Mazzoleni G, et al. Long-term outcomes of transoral incisionless fundoplication for gastro-esophageal reflux disease: systematic-review and meta-analysis. *Endosc Int Open*. 2021 Feb;9(2):E239-E246. doi: 10.1055/a-1322-2209. Epub 2021 Feb 3.
186. Testoni PA, Testoni S. Review article: Transoral fundoplication for gastroesophageal reflux disease. *Ann Esophagus* 2018;1:7. doi: 10.21037/aoe.2018.08.01.
187. Testoni PA, Testoni S, Distefano G, Mazzoleni G, Fanti L, Passaretti S. Transoral incisionless fundoplication with EsophyX for gastroesophageal reflux disease: clinical efficacy is maintained up to 10 years. *Endosc Int Open*. 2019;7(5):E647–E654. doi:10.1055/a-0820-2297.
188. Testoni PA, Testoni S, Mazzoleni G, Vailati C, Passaretti S. Long-term efficacy of transoral incisionless fundoplication with Esophyx (TIF 2.0) and factors affecting outcomes in GERD patients followed for up to 6 years: a prospective single-center study. *Surg Endosc*. 2015 Sep;29(9):2770-80.
189. Thomson AB, et al. Safety of the long-term use of proton pump inhibitors. *World J Gastroenterol* 2010 May 21; 16(19): 2323-2330.
190. Toomey P, Teta A, Patel K, Ross S, Sukharamwala P, Rosemurgy A. Transoral Incisionless Fundoplication: Is It as Safe and Efficacious as a Nissen or Toupet Fundoplication? Presented at the Annual Scientific Meeting and Postgraduate Course Program, Southeastern Surgical Congress, Savannah, GA, February 22–25, 2014.
191. Torquati A, Houston HL, Kaiser J, Holzman MD, Richards WO. Long-term follow-up study of the Stretta procedure for the treatment of gastroesophageal reflux disease. *Surgical endoscopy*. 2004 Oct;18(10):1475.
192. Trad KS, Barnes WE, Prevou ER, et al. The TEMPO Trial at 5 Years: Transoral Fundoplication (TIF 2.0) Is Safe, Durable, and Cost-effective. *Surg Innov*. 2018;25(2):149–157. doi:10.1177/1553350618755214.
193. Trad KS, Barnes WE, Simoni G, Shughoury AB, et al. Transoral fundoplication offers durable symptom control for chronic GERD: 3-year report from the TEMPO randomized trial with a crossover arm. *Surg Endosc*. 2017;31(6):2498–2508. doi:10.1007/s00464-016-5252-8.
194. Trad KS, Barnes WE, Simoni G, Shughoury AB, Mavrelis PG, Raza M, Heise JA, Turgeon DG, Fox MA. Transoral Incisionless Fundoplication Effective in Eliminating GERD Symptoms in Partial Responders to Proton Pump Inhibitor Therapy at 6 Months: The TEMPO Randomized Clinical Trial. *Surg Innov*. 2015 Feb;22(1):26-40.
195. Trad KS, Fox MA, Simoni G, Ahmad B, Shughoury AB, Mavrelis PG, Raza M, Heise JA, Turgeon DG, Barnes WE. Efficacy of Transoral Fundoplication For Treatment of Chronic Gastroesophageal Reflux Disease Incompletely Controlled with High-Dose PPI Therapy: A Randomized, Multicenter, Open Label, Crossover Study. *BMC Gastroenterol*. 2014 Oct 6; 14(1):174.
196. Trad KS, et al. Transoral incisionless fundoplication: current status. *Curr Opin Gastroenterol* 2016, 32:000–000.
197. Trad KS, Turgeon DG, Emir D. Long-term outcomes after transoral incisionless fundoplication in patients with GERD and LPR symptoms. *Surg Endosc*. DOI 10.1007/s00464-011-1932-6. Published online 09/30/11.
198. Trad KS, Turgeon DG, Deljkich E. Long-term outcomes after transoral incisionless fundoplication in patients with GERD and LPR symptoms. *Surg Endosc*. 2012 Mar;26(3):650-60. Epub 2011 Sep 30.
199. Trad KS, et al. Transoral Incisionless Fundoplication Effective in Eliminating GERD Symptoms in Partial Responders to Proton Pump Inhibitor Therapy at 6 Months: The TEMPO Randomized Clinical Trial. *Surg Innov*, April 2014.
200. The Merck Manual of diagnosis and Therapy, Gastroesophageal Reflux Disease, 1995 – 2001.
201. Triadafilopoulos G. Stretta: A valuable endoscopic treatment modality for gastroesophageal reflux disease. *World J Gastroenterol*. 2014 Jun 28;20(24):7730-8.

202. University of Michigan Health System (UMHS). Gastroesophageal reflux disease (GERD). Ann Arbor (MI): University of Michigan Health System; 2012 May.
203. UpToDate. Laryngopharyngeal reflux in adults: Evaluation, diagnosis, and management. 2022. Accessed at uptodate.com.
204. UpToDate. Overview of the treatment of achalasia. 2022. Accessed at uptodate.com.
205. UpToDate. Magnetic sphincter augmentation (MSA). 2021. Accessed at uptodate.com.
206. UpToDate. Peroral endoscopic myotomy (POEM). 2021. Accessed at uptodate.com.
207. UpToDate. Radiofrequency treatment for gastroesophageal reflux disease. 2021. Accessed at uptodate.com.
208. UpToDate. Surgical management of gastroesophageal reflux in adults. 2021. Accessed at uptodate.com.
209. UpToDate. Surgical myotomy for achalasia. 2022. Accessed at uptodate.com.
210. U. S. Food and Drug Administration (FDA), Center for Devices and Radiologic Health. 510(K) Summary, CSM Stretta™ System. # K000245. 04/18/00.
211. U. S. Food and Drug Administration (FDA), Center for Devices and Radiologic Health. Summary of Safety and Effectiveness Information, Bard® Endoscopic Suturing System. # K994290. 03/20/00.
212. 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.
213. U.S. Food and Drug Administration (FDA). LINX™ Reflux Management System. Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee 2012. Accessed 01/09/14.
214. U.S. Food and Drug Administration (FDA). Pre-market Approval Order (PMA) P100049: LINX™ Reflux Management System (March 22, 2012).
215. Vaezi MF, Pandolfino JE, Vela MF. ACG clinical guideline: diagnosis and management of achalasia. *Am J Gastroenterol*. 2013 Aug;108(8):1238-49.
216. Vaezi MF, Shaheen NJ, Muthusamy VR. State of Evidence in Minimally Invasive Management of Gastroesophageal Reflux: Findings of a Scoping Review. *Gastroenterology*. 2020 Oct;159(4):1504-1525. doi: 10.1053/j.gastro.2020.05.097. Epub 2020 Jul 1.
217. Vakil M, et al. The Montreal Definition and Classification of Gastroesophageal Reflux Disease: A Global Evidence-Based Consensus. *Am J Gastroenterol* 2006;101:1900–1920.
218. Viswanath Y, Maguire N, Obuobi RB, Dhar A, Punnoose S. Endoscopic day case antireflux radiofrequency (Stretta) therapy improves quality of life and reduce proton pump inhibitor (PPI) dependency in patients with gastro-oesophageal reflux disease: a prospective study from a UK tertiary centre. *Frontline gastroenterology*. 2019 Apr;10(2):113.
219. Wang X, et al. Peroral endoscopic myotomy versus pneumatic dilation for achalasia in patients aged ≥ 65 years. *Rev Esp Enferm Dig*. 2016 Oct;108(10):637-641.
220. Wang XH, et al. Full-thickness myotomy is associated with higher rate of postoperative gastroesophageal reflux disease. *World J Gastroenterol*. 2016 Nov 14;22(42):9419-9426.
221. Warren HF, Reynolds JL, et al. Multi-institutional outcomes using magnetic sphincter augmentation versus Nissen fundoplication for chronic gastroesophageal reflux disease. *Surg Endosc*. 2016 Aug;30(8):3289-96. doi: 10.1007/s00464-015-4659-y. Epub 2015 Nov 5.
222. Wendling MR, et al. Impact of transoral incisionless fundoplication (TIF) on subjective and objective GERD indices: a systematic review of the published literature. *Surg Endosc*. May 2013.
223. Werner YB, Hakanson B, et al. Endoscopic or Surgical Myotomy in Patients with Idiopathic Achalasia. *N Engl J Med*. 2019 Dec 5;381(23):2219-2229. doi: 10.1056/NEJMoa1905380.



224. Wilson EB, et al. The Effects of Transoral Incisionless Fundoplication on Chronic GERD Patients: 12-Month Prospective Multicenter Experience. *Surg Laparosc Endosc Percutan Tech*, Feb 2014; 24(1):36-46.
225. Yadlapati R, Gyawali CP, Pandolfino JE; CGIT GERD Consensus Conference Participants. AGA Clinical Practice Update on the Personalized Approach to the Evaluation and Management of GERD: Expert Review. *Clin Gastroenterol Hepatol*. 2022 May;20(5):984-994.e1. doi: 10.1016/j.cgh.2022.01.025. Epub 2022 Feb 2. Erratum in: *Clin Gastroenterol Hepatol*. 2022 Jul 9.
226. Yan C, et al. Comparison of Stretta procedure and Toupet fundoplication for gastroesophageal reflux disease-related extra-esophageal symptoms. *World J Gastroenterol*. 2015 Dec 7;21(45):12882-7.
227. Yeh RW, Triadafilopoulos G. Endoscopic antireflux therapy: the Stretta procedure. *Thorac Surg Clin*. 2005 Aug; 15(3): 395-403.
228. Yew KC, Seng-Kee C. Antireflux Endoluminal Therapies: Past and Present. *Gastroenterology Research & Practice* (2013).
229. Youn YH, et al. Peroral Endoscopic Myotomy for Treating Achalasia and Esophageal Motility Disorders. *J Neurogastroenterol Motil*. 2016 Jan 31;22(1):14-24.
230. Zaninotto G, Bennett C, et al. International Society for Diseases of the Esophagus. The 2018 ISDE achalasia guidelines. *Diseases of the Esophagus* (2018) 31, 1–29.
231. Zhuang QJ, Tan ND, Chen SF, Zhang MY, Xiao YL. Magnetic sphincter augmentation in treating refractory gastroesophageal reflux disease: A systematic review and meta-analysis. *J Dig Dis*. 2021 Dec;22(12):695-705. doi: 10.1111/1751-2980.13063. Epub 2021 Nov 30. PMID: 34693633.

## COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/25/22.

## GUIDELINE UPDATE INFORMATION:

06/15/01	New Medical Coverage Guideline.
03/15/02	Additions to Non-Covered section/Added CPT code 0008T.
04/15/03	Medical Coverage Guideline Reviewed.
01/01/04	Annual HCPCS coding update.
04/15/04	Review and revision of guideline consisting of updated references and added information regarding endoscopic submucosal biocompatible polymer (investigational).
10/01/04	4th quarter HCPCS coding update consisting of addition of S2215 (investigational).
01/01/05	Annual HCPCS update consisting of addition of 43257 and deletion of 0057T.
04/15/05	Review and revision of guideline consisting of updated references.
01/01/06	Annual HCPCS coding update consisting of the deletion of S2215 and the addition of 0133T.
04/15/06	Review and revision of guideline consisting of updated references.
01/01/07	HCPCS update consisting of the deletion of 0008T.
04/15/07	Review and revision of guideline consisting of updated references.
06/15/07	Reformatted guideline.
07/01/07	HCPCS update consisting of the deletion of 0133T.
03/15/08	Review and revision of guideline consisting of updated references.
03/15/09	Review and revision of guideline consisting of updated references.

05/15/09	Scheduled review; added informational statements relating to Stretta and Enteryx; no change in position statements; references updated.
06/15/10	Scheduled review; position statement unchanged, references updated.
03/15/11	Review Position Statement for Stretta procedure; Position Statement unchanged. References updated.
11/15/11	Revision consisting of the addition of clarification regarding TIF and Esophyx.
11/15/12	Annual review; position statement unchanged; references updated.
11/15/13	Annual review; position statement unchanged; Coding section revised; Program Exceptions section updated; references updated.
01/01/14	Annual HCPCS coding update: added 43212 and 43266; revised 43201, 43236, and 43257.
03/15/14	Revision to add Position Statement regarding magnetic sphincter augmentation procedures; coding and references updated.
10/15/14	Annual review; add position statement for POEM; other position statements are unchanged; update Description and Definition sections; update references.
07/01/15	Quarterly CPT/HCPCS update: added codes 0392T and 0393T.
06/15/16	Unscheduled review. Revised description section, maintained position statement. Revised CPT coding, Medicare Advantage program exception, and index terms. Updated references.
01/01/17	Annual CPT/HCPCS update. Added 43284, 43285. Deleted 0392T, 0393T.
02/15/17	Scheduled review. Maintained Position Statement section. Revised Description section and index terms. Updated references.
04/20/17	Deleted code 43499.
02/15/19	Revision. Updated description section. Maintained position statement. Updated references.
05/15/19	Deleted codes 43201, 43212, 43236, 43241, and 43266.
12/15/19	Unscheduled review. Maintained position statement and updated references.
04/15/20	Unscheduled review. Maintained position statement and updated references.
11/15/20	Scheduled review. Revised description and maintained position statement. Updated references.
07/15/21	Revision. Updated references and Program Exceptions section, and maintained position statement.
09/15/22	Scheduled review. Revised description and CPT coding. Added coverage criteria for peroral endoscopic myotomy (POEM). Designated D-POEM, G-POEM, and Z-POEM as experimental or investigational. Revised definitions and updated references.