Medical Coverage Policy | Transesophageal Endoscopic Treatments for Gastroesophageal Reflux Disease

EFFECTIVE DATE: 10|01|2015
POLICY LAST REVIEWED: 2|05|2025

OVERVIEW

Transesophageal endoscopic therapies are being developed for the treatment of gastroesophageal reflux disease (GERD). A variety of procedures are being evaluated, including transesophageal (or transoral) incisionless fundoplication (TIF), application of radiofrequency (RF) energy, and injection/implantation of prosthetic devices or bulking agents.
Note: This policy does not pertain to treatment for Barrett's Esophagus, which is covered.

This policy is applicable to Commercial Products only. For Medicare Advantage Plans, see Related Policies section below.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Commercial Products

The following procedures for the treatment gastroesophageal reflux disease are not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Transoral incisionless fundoplication (TIF) (eg, EsophyX; MUSE, GERDX)
- Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (i.e., Stretta® procedure)
- Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., polymethylmethacrylate beads, zirconium oxide spheres)

Implantation of inert polymers (Enteryx™) is considered a **contract exclusion** as it was withdrawn from the market following serious complications.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Subscriber Agreement for the applicable services that are not medically necessary and contract exclusions.

BACKGROUND

Gastroesophageal Reflux Disease

Gastroesophageal reflux disease (GERD) is a common disorder characterized by heartburn and other symptoms related to reflux of stomach acid into the esophagus. Nearly all individuals experience such symptoms at some point in their lives; a smaller number have chronic symptoms and are at risk for complications of GERD. The prevalence of GERD has been estimated to be 20% in the United States.

Pathophysiology

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.

In addition to troubling symptoms, some patients will have a more serious disease, which results in complications such a serosive esophagitis, dysphagia, Barrett esophagus, and esophageal carcinoma. Pulmonary complications may result from aspiration of stomach acid into the lungs and can include asthma, pulmonary fibrosis, and bronchitis, or symptoms of chronic hoarseness, cough, and sore throat.

Treatment
Guidelines on the management of GERD emphasize initial medical management. Weight loss, smoking cessation, head of the bed elevation, and elimination of food triggers are all recommended in recent practice guidelines.

Proton pump inhibitors (PPIs) have been shown to be the most effective medical treatment. In a Cochrane systematic review, van Pinxteren et al (2010) reported that PPIs demonstrated superiority to H 2-receptor antagonists and prokinetics in both network meta-analyses and direct comparisons.

Surgical Treatment
The most common surgical procedure used for GERD remains laparoscopic Nissen fundoplication; however, the utilization of this procedure steadily declined between 2009 and 2013 with the advancement of novel nonmedical (endoscopic and surgical) techniques.
Fundoplication involves wrapping a portion of the gastric fundus around the distal esophagus to increase lower esophageal sphincter pressure. If a hiatal hernia is present, the procedure also restores the position of the lower esophageal sphincter to the correct location. Laparoscopic fundoplication was introduced in 1991and has been rapidly adopted because it avoids complications associated with an open procedure. Although fundoplication results in a high proportion of patients reporting symptom relief, complications can occur, and sometimes require conversion to an open procedure. Patients who have relief of symptoms of GERD after fundoplication may have dysphagia or gas-bloat syndrome (excessive gastrointestinal gas).

Other Treatment Options
Due in part to the high prevalence of GERD, there has been interest in creating a minimally invasive transesophageal therapeutic alternative to open or laparoscopic fundoplication or chronic medical therapy. This type of procedure may be considered natural orifice transluminal surgery. Three types of procedures have been investigated.

1. Transesophageal endoscopic gastroplasty (gastroplication, transoral incisionless fundoplication) can be performed as an outpatient procedure. During this procedure, the fundus of the stomach is folded and then held in place with staples or fasteners that are deployed by the device. The endoscopic procedure is designed to recreate a valve and barrier to reflux.

2. Radiofrequency energy has been used to produce submucosal thermal lesions at the gastroesophageal junction (this technique has also been referred to as the Stretta procedure). Specifically, radiofrequency energy is applied through 4 electrodes inserted into the esophageal wall at multiple sites both above and below the squamocolumnar junction. The mechanism of action of the thermal lesions is not precisely known but may be related to the ablation of the nerve pathways responsible for sphincter relaxation or may induce a tissue-tightening effect related to heat-induced collagen contraction and fibrosis.

3. Submucosal injection or implantation of a prosthetic or bulking agent to enhance the volume of the lower esophageal sphincter has also been investigated. One bulking agent, pyrolytic carbon-coated zirconium oxidespheres (Durasphere), has been evaluated. The Gatekeeper™ Reflux Repair System (Medtronic) used a soft, pliable, expandable prosthesis made of a polyacrylonitrile-based hydrogel. The prosthesis was implanted into the esophageal submucosa, and with time, the prosthesis absorbed water and expanded, creating bulk in the region of implantation. However, the only identified RCT was terminated early due to lack of efficacy, and it was voluntarily withdrawn by the manufacturer.

Endoscopic submucosal implantation of polymethylmethacrylate beads into the lower esophageal folds has also been investigated.

Regulatory Status
The EsophyX® (EndoGastric Solutions) is a transesophageal (or transoral) incisionless fundoplication (TIF) device that was originally cleared for marketing by the FDA through the 510(k) process in 2007 and has subsequently undergone 2 evolutions: Generation 2=EsophyX2 iterations (E2-Plus, HD) and Generation 3=Z iterations (EZ/ZR, Z+).

Some of the key Regulatory Status changes are summarized herein. In 2007, EsophyX® (EndoGastric Solutions) was cleared for marketing by the FDA through the 510(k) process for full-thickness plication. In 2016, EsophyX® Z Device with Serosa Fuse Fasteners was cleared for marketing by the FDA through the 510(k) process (K160960) for use in transoral tissue approximation, full-thickness plication, ligation in the gastrointestinal tract, narrowing the gastroesophageal junction, and reduction of hiatal hernias of 2 cm or less in patients with symptomatic chronic GERD.

In June 2017, EsophyX2 HD and the third generation EsophyX Z Devices with SerosaFuse fasteners and accessories were cleared for marketing by the FDA through the 510(k) process (K171307) for expanded indications, including patients who require and respond to pharmacologic therapy and patients with hiatal hernias larger than 2 cm when a laparoscopic hiatal hernia repair reduces a hernia to 2 cm or less.

The most recent FDA 510(k) clearance (K172811) occurred in October 2017for new product specification iterations of EsophyX2 HD and EsophyX Z Devices. This clearance allows for "a moderate increase in the upper limit of the temporary Tissue Mold clamping pressure occurring during each fastener deployment." FDA product code: ODE.

The Medigus SRS Endoscopic Stapling System (MUSE, Medigus) was cleared for marketing by the FDA through the510(k) process in 2012 (K120299) and 2014 (K132151). MUSE is intended for endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach to create anterior partial fundoplication for the treatment of symptomatic chronic GERD in patients who require and respond to pharmacologic therapy. FDA product code: ODE.

The GERDX-System (K233240) was cleared through the 510(k) process in 2024 (K233240). The device is intended for endoscopic full-thickness plication for chronic GERD in individuals who require and respond to pharmacological therapy.[10,] FDA product code: ODE. The manufacturer website includes a description for use in presence of a hiatal hernia up to 3 cm in size. The device is clinically, biologically, and technologically identical to the NDO Surgical Endoscopic Plication System (K071553) which was approved by the FDA in 2003 and has since been removed from the market due to risk of complications. Technological details of the GERDX-System have been improved from the predicate device to improve safety.

In 2000, the CSM Stretta® System was cleared for marketing by the FDA through the 510(k) process for general use in the electrosurgical coagulation of tissue and was specifically intended for use in the treatment of GERD. In 2010, Mederi Therapeutics began manufacturing the Stretta® device. Mederi was acquired by Respiratory Technology Corporation in2018. FDA product code: GEI.

Durasphere® is a bulking agent approved for the treatment of urinary and fecal incontinence (see evidence review7.01.19). Use of this product for esophageal reflux would be considered off-label use. The website of Carbon Medical Technologies states that the Durasphere® GR product is “intended to treat problems associated with GERD” but is considered an investigational device in the U.S.

CODING

Commercial Products
The following CPT code(s) is not medically necessary:

43257 Upper gastrointestinal endoscopy, with delivery of thermal energy to the muscle of the lower esophageal sphincter and/or gastric cardia

The following CPT code(s) are not medically necessary when filed with ICD-10 Diagnosis K21.00-K21.9:

43201 Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43210 Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed
43212 Esophagoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)
43236 Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43266 Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and dilation and guide wire passage, when performed)

RELATED POLICIES

Medicare Advantage Plans National and Local Coverage Determinations

PUBLISHED
Provider Update, April 2025
Provider Update, March 2024
Provider Update, February/December 2022
Provider Update, February 2021
Provider Update, February 2020

REFERENCES

1. Shaqran TM, Ismaeel MM, Alnuaman AA, et al. Epidemiology, Causes, and Management of Gastro-esophageal Reflux Disease: A Systematic Review. Cureus. Oct 2023; 15(10): e47420. PMID 38022211
2. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol. Mar 2013; 108(3): 308-28; quiz 329. PMID 23419381
3. van Pinxteren B, Sigterman KE, Bonis P, et al. Short-term treatment with proton pump inhibitors, H2-receptor antagonists and prokinetics for gastro-oesophageal reflux disease-like symptoms and endoscopy negative reflux disease. Cochrane Database Syst Rev. Nov 10 2010; (11): CD002095. PMID 21069670
4. Khan F, Maradey-Romero C, Ganocy S, 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. Jun 2016; 43(11): 1124-31. PMID 27060607
5. Ihde GM. The evolution of TIF: transoral incisionless fundoplication. Therap Adv Gastroenterol. 2020; 13: 1756284820924206. PMID 32499834
6. Food and Drug Administration (FDA). 510(k) Summary: EsophyX (K160960). 2016; https://www.accessdata.fda.gov/cdrh_docs/pdf16/K160960.pdf. Accessed October 18, 2024.
7. Food and Drug Administration (FDA). EsophyX Summary K171307. 2017; https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171307.pdf. Accessed October 19, 2024.
8. Food and Drug Administration (FDA). EsophyX Summary K172811. 2017; https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172811.pdf. Accessed October 17, 2024.
9. Food and Drug Administration (FDA). 510(k) Summary: EsophyX Z+ (K240879). 2024; https://www.accessdata.fda.gov/cdrh_docs/pdf24/K240879.pdf. Accessed October 14, 2024.
10. Food and Drug Administration (FDA). 510(k) Summary: GERDX (K233240). 2024; www.accessdata.fda.gov/cdrh_docs/pdf23/K233240.pdf. Accessed October 13, 2024.
11. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Transesophageal Endoscopic Treatments for Gastroesophageal Reflux Disease. TEC Assessment. 2003;Volume 18:Tab 20. PMID

12. McCarty TR, Itidiare M, Njei B, et al. Efficacy of transoral incisionless fundoplication for refractory gastroesophageal reflux disease: a systematic review and meta-analysis. Endoscopy. Jul 2018; 50(7): 708-725. PMID 29625507
13. Richter JE, Kumar A, Lipka S, et al. Efficacy of Laparoscopic Nissen Fundoplication vs Transoral Incisionless Fundoplication or Proton Pump Inhibitors in Patients With Gastroesophageal Reflux Disease: A Systematic Review and Network Meta-analysis. Gastroenterology. Apr 2018; 154(5): 1298-1308.e7. PMID 29305934
14. 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. Feb 2021; 9(2): E239-E246. PMID 33553587
15. Rausa E, Ferrari D, Kelly ME, et al. Efficacy of laparoscopic Toupet fundoplication compared to endoscopic and surgical procedures for GERD treatment: a randomized trials network meta-analysis. Langenbecks Arch Surg. Jan 21 2023; 408(1): 52. PMID 36680602
16. Haseeb M, Brown JRG, Hayat U, et al. Impact of second-generation transoral incisionless fundoplication on atypical GERD symptoms: a systematic review and meta-analysis. Gastrointest Endosc. Mar 2023; 97(3): 394-406.e2. PMID 36402203
17. Hunter JG, Kahrilas PJ, Bell RC, et al. Efficacy of transoral fundoplication vs omeprazole for treatment of regurgitation in a randomized controlled trial. Gastroenterology. Feb 2015; 148(2): 324-333.e5. PMID 25448925
18. Trad KS, Barnes WE, Simoni G, 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. Feb 2015; 22(1): 26-40. PMID 24756976
19. Trad KS, Fox MA, Simoni G, 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. Jun 2017; 31(6): 2498-2508. PMID 27655380
20. 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. Apr 2018; 25(2): 149-157. PMID 29405886
21. Håkansson B, Montgomery M, Cadiere GB, et al. Randomised clinical trial: transoral incisionless fundoplication vs. sham intervention to control chronic GERD. Aliment Pharmacol Ther. Dec 2015; 42(11-12): 1261-70. PMID 26463242
22. Witteman BP, Conchillo JM, Rinsma NF, et al. Randomized controlled trial of transoral incisionless fundoplication vs. proton pump inhibitors for treatment of gastroesophageal reflux disease. Am J Gastroenterol. Apr 2015; 110(4): 531-42. PMID 25823768
23. Toomey P, Teta A, Patel K, et al. Transoral incisionless fundoplication: is it as safe and efficacious as a Nissen or Toupet fundoplication?. Am Surg. Sep 2014; 80(9): 860-7. PMID 25197871
24. Frazzoni M, Conigliaro R, Manta R, et al. Reflux parameters as modified by EsophyX or laparoscopic fundoplication in refractory GERD. Aliment Pharmacol Ther. Jul 2011; 34(1): 67-75. PMID 21539587
25. Bell RCW, Freeman K, Heidrick R, et al. Transoral incisionless fundoplication demonstrates durability at up to 9 years. Therap Adv Gastroenterol. 2021; 14: 17562848211004827. PMID 33948113
26. Kalapala R, Karyampudi A, Nabi Z, et al. Endoscopic full-thickness plication for the treatment of PPI-dependent GERD: results from a randomised, sham controlled trial. Gut. Apr 2022; 71(4): 686-694. PMID 33849942
27. 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. Feb 01 2017; 30(3): 1-8. PMID 27868281
28. Testoni PA, Testoni S, Mazzoleni G, et al. 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. Sep 2015; 29(9): 2770-80. PMID 25480624
29. Testoni PA, Testoni S, Distefano G, et al. Transoral incisionless fundoplication with EsophyX for gastroesophageal reflux disease: clinical efficacy is maintained up to 10 years. Endosc Int Open. May 2019; 7(5): E647-E654. PMID 31058207

30. Testoni SGG, Cilona MB, Mazzoleni G, et al. Transoral incisionless fundoplication with Medigus ultrasonic surgical endostapler (MUSE) for the treatment of gastro-esophageal reflux disease: outcomes up to 3 years. Surg Endosc. Jul 2022; 36(7): 5023-5031. PMID 34799745
31. Huang X, Chen S, Zhao H, et al. Efficacy of transoral incisionless fundoplication (TIF) for the treatment of GERD: a systematic review with meta-analysis. Surg Endosc. Mar 2017; 31(3): 1032-1044. PMID 27495332
32. Lipka S, Kumar A, Richter JE. No evidence for efficacy of radiofrequency ablation for treatment of gastroesophageal reflux disease: a systematic review and meta-analysis. Clin Gastroenterol Hepatol. Jun 2015; 13(6): 1058-67.e1. PMID 25459556
33. Arts J, Bisschops R, Blondeau K, et al. A double-blind sham-controlled study of the effect of radiofrequency energy on symptoms and distensibility of the gastro-esophageal junction in GERD. Am J Gastroenterol. Feb 2012; 107(2): 222-30. PMID 22108449
34. Aziz AM, El-Khayat HR, Sadek A, et al. A prospective randomized trial of sham, single-dose Stretta, and double-dose Stretta for the treatment of gastroesophageal reflux disease. Surg Endosc. Apr 2010; 24(4): 818-25. PMID 19730952
35. Corley DA, Katz P, Wo JM, et al. Improvement of gastroesophageal reflux symptoms after radiofrequency energy: a randomized, sham-controlled trial. Gastroenterology. Sep 2003; 125(3): 668-76. PMID 12949712
36. Coron E, Sebille V, Cadiot G, et al. Clinical trial: Radiofrequency energy delivery in proton pump inhibitor-dependent gastro-oesophageal reflux disease patients. Aliment Pharmacol Ther. Nov 01 2008; 28(9): 1147-58. PMID 18616516
37. Fass R, Cahn F, Scotti DJ, et al. Systematic review and meta-analysis of controlled and prospective cohort efficacy studies of endoscopic radiofrequency for treatment of gastroesophageal reflux disease. Surg Endosc. Dec 2017; 31(12): 4865-4882. PMID 28233093
38. Xie P, Yan J, Ye L, et al. Efficacy of different endoscopic treatments in patients with gastroesophageal reflux disease: a systematic review and network meta-analysis. Surg Endosc. Apr 2021; 35(4): 1500-1510. PMID 33650003
39. Kalapala R, Shah H, Nabi Z, et al. Treatment of gastroesophageal reflux disease using radiofrequency ablation (Stretta procedure): An interim analysis of a randomized trial. Indian J Gastroenterol. Sep 2017; 36(5): 337-342. PMID 29030802
40. Zerbib F, Sacher-Huvelin S, Coron E, et al. Randomised clinical trial: oesophageal radiofrequency energy delivery versus sham for PPI-refractory heartburn. Aliment Pharmacol Ther. Aug 2020; 52(4): 637-645. PMID 32656869
41. Liang WT, Yan C, Wang ZG, et al. Early and Midterm Outcome After Laparoscopic Fundoplication and a Minimally Invasive Endoscopic Procedure in Patients with Gastroesophageal Reflux Disease: A Prospective Observational Study. J Laparoendosc Adv Surg Tech A. Aug 2015; 25(8): 657-61. PMID 26258269
42. Ma L, Li T, Liu G, et al. Stretta radiofrequency treatment vs Toupet fundoplication for gastroesophageal reflux disease: a comparative study. BMC Gastroenterol. May 27 2020; 20(1): 162. PMID 32460696
43. Liang WT, Wang ZG, Wang F, et al. Long-term outcomes of patients with refractory gastroesophageal reflux disease following a minimally invasive endoscopic procedure: a prospective observational study. BMC Gastroenterol. Oct 10 2014; 14: 178. PMID 25304252
44. Noar M, Squires P, Noar E, et al. Long-term maintenance effect of radiofrequency energy delivery for refractory GERD: a decade later. Surg Endosc. Aug 2014; 28(8): 2323-33. PMID 24562599
45. Ganz RA, Fallon E, Wittchow T, et al. A new injectable agent for the treatment of GERD: results of the Durasphere pilot trial. Gastrointest Endosc. Feb 2009; 69(2): 318-23. PMID 19185691
46. Feretis C, Benakis P, Dimopoulos C, et al. Endoscopic implantation of Plexiglas (PMMA) microspheres for the treatment of GERD. Gastrointest Endosc. Apr 2001; 53(4): 423-6. PMID 11275880
47. Yadlapati R, Gyawali CP, Pandolfino JE, et al. AGA Clinical Practice Update on the Personalized Approach to the Evaluation and Management of GERD: Expert Review. Clin Gastroenterol Hepatol. May 2022; 20(5): 984-994.e1. PMID 35123084

48. Katz PO, Dunbar KB, Schnoll-Sussman FH, et al. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. Am J Gastroenterol. Jan 01 2022; 117(1): 27-56. PMID 34807007
49. Muthusamy VR, Lightdale JR, Acosta RD, et al. The role of endoscopy in the management of GERD. Gastrointest Endosc. 2015; 81(6): 1305-10. PMID 25863867
50. American Society of General Surgeons (ASGS). Coverage of Transoral fundoplication. 2011; https://theasgs.org/position-statements/coverage-of-transoral-fundoplication-2/. Accessed October 18, 2024.
51. Slater BJ, Collings A, Dirks R, et al. Multi-society consensus conference and guideline on the treatment of gastroesophageal reflux disease (GERD). Surg Endosc. Feb 2023; 37(2): 781-806. PMID 36529851
52. National Institute for Health and Care Excellence (NICE). Endoscopic radiofrequency ablation for gastro-oesophageal reflux disease [IPG461]. 2013; https://www.nice.org.uk/guidance/ipg461. Accessed October 16, 2024.
53. National Institute for Health and Care Excellence (NICE). Endoluminal gastroplication for gastro-oesophageal reflux disease [IPG404]. 2011; https://www.nice.org.uk/guidance/ipg404. Accessed October 18, 2024.