



## MASSACHUSETTS

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### Medical Policy

## Surgical and Transesophageal Endoscopic Procedures to Treat Gastroesophageal Reflux Disease

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### Policy Number: 920

BCBSA Reference Number: 7.01.137; 2.01.38

NCD/LCD: N/A

### Related Policies

Endoscopic Radiofrequency Ablation or Cryoablation for Barrett's Esophagus, [#218](#)  
Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence, [#471](#)

### Policy

**Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity  
Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members**

**Prior Authorization Request Form: Surgical and Transesophageal Endoscopic Procedures to Treat Gastroesophageal Reflux Disease**

**This form must be completed and faxed to: Medical and Surgical: 1-888-282-0780; Medicare Advantage: 1-800-447-2994**

[Click here for Surgical and Transesophageal Endoscopic Procedures to Treat Gastroesophageal Reflux Disease Form, #956](#)

Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is considered **MEDICALLY NECESSARY** when the following criteria are met:<sup>1</sup>

- Patient has a history of severe GERD for  $\geq 1$  year with daily symptoms, **AND**
- Patient has tried and failed optimal non-surgical management of symptoms, including lifestyle modification, weight loss (if indicated), and daily proton pump inhibitor use for  $\geq 6$  months, **AND**
- Patient has proven gastroesophageal reflux by either endoscopy or ambulatory pH monitoring, **AND**
- Patient has evidence of adequate peristalsis by manometry or barium esophagram, **AND**
- None of the following contraindications are present:
  - Morbid obesity (BMI  $>35$ )
  - Suspected or known allergies to metals such as iron, nickel, titanium, or stainless steel
  - Grade C or D (LA classification) esophagitis
  - Scleroderma
  - Esophageal stricture or gross esophageal anatomic abnormalities

- Suspected or confirmed esophageal or gastric cancer
- Prior esophageal or gastric surgery or endoscopic intervention.

Transoral incisionless fundoplication (TIF) (ie, EsophyX®) is considered **MEDICALLY NECESSARY** as a treatment of gastroesophageal reflux disease when the following criteria are met:<sup>1</sup>

- Patient has a history of severe GERD for ≥1 year with daily symptoms, **AND**
- Patient has tried and failed optimal non-surgical management of symptoms, including lifestyle modification, weight loss (if indicated), and daily proton pump inhibitor use for ≥ 6 months, **AND**
- Patient has proven gastroesophageal reflux by either endoscopy, ambulatory pH monitoring, or barium esophagram, **AND**
- None of the following contraindications are present:
  - Hiatal hernia >2cm in axial height and >2cm in greatest transverse dimension
  - Morbid obesity (BMI >35)
  - Esophagitis grade C or D
  - Barrett's esophagus > 2 cm
  - Non-healing esophageal ulcer
  - Fixed esophageal stricture or narrowing
  - Portal hypertension and/or varices
  - Active gastro-duodenal ulcer disease
  - Gastric outlet obstruction or stenosis
  - Gastroparesis
  - Prior esophageal surgery
  - Scleroderma
  - Suspected or confirmed esophageal or gastric cancer.

Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (ie, the Stretta® procedure) is considered **INVESTIGATIONAL** as a treatment of gastroesophageal reflux disease.

Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (eg, polymethylmethacrylate beads, zirconium oxide spheres) is **INVESTIGATIONAL** as a treatment of gastroesophageal reflux disease.

## Prior Authorization Information

### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>required</b> . *
Commercial PPO and Indemnity	Prior authorization is <b>not required</b> .
Medicare HMO Blue <sup>SM</sup>	Prior authorization is <b>required</b> . *
Medicare PPO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .

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## CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above **medical necessity criteria MUST** be met for the following codes to be covered for **Commercial Members: Managed Care (HMO and POS), PPO, Indemnity Medicare HMO Blue and Medicare PPO Blue:**

### CPT Codes

CPT codes:	Description
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed

### ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
0DV48ZZ	Restriction of Esophagogastric Junction, Via Natural or Artificial Opening Endoscopic
0DV44CZ	Restriction of Esophagogastric Junction with Extraluminal Device, Percutaneous Endoscopic Approach

The following CPT codes are considered investigational for **Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

### CPT Codes

CPT codes:	Code Description
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43212	Esophagoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)
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

## Description

### Gastroesophageal Reflux Disease

Gastroesophageal reflux disease (GERD) is defined as reflux of stomach acid into the esophagus that causes symptoms and/or mucosal injury. GERD is a common medical disorder, with estimates of 10% to 20% prevalence in developed countries. The severity of GERD varies widely. Many patients have mild, intermittent symptoms that do not require treatment or only require episodic use of medications. Other patients have chronic, severe GERD that can lead to complications such as Barrett esophagus and esophageal cancer.

## Treatment

For patients with severe disease, chronic treatment with acid blockers is an option. For some patients, medications are inadequate to control symptoms; other patients prefer to avoid the use of indefinite, possibly lifelong medications. Surgical treatments are available for these patients, primarily a Nissen fundoplication performed either laparoscopically or by open surgery. A number of less invasive procedures are also being evaluated as an intermediate option between medical therapy and surgery.

The LINX Reflux Management System is composed of a small flexible band of 10 to 18 interlinked titanium beads with magnetic cores. Using standard laparoscopic techniques, the band is placed around the esophagus at the level of the gastroesophageal junction. The magnetic attraction between the beads is intended to augment the lower esophageal sphincter to prevent gastric reflux into the esophagus, without compressing the esophageal wall. It is proposed that swallowing food or liquids creates sufficient pressure to overcome the magnetic bond between the beads, allowing the beads to separate and temporarily increase the size of the ring. The target population is patients who have GERD symptoms despite maximum medical therapy (eg, proton pump inhibitors) but who do not want to risk the adverse effects of a surgical procedure like Nissen fundoplication. Adverse events of the LINX Reflux Management System may include dysphagia or odynophagia. The device can be removed by a laparoscopic procedure if severe adverse events occur or if magnetic resonance imaging is needed for another condition.

## Summary

A laparoscopically implanted ring composed of interlinked titanium beads with magnetic cores has been developed for the treatment of gastroesophageal reflux disease (GERD). The device is placed around the esophagus at the level of the gastroesophageal junction and is being evaluated in patients who have GERD symptoms, despite maximal medical therapy.

For individuals who have GERD who receive magnetic sphincter augmentation (MSA), the evidence includes prospective and retrospective observational comparative studies, 2 single-arm interventional trials, and single-arm observational studies. Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. In the 2 single-arm, uncontrolled manufacturer-sponsored studies submitted to the U.S. Food and Drug Administration with materials for device approval, subjects showed improvements in Gastroesophageal Reflux Disease Health Related Quality of Life (GERD-HRQL) scores and reduced proton pump inhibitor use. Similarly, observational comparative studies, most often comparing MSA with laparoscopic Nissen fundoplication, generally have shown that GERD-HRQL scores do not differ significantly between fundoplication and MSA, and patients can reduce proton pump inhibitor use after MSA. However, the comparative studies are retrospective and nonrandomized, may be affected by selection bias, and the subjective outcome measures used in these studies (eg, the GERD-HRQL scores) may be biased. A randomized trial is in progress (NCT02505945); it will compare treatment with the MSA and treatment with double-dose proton pump inhibitors. Randomized comparisons of MSA with laparoscopic Nissen fundoplication are also needed to evaluate the relative risk-benefit of these 2 procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

## Policy History

Date	Action
1/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
1/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
10/2018	New medically necessary indications described. Title changed. Clarified coding information. Effective 10/1/2018. The following ongoing investigational statements were transferred from policy 635: <ul style="list-style-type: none"><li>• Transesophageal radiofrequency to create submucosal thermal lesions</li><li>• Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent.</li></ul>

1/2017	BCBSA National medical policy review. Title changed. New references added.
1/2016	Clarified coding information.
11/2015	New references added from BCBSA National medical policy.
7/2015	Clarified coding information.
10/2014	New references added from BCBSA National medical policy.
1/2014	Updated to add new HCPCS code C9737.
12/2013	New references from BCBSA National medical policy.
3/2013	New policy describing non-coverage. Effective 3/1/2013.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

1. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. *Am J Gastroenterol*. Mar 2013;108(3):308-328; quiz 329. PMID 23419381.
2. 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.
3. Ip S, Bonis P, Tatsoni A, et al. Comparative Effectiveness of Management Strategies for Gastroesophageal Reflux Disease (Evidence Report/Technology Assessment No. 1). Rockville, MD: Agency for Healthcare Research and Quality; 2005.
4. Ip S, Chung M, Moorthy D, et al. Management strategies for gastroesophageal reflux disease: An update (Comparative Effectiveness Review No. 29). Rockville, MD: Agency for Healthcare Research and Quality; 2011.
5. Humphries LA, Hernandez JM, Clark W, et al. Causes of dissatisfaction after laparoscopic fundoplication: the impact of new symptoms, recurrent symptoms, and the patient experience. *Surg Endosc*. May 2013;27(5):1537-1545. PMID 23508812.
6. Hummel K, Richards W. Endoscopic treatment of gastroesophageal reflux disease. *Surg Clin North Am*. Jun 2015;95(3):653-667. PMID 25965137.
7. Food and Drug Administration (FDA). 510(k) Summary: EsophyX (K106960). 2016; [https://www.accessdata.fda.gov/cdrh\\_docs/pdf16/K160960.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf16/K160960.pdf). Accessed October 29, 2018.
8. Food and Drug Administration (FDA). EsophyX Summary K171307. 2017; [https://www.accessdata.fda.gov/cdrh\\_docs/pdf17/K171307.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171307.pdf). Accessed October 29, 2018.
9. 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.
10. 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.
11. 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 e1297. PMID 29305934.
12. 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 e325. PMID 25448925.
13. 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.

14. 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.
15. 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.
16. Hakansson 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):1261-1270. PMID 26463242.
17. 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):531-542. PMID 25823768.
18. 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):860-867. PMID 25197871.
19. 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.
20. 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.
21. 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):2770-2780. PMID 25480624.
22. 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,* 2019 May 7;7(5). PMID 31058207.
23. 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.
24. 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):1058-1067 e1051. PMID 25459556.
25. 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):668-676. PMID 12949712.
26. 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):818-825. PMID 19730952.
27. 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):222-230. PMID 22108449.
28. 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.
29. 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 1 2008;28(9):1147-1158. PMID 18616516.
30. 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.
31. 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):657-661. PMID 26258269.
32. 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.

33. 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):2323-2333. PMID 24562599.
34. 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):318-323. PMID 19185691.
35. Fockens P, Cohen L, Edmundowicz SA, et al. Prospective randomized controlled trial of an injectable esophageal prosthesis versus a sham procedure for endoscopic treatment of gastroesophageal reflux disease. *Surg Endosc.* Jun 2010;24(6):1387-1397. PMID 20198491.
36. 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):423-426. PMID 11275880.
37. ASGE Standards of Practice Committee, Muthusamy VR, Lightdale JR, et al. The role of endoscopy in the management of GERD. *Gastrointest Endosc.* Apr 2015;81(6):1305-1310. PMID 25863867.
38. Society of American Gastrointestinal and Endoscopic Surgeons. Clinical Spotlight Review: Endoluminal Treatments for Gastroesophageal Reflux Disease (GERD). 2017; <https://www.sages.org/publications/guidelines/endoluminal-treatments-for-gastroesophageal-reflux-disease-gerd/>. Accessed October 17, 2019.
39. American Society of General Surgeons (ASGS). Coverage of Transoral fundoplication. 2011; <https://theasgs.org/position-statements/coverage-of-transoral-fundoplication-2/>. Accessed October 17, 2019.
40. 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 17, 2019.
41. 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 17, 2019.
42. National Institute for Health and Care Excellence (NICE). Endoscopic injection of bulking agents for gastro-oesophageal reflux disease [IPG55]. 2004; Warren HF, Reynolds JL, Lipham JC, et al. Multi-institutional outcomes using magnetic sphincter augmentation versus Nissen fundoplication for chronic gastroesophageal reflux disease. *Surg Endosc.* Aug 2016;30(8):3289- 3296. PMID 26541740

## Endnotes

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<sup>1</sup> Based on expert opinion