

Medical Coverage Policy | Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux



EFFECTIVE DATE: 01|01|2017

POLICY LAST REVIEWED: 01|07|2026

OVERVIEW

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 maximum medical therapy.

This policy is for the insertion only. For removal of the devices, please refer to the policy in the related policy section.

MEDICAL CRITERIA

Not applicable.

PRIOR AUTHORIZATION

Not applicable.

POLICY STATEMENT

Medicare Advantage Plans

Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes

Commercial Products

Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary/not covered.

BACKGROUND

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. For patients with severe disease, chronic treatment with acid blockers is an option. For some patients, medications are not adequate 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. Magnetic sphincter augmentation is a 30-minute surgical procedure performed under general anesthesia that includes testing of the esophageal sphincter. This is a minimally invasive procedure conducted in an inpatient surgical center and requires an overnight stay. The device manufacturer claims individuals resume a normal diet within 24 hours post-surgery. The device can be removed by a laparoscopic procedure if severe adverse events occur or if magnetic resonance imaging is needed for another condition.

REGULATORY STATUS

In 2012, the LINX™ Reflux Management System (Torax Medical, Shoreview, MN) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for patients diagnosed with GERD, as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximum therapy for the treatment of reflux. The FDA initially required 5-year follow-up of 100 patients from the investigational device exemption pivotal study to evaluate the safety and efficacy of the device, which was completed in March 2016. In 2018, the manufacturer initiated a device recall due to a possible separation of the bead component with the adjacent wire link causing a potential discontinuous or open LINX device. This recall was terminated on November 4, 2020.

In March 2018, the FDA approved an update of the LINX® Reflux Management System precautions statement, stating that the use of the system "in patients with a hiatal hernia larger than 3 cm should include hiatal hernia repair to reduce the hernia to less than 3 cm and that the LINX Reflux Management System has not been evaluated in patients with an unrepaired hiatal hernia greater than 3 cm, add a hiatal hernia clinical data summary in the instructions for use, update the instructions for use section to highlight the recommendation to repair a hiatal hernia, if present, at the time of the LINX Reflux Management System implantation, and update the patient information booklet to align with the instructions for use and include 5 year clinical study results."

In February 2024, the FDA revised the labeling for the LINX® Reflux Management System. They removed a precautionary statement about Barrett's Esophagus (BE) from the instructions for use. However, the updated labeling now includes this guidance: "LINX has not been proven to effectively treat BE by causing regression or preventing progression to cancer. Patients with BE who use LINX to manage GERD symptoms should consult their physician about ongoing BE treatment, which may include continued use of proton pump inhibitors (PPIs)."

For individuals who have GERD who receive magnetic esophageal sphincter augmentation (MSA), the evidence includes 1 randomized controlled trial (RCT) comparing MSA to proton pump inhibitor (PPI) therapy,⁶ nonrandomized studies comparing MSA to laparoscopic Nissen fundoplication (LNF), laparoscopic Toupet fundoplication (LTF), or anti-reflex mucosectomy (ARM), single-arm cohort studies, and systematic reviews comparing MSA to LNF. Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. An RCT comparing MSA to omeprazole 20 mg twice daily found that significantly more patients who received MSA reported improvements in symptoms and quality of life (QOL) at 6 months. A major limitation of the trial was that the patients had not received optimal medical treatment prior to enrollment. Six non-randomized comparative studies of MSA to laparoscopic fundoplication showed mixed outcomes, with some studies indicating similar improvements in QOL, PPI use, and satisfaction, while others reported no significant differences in symptom improvement but a higher rate of dysphagia in the MSA group, and another study observed transient differences in favor of fundoplication in QOL, with the MSA group having worse quality of life scores at final follow-up. Limitations in these comparative studies included a lack of randomization, blinding, heterogeneity in surgical techniques, outdated MSA protocols, imbalanced baseline patient characteristics, and selection bias in treatment choice. In the 2 single-arm, uncontrolled pivotal trials submitted to the FDA with materials for device approval, subjects showed improvements in GERD-HRQL scores and reduced PPI use. Similarly, observational comparative studies included in systematic reviews, most often comparing MSA with LNF, generally have shown that GERD-HRQL scores do not differ significantly between fundoplication and MSA, and patients can reduce PPI use after MSA. However, the comparative studies are retrospective and nonrandomized, and may be affected by selection bias. Randomized comparisons of MSA with LNF are needed to evaluate the relative risk-benefit of

these 2 procedures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

The following code(s) is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

43284 Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed

RELATED POLICIES

Removal of Implantable Devices

PUBLISHED

Provider Update, March 2026

Provider Update, February 2025

Provider Update, December 2024

Provider Update, October 2023

Provider Update, March 2022

REFERENCES:

1. U.S. Food and Drug Administration (FDA). Class 2 Device Recall LINX Reflux Management System. May 31, 2018. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=163589>. Accessed September 23, 2025.
2. U.S. Food & Drug Administration (FDA). Premarket Approval: Linx Reflux Management System [P100049/S021]. March 15, 2018; <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100049S021>. Accessed September 22, 2025.
3. U.S. Food & Drug Administration (FDA). Premarket Approval: Linx Reflux Management System[P100049/S037]. Feb 22, 2018; <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100049S037>. Accessed September 24, 2025.
4. Kothari BL, Borgert AJ, Kallies KJ, et al. Lack of Correlation Between Subjective and Objective Measures of Gastroesophageal Reflux Disease: Call for a Novel Validated Assessment Tool. *Surg Innov.* Jun 2021; 28(3): 290-294. PMID 32867603
5. Guidozi N, Wiggins T, Ahmed AR, et al. Laparoscopic magnetic sphincter augmentation versus fundoplication for gastroesophageal reflux disease: systematic review and pooled analysis. *Dis Esophagus.* Nov 13 2019; 32(9). PMID 31069388
6. Aiolfi A, Asti E, Bernardi D, et al. Early results of magnetic sphincter augmentation versus fundoplication for gastroesophageal reflux disease: Systematic review and meta-analysis. *Int J Surg.* Apr 2018; 52: 82-88. PMID 29471155
7. Zhuang QJ, Tan ND, Chen SF, et al. Magnetic sphincter augmentation in treating refractory gastroesophageal reflux disease: A systematic review and meta-analysis. *J Dig Dis.* Dec 2021; 22(12): 695-705. PMID 34693633
8. 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
9. Tade Y, Newman D, Walters RW, et al. Fundoplication significantly improves objective and subjective reflux outcomes-a meta-analysis. *Surg Endosc.* Jul 2025; 39(7): 4496-4504. PMID 40442360
10. Fadel MG, Tarazi M, Dave M, et al. Magnetic sphincter augmentation in the management of gastroesophageal reflux disease: a systematic review and meta-analysis. *Int J Surg.* Oct 01 2024; 110(10):6355-6366. PMID 38729117
11. Bell R, Lipham J, Louie BE, et al. Magnetic Sphincter Augmentation Superior to Proton Pump Inhibitors for Regurgitation in a 1-Year Randomized Trial. *Clin Gastroenterol Hepatol.* Jul 2020; 18(8): 1736-1743.e2. PMID 31518717

12. 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.* Jan 2019; 89(1): 14-22.e1. PMID 30031018
13. Bonavina L, Horbach T, Schoppmann SF, et al. Three-year clinical experience with magnetic sphincter augmentation and laparoscopic fundoplication. *Surg Endosc.* Jul 2021; 35(7): 3449-3458. PMID 32676727
14. Asti E, Milito P, Froiio C, et al. Comparative outcomes of Toupet fundoplication and magnetic sphincter augmentation. *Dis Esophagus.* Jun 15 2023; 36(Supplement_1). PMID 36544397
15. Callahan ZM, Amundson J, Su B, et al. Outcomes after anti-reflux procedures: Nissen, Toupet, magnetic sphincter augmentation or anti-reflux mucosectomy?. *Surg Endosc.* May 2023; 37(5): 3944-3951. PMID 35999311
16. O'Neill SM, Jalilvand AD, Colvin JS, et al. S148: Long-term patient-reported outcomes of laparoscopic magnetic sphincter augmentation versus Nissen fundoplication: a 5-year follow-up study. *Surg Endosc.* Sep 2022; 36(9): 6851-6858. PMID 35041056
17. Wisniowski P, Putnam LR, Gallagher S, et al. Short term safety of magnetic sphincter augmentation vs minimally invasive fundoplication: an ACS-NSQIP analysis. *Surg Endosc.* Apr 2024; 38(4): 1944-1949. PMID 38334778
18. Ibach MJ, Dahlke PM, Wiegrebe S, et al. Medium-term outcomes after magnetic sphincter augmentation vs. fundoplication for reflux disease due to hiatal hernia: a propensity-score matched comparison in 282 patients. *Surg Endosc.* Sep 2024; 38(9): 5068-5075. PMID 39014181
19. U.S. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED): LINX Reflux Management System (P100049). 2012; https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100049B.pdf. Accessed September 21, 2025.
20. Reynolds JL, Zehetner J, Bildzukewicz N, et al. Magnetic sphincter augmentation with the LINX device for gastroesophageal reflux disease after U.S. Food and Drug Administration approval. *Am Surg.* Oct 2014; 80(10): 1034-8. PMID 25264655
21. Warren HF, Louie BE, Farivar AS, et al. Manometric Changes to the Lower Esophageal Sphincter After Magnetic Sphincter Augmentation in Patients With Chronic Gastroesophageal Reflux Disease. *Ann Surg.* Jul 2017; 266(1): 99-104. PMID 27464617
22. Ganz RA, Peters JH, Horgan S, et al. Esophageal sphincter device for gastroesophageal reflux disease. *N Engl J Med.* Feb 21 2013; 368(8): 719-27. PMID 23425164
23. Ganz RA, Edmundowicz SA, Taiganides PA, et al. Long-term Outcomes of Patients Receiving a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux. *Clin Gastroenterol Hepatol.* May 2016; 14(5): 671-7. PMID 26044316
24. Louie BE, Smith CD, Smith CC, et al. Objective Evidence of Reflux Control After Magnetic Sphincter Augmentation: One Year Results From a Post Approval Study. *Ann Surg.* Aug 2019; 270(2): 302-308. PMID 29697454
25. Alicuben ET, Bell RCW, Jobe BA, et al. Worldwide Experience with Erosion of the Magnetic Sphincter Augmentation Device. *J Gastrointest Surg.* Aug 2018; 22(8): 1442-1447. PMID 29667094
26. Ayazi S, Zheng P, Zaidi AH, et al. Magnetic Sphincter Augmentation and Postoperative Dysphagia: Characterization, Clinical Risk Factors, and Management. *J Gastrointest Surg.* Jan 2020; 24(1): 39-49. PMID 31388888
27. 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. *J Am Coll Surg.* Apr 2014; 218(4): 776-81. PMID 24529809
28. Rona KA, Reynolds J, Schwameis K, et al. Efficacy of magnetic sphincter augmentation in patients with large hiatal hernias. *Surg Endosc.* May 2017; 31(5): 2096-2102. PMID 27553803
29. Ferrari D, Asti E, Lazzari V, et al. Six to 12-year outcomes of magnetic sphincter augmentation for gastroesophageal reflux disease. *Sci Rep.* Aug 13 2020; 10(1): 13753. PMID 32792508
30. Ayazi S, Zheng P, Zaidi AH, et al. Clinical Outcomes and Predictors of Favorable Result after Laparoscopic Magnetic Sphincter Augmentation: Single-Institution Experience with More than 500 Patients. *J Am Coll Surg.* May 2020; 230(5): 733-743. PMID 32081749
31. Dunn CP, Zhao J, Wang JC, et al. Magnetic sphincter augmentation with hiatal hernia repair: long term outcomes. *Surg Endosc.* Oct 2021; 35(10): 5607-5612. PMID 33029733

32. Bridges LC, Shillinglaw JP, Smith BE, et al. Augmentation of the Esophageal Sphincter Using LINX. *Am Surg.* Sep 2022; 88(9): 2170-2175. PMID 35593894
33. Eriksson SE, Maurer N, Zheng P, et al. Impact of Objective Colonic and Whole Gut Motility Data as Measured by Wireless Motility Capsule on Outcomes of Antireflux Surgery. *J Am Coll Surg.* Feb 01 2023; 236(2): 305-315. PMID 36648258
34. Bologheanu M, Matic A, Feka J, et al. Severe Dysphagia is Rare After Magnetic Sphincter Augmentation. *World J Surg.* Sep 2022; 46(9): 2243-2250. PMID 35486162
35. Nikolic M, Matic A, Feka J, et al. Expanded Indication for Magnetic Sphincter Augmentation: Outcomes in Weakly Acidic Reflux Compared to Standard GERD Patients. *J Gastrointest Surg.* Mar 2022; 26(3): 532-541. PMID 34590216
36. Sarici IS, Eriksson SE, Zheng P, et al. Need for frequent dilations after magnetic sphincter augmentation: an assessment of associated factors and outcomes. *Surg Endosc.* Sep 2023; 37(9): 7159-7169. PMID 37336846
37. Leeds SG, Ngov A, O Ogola G, et al. Safety of magnetic sphincter augmentation in patients with prior bariatric and anti-reflux surgery. *Surg Endosc.* Sep 2021; 35(9): 5322-5327. PMID 32989530
38. Khaitan L, Hill M, Michel M, et al. Feasibility and Efficacy of Magnetic Sphincter Augmentation for the Management of Gastroesophageal Reflux Disease Post-Sleeve Gastrectomy for Obesity. *Obes Surg.* Jan 2023; 33(1): 387-396. PMID 36471179
39. DeMarchi J, Schwiers M, Soberman M, et al. Evolution of a novel technology for gastroesophageal reflux disease: a safety perspective of magnetic sphincter augmentation. *Dis Esophagus.* Nov 11 2021; 34(11). PMID 34117494
40. Fletcher R, Dunst CM, Abdelmoaty WF, et al. Safety and efficacy of magnetic sphincter augmentation dilation. *Surg Endosc.* Jul 2021; 35(7): 3861-3864. PMID 32671521
41. 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
42. American Foregut Society (AFS). American Foregut Surgery Statement on Appropriate Patient Selection and Use of Magnetic Sphincter Augmentation (LINX). n.d.; <https://www.americanforegutsociety.org/wp-content/uploads/2021/04/AFS-LINX-Final.pdf>. Accessed September 24, 2025.
43. Khaitan L, Abu Dayyeh BK, Lipham J, et al. American Foregut Society (AFS) Committee Statement on Combined Magnetic Sphincter Augmentation and Bariatric Surgery. n.d.; https://www.americanforegutsociety.org/wp-content/uploads/2021/04/AFS_MSA_Bariatric_Surgery_Final-1.pdf. Accessed October 10, 2023.
44. 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
45. 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
46. National Institute for Health and Care Excellence (NICE). Laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease [GID-IPG749]. 2023; <https://www.nice.org.uk/guidance/ipg749>. Accessed September 23, 2025.

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