

MEDICAL POLICY

Medical Policy Title	Magnetic Sphincter Augmentation for the Treatment of Gastroesophageal Reflux Disease (GERD)
Policy Number	7.01.89
Current Effective Date	April 17, 2025
Next Review Date	April 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to [Product Disclaimer](#))

POLICY STATEMENT(S)

- I. Magnetic sphincter augmentation (e.g., LINX Reflux Management System) is considered a **medically appropriate** treatment option in the management of GERD, when **ALL** of the following conditions are met:
 - A. The individual is 18 years of age or older;
 - B. The individual has chronic, bothersome symptomatic gastroesophageal reflux (GERD) established by endoscopy, fluoroscopy or ambulatory pH testing;
 - C. Symptoms are inadequately controlled with appropriate daily proton pump inhibitor (PPI) use (unless intolerant to or contraindicated) for at least six (6) months or a need to stop PPI therapy;
 - D. For individuals with a hiatal hernia greater than 3 centimeters (cm), submitted records must indicate that the hiatal hernia will be repaired prior to or at the same time as the LINX procedure;
 - E. The LINX device is being used as an alternative to surgical fundoplication for symptomatic GERD;
 - F. The procedure is being performed by a physician who has completed procedure-specific training in the use of the LINX Reflux Management System with privileges to perform the procedure;
 - G. The individual has none of the following contraindications or precautions to implantation of the LINX device:
 1. suspected or known allergy to titanium, stainless steel, nickel, or iron (ferrous) materials;
 2. require magnetic resonance imaging (MRI) of >1.5 Tesla;
 3. obesity with a body-mass-index (BMI) >35 Kg/m²;
 4. active esophageal or gastric cancer;
 5. major esophageal motility disorder (e.g., Achalasia, distal esophageal spasm, hypercontractile esophagus and absent contractility. This does not include minor disorders of peristalsis [e.g., ineffective esophageal motility]);

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6. presence of electrical implant (e.g., pacemaker, defibrillator, abdominal implant);
 7. esophageal or gastric varices;
 8. esophageal stricture (e.g., Schatzki's ring, or obstructive lesions);
 9. scleroderma.
- II. Use of magnetic sphincter augmentation (e.g., LINX Reflux Management System) for any other indication is considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

- I. Prior to surgery, patients with symptoms of GERD must undergo a complete pre-operative evaluation, which should include an endoscopy, an esophageal manometry, Bravo pH testing, and an upper GI series (barium swallow). A comprehensive center is recommended for this evaluation.
- II. Non-clinical testing has demonstrated that the LINX device is magnetic resonance (MR) conditional. This device can be scanned safely under certain conditions (e.g., static magnetic field 1.5-Tesla [1.5T]). The LINX device contains permanent magnets. The patient may feel pressure around the lower esophagus (Torax Medical, 2023).
- III. LINX device is a long-term implant. Explant (removal) or replacement maybe indicated at any time.
- IV. The patient has completed a shared decision-making information session prior to the procedure to improve patient satisfaction, increase patient's knowledge of their condition, and assess readiness to make behavior changes. This shared decision-making session should include instruction including but not limited to:
 - A. Explanation of the upcoming procedure and surgery
 - B. Risks and benefits of the procedure/surgery
 - C. How to manage the chronic condition
 - D. General healthcare expectations
 - E. Alternatives to the procedure/surgery

DESCRIPTION

Gastroesophageal reflux disease (GERD) is a common disorder characterized by classic symptoms of heartburn and regurgitation, as well as other symptoms such as pain, dysphagia, and dry

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cough/throat clearing). Most individuals experience symptoms of gastroesophageal reflux at some point in their lives, with a smaller number having chronic symptoms that put them at risk for complications of GERD (e.g., erosive esophagitis, dysphagia, Barrett esophagus, asthma).

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.

Guidelines on the medical management of GERD emphasize initial lifestyle modification (e.g., weight loss, smoking cessation, head of the bed elevation, elimination of food triggers) and medication therapy (e.g., antacids, proton pump inhibitors). Surgical and endoscopic procedures are options for patients who have persistent symptoms or develop complications despite optimal medical therapy.

Magnetic sphincter augmentation (MSA) with the LINX Reflux Management System (Torax Medical) was developed for the treatment of GERD. The device consists of a laparoscopically implanted ring composed interlinked titanium beads with magnetic cores that is placed around the esophagus at the level of the gastroesophageal junction using standard laparoscopic techniques. The magnetic attraction between the beads is intended to augment the lower esophageal sphincter (LES) to prevent gastric reflux into the esophagus without compressing the esophageal wall. It provides a slightly higher pressure than the reflux pressure, keeping the contents in the stomach. However, its pressure is significantly lower than the pressure generated by the esophagus when liquids or food goes down, allowing the magnetic beads to open apart allowing it to pass through the LES and LINX. After the swallow goes through, the magnetic attraction closes it back comfortably around the LES.

The LINX Reflux Management System has been evaluated in a target population consisting of patients who have GERD symptoms despite maximum medical therapy (e.g., proton pump inhibitors), but who do not want to risk the adverse effects (potential loss of ability to belch or vomit) of a surgical procedure like a Nissen fundoplication. Adverse events of the LINX Reflux Management System may include dysphagia or odynophagia.

According to the manufacturer (Torax Medical 2023), the LINX Reflux Management System magnetic resonance (MR) conditional in a magnetic resonance imaging (MRI) system up to 1.5 Tesla (1.5T). Scanning under different conditions may result in serious injury to the patient and/or interfere with the magnetic strength and function of the device. In the event that an MRI above 1.5 Tesla (1.5T) is required, and alternative diagnostic procedures cannot be used, the LINX device can be removed. The LINX device should not be used in anyone who may be allergic or is allergic to titanium, stainless steel, nickel, or iron (ferrous) materials.

SUPPORTIVE LITERATURE

Treatment of GERD

Data submitted to the U.S. Food and Drug Administration (FDA) for the LINX Reflux Management System included two single-arm, FDA-regulated, investigational device exemption (IDE) trials with a

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total of 144 subjects, and follow-up data between two and four years. The feasibility IDE study enrolled 44 subjects at four clinical sites (two U.S. and two European) and has published data out to four years (Bonavina 2010, Lipham 2012). A total of 24 of the 44 subjects (54.5%) in the feasibility study experienced adverse events related to the device and/or procedure, and two subjects experienced SAEs. The most common adverse event was dysphagia (22 events in 20 subjects, which resolved in 90 days). No SAEs related to the device or procedure occurred after the first year. In the pivotal study, dysphagia was commonly observed, occurring in 68% of patients (49% mild, 16% moderate, and 5% severe), and an SAE related to the device or implantation procedure occurred in eight of the 144 subjects (6%). Most cases of dysphagia either self-improved or improved with endoscopic esophageal balloon dilation. Three subjects underwent device removal for severe dysphagia and/or odynophagia. Three subjects were hospitalized for nausea and/or vomiting. One subject reported the inability to vomit. No device migration was observed on radiographs taken at 12 months. Success on the subject level was defined as normalization of acid (pH <4 for $\leq 4.5\%$ of time) or reduced total acid exposure time (pH <4) by at least 50%, relative to baseline measurements. In the feasibility study, esophageal pH testing was performed out to 36 months in only one of the four centers. The percentage of subjects who achieved success was 79.5% (31/39) at 12 months, 90% (18/20) at 24 months, and 85% (17/20) at 36 months. The proportion of patients with reduction in PPI therapy by 50% or more was 89.7% (35/39) at 12 months, 82.9% (29/35) at 24 months, and 87.5% (28/32) at 36 months. Improvement in GERD HRQL scores by more than 50% occurred in 97.4% (38/39) of subjects at 12 months, 88.6% (31/35) at 24 months, and 96.3% (26/27) at 36 months.

Ganz and colleagues (2013) published results from the pivotal IDE study, which included 100 subjects from 14 clinical sites (13 U.S. and one European) who had documented symptoms of GERD for longer than six months (regurgitation or heartburn that responds to acid neutralization or suppression), required daily proton pump inhibitor (PPI) or other anti-reflux drug therapy, had symptomatic improvement on PPI therapy, and had a total distal ambulatory esophageal pH less than four for 4.5% or more of the time when off GERD medications. The primary efficacy endpoint of pH normalization or greater than 50% reduction in acid exposure time when off PPI was met by 64% of the subjects. The mean total acid exposure time was reduced from 11.6% at baseline to 5.1% at 12 months (56% reduction). The secondary efficacy endpoints met the study success criteria. Ninety-two percent of subjects had at least a 50% improvement in GERD-HRQL symptom score (the mean GERD-HRQL total score decreased from 28.4 at baseline to 5.9 and 5.5 at 12 and 24 months, respectively), and 93% had reduced PPI use (79% and 83% of subjects were free from daily dependence at 12 and 24 months, respectively, compared with 0% at baseline). Dysphagia was observed in 68% of patients post-operatively, in 11% at one year, and in 4% at three years. Nineteen patients underwent esophageal dilation for dysphagia. Six patients (6%) experienced an SAE, including severe dysphagia and vomiting. The device was removed in four of these six patients with an SAE and in two additional patients for persistent reflux and chest pain.

Ganz and colleagues (2016) published five-year results for the 100 patients in the pivotal IDE trial were published. Eighty-five patients had a follow-up at 5 years. Of those 85 patients, 83% achieved a 50% reduction in GERD-HRQL scores (95% confidence interval [CI], 73% to 91%), and 89.4% had a

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reduction of 50% or more in an average daily dose of PPI (95% CI, 81% to 95%). No new major safety concerns emerged. The device was removed in seven patients.

Buckley and colleagues (2018) conducted a multicenter, prospective study of 200 consecutive patients who underwent MSA with the LINX device during repair of paraesophageal and hernias over 3 cm axial component; 78% of patients had axial hiatal hernia ≥ 5 cm or large paraesophageal component. Non-permanent mesh reinforcement of hiatal repair was performed in 83% of the patients. The authors reported favorable outcomes with a median of 9 months follow-up. By comparing study finding to published reports of MSA in patients with <3 cm hernias, the authors conclude that the safety and clinical efficacy of MSA are independent of initial hernia size.

Alicuben and colleagues (2018) reported low device erosion rates worldwide (0.3% at four years after device implantation). Smith et al. (2017) reported, based on the Manufacturer and User Facility Device Experience (MAUDE) database, that a total of 3,283 procedures were reviewed, with device removal occurring in 2.7% of cases. Complications post-magnetic sphincter device implantations are reportedly low, as compared to the total number of procedures performed. No deaths, life-threatening events or device malfunctions were reported. The most common causes of removal were dysphagia, continued reflux, and device erosion into the esophagus.

In two separate meta-analyses by Aiolfi and colleagues (2018) and Skubleny and colleagues (2017), magnetic sphincter augmentation (MSA) was compared to fundoplication for the treatment of GERD. Three and seven observational cohort studies, respectively, were included for review, corresponding to 688 patients and 1,211 patients. Both of the studies concluded that MSA and fundoplication are safe and effective up to one-year follow-up; however, MSA is superior to fundoplication in preserving a patient's ability to vomit and belch. Limitations included the exclusion of randomized, controlled trials and short follow-up periods of the included studies.

Louie and colleagues (2019) reported one-year outcomes from the five-year, FDA-mandated study of the safety and effectiveness of MSA with the LINX Reflux Management System. A total of 200 patients were treated with MSA in a multi-center, prospective, uncontrolled trial. Effectiveness and safety were evaluated based on disease-specific questionnaires, PPI use, esophagogastroduodenoscopy, and pH testing. Predefined success criteria of achieving a 50% or greater reduction in total GERD-HRQL score was achieved by 84.3% of patients at one year. Of the 164 patients agreeing to complete esophageal pH monitoring, 76.8% achieved successful reduction in esophageal acid, 74.4% had normal esophageal acid exposure, and 72.4% had a normal DeMeester Score. The device removal rate at one year was 2.5%. One erosion and no SAEs were reported. The authors concluded that MSA is a safe and effective option for patients desiring a surgical option other than fundoplication to control their chronic symptoms of GERD.

Bell and colleagues (2020) conducted a randomized controlled trial (RCT) with 152 patients with GERD who were randomized 2:1 to treatment with omeprazole 20mg twice daily (BID) (n=102) or laparoscopic magnetic sphincter augmentation (MSA) (n=50). Patients were assessed at baseline and at six months using the Foregut Symptom Questionnaire (FSQ), Reflux Disease Questionnaire (RDQ), and GERD-HRQL questionnaire. At six months, patients also underwent 24-hour impedance-pH testing evaluated by a blinded, independent laboratory. A total of 89% of MSA-treated patients

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reported relief of regurgitation, compared with 10% of the BID PPI group at the six-month primary endpoint. By intention-to-treat analysis, 84% of patients in the MSA group and 10% in the BID PPI group met this primary endpoint. Eighty-one percent of patients with MSA versus 8% of patients with BID PPI had 50% or more improvement in GERD–HRQL scores, and 91% remained off PPI therapy. A normal number of reflux episodes and acid exposures was observed in 91% and 89% of MSA patients, respectively, compared with 58% and 75% of BID PPI patients, at six months. No significant safety issues were observed. In MSA patients, 28% reported transient dysphagia, and 4% reported ongoing dysphagia. The authors concluded that MSA provides significantly better control of moderate-to-severe regurgitation, when compared with BID PPI.

Bonavina and colleagues (2021) published 3-year outcomes from a prospective, observational registry evaluating MSA and laparoscopic fundoplication in 631 patients (465 MSA; 166 laparoscopic fundoplication) enrolled between 2009 and 2014 across 22 medical centers in Europe. Patients had a diagnosis of GERD confirmed by abnormal esophageal acid exposure and chronic reflux symptoms despite daily use of PPIs. Patients with severe GERD marked by hiatal hernia >3 cm, Barrett esophagus, motility disorder, and Grade C or D esophagitis by LA classification were also included. The type of anti-reflux procedure performed was provisionally determined by the surgeon in consultation with the patient. MSA was recommended when patients met labeling requirements for MSA (hiatal hernia ≤ 3 cm, esophagitis < Grade C, absence of Barrett esophagus, and absence of motility disorders); however, the final choice of procedures was made by the surgeon at the time of laparoscopy. Various forms of laparoscopic fundoplication were performed, including Nissen (62%), Toupet (31%), and Other/Unspecified (eg, Dor; 7%). Improvements in total GERD-HRQL scores were observed in both MSA (22.0 to 4.6) and laparoscopic fundoplication (23.6 to 4.9) groups with similar increases in GERD-HRQL satisfaction. A higher proportion of patients maintained the ability to vomit in them MSA group compared to laparoscopic fundoplication (91.2% vs. 68.0%). Similar declines in PPI usage were observed in both groups (MSA 97.8% to 24.2% and laparoscopic fundoplication 95.8% to 19.5%). Limitations of the study include lack of randomization and blinding, heterogeneity in laparoscopic fundoplication techniques, and selection bias as patients with less severe symptoms received MSA.

The FDA Manufacturer and User Facility Device Experience (MAUDE) report and manufacturer complaint databases were analyzed from 2013 to 2020 to determine rates of surgical device erosion and explants (DeMarch 2021). Overall, 7-year cumulative risk of removal was 4.81% (95% CI, 4.31% to 5.36%), with 2.2% of devices (609/27779) having been reported as removed. Primary reasons for device removal included dysphagia/odynophagia (47.9%), persistent GERD (20.5%), and unknown/other (11.2%). The 7-year cumulative risk of erosion was 0.28% (95% CI, 0.17% to 0.46%), with 27 reports of erosion. Device size was significantly related (< 0.0001) to the likelihood of an explant, with the smallest size having the highest explant rate. Clinical practice changes since magnetic sphincter augmentation has been incorporated into clinical use are associated with improved outcomes and should be further characterized.

Callahan and colleagues (2023) published a retrospective review of a prospective database evaluating patients who underwent MSA, laparoscopic Nissen fundoplication (LNF), Toupet fundoplication (TNF) or anti-reflux mucosectomy (ARMs). Patients were followed up at 3 weeks, 6 months, 1 year, 2 years,

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and 5 years post-operation. A total of 649 patients had reflux surgery during the study period from 2008 to 2021 including 356 LNF, 207 LTF, 46 MSA, and 40 ARMs procedures. These groups were imbalanced on several baseline characteristics including age, body mass index (BMI), gender, hypertension medication usage, pre-operative dysphagia, esophageal motility, and hernia type. Procedure time was significantly shorter in patients treated with MSA or ARM compared to fundoplication ($p < 0.001$). At 3 weeks follow-up patients in the MSA group had higher reflux symptoms index scores and GERD-HRQL scores than patients in the Toupe fundoplication group (15.4 vs 9.5; $p=.044$ and 9.6 vs 4.8; $p=.043$, respectively), but these differences had resolved by 6 months with all four treatment groups showing similar outcomes. One-year follow-up data on GERD-HRQL showed a significant difference between the MSA group and ARM groups with the MSA group having worse symptoms (6.9 vs 2.5; $p=.048$); this difference was not observed at 2-year follow-up, but at 5 years MSA patients had worse GERD-HRQL scores compared to the Toupet fundoplication group (17.8 vs 4.9; $p=.024$). All groups had similar scores at all time points follow-up for gas bloating and dysphagia symptoms. Limitations of the study include lack of randomization and blinding, imbalance of baseline patient characteristics, and changes in secular trends over the study period which resulted in predominantly younger patients with normal manometry receiving LNF.

Fadel and colleagues (2024) conducted a systematic review and meta-analysis to assess the clinical outcomes of magnetic sphincter augmentation (MSA) and to provide comparison between MSA and the current gold standard treatment, fundoplication, in the management of GERD. Thirty-nine studies with 8075 patients were included (6983 patients underwent MSA and 1092 patients had laparoscopic fundoplication procedure). Based on three studies ($n=719$ patients), MSA had a statistically significant shorter operative time ($p < 0.001$), with a reduced length of stay by 14.8 hours across studies. There was no postoperative mortality encountered in any study. Random-effect analysis of studies that reported on the incidence of postoperative dysphagia following MSA suggested significantly more dilatation required in the MSA group ($P=0.013$). The pooled analysis and random-effect analysis of the 15 studies revealed that significantly more patients (99.7%, $p < 0.0001$) retained the ability to belch after undergoing MSA. There were 13 studies of 1504 patients investigating the ability to emesis, with 80.1% of patients maintaining the ability to emesis with MSA. There was a difference found in the ability to emesis between two groups in five studies ($p < 0.001$). In the 13 studies of 696 patients undergoing MSA, bloating was reported in 2.9%, with significantly less postoperative bloating following MSA reported when compared to fundoplication in five studies ($p=0.003$). There were eight studies reporting and directly comparing the need for surgical reintervention comprising of 1674 patients. Surgical reintervention was no different between the MSA and fundoplication group ($P=0.446$). The authors concluded that the findings of this systematic review and meta-analysis demonstrated that MSA surgery was associated with high rates of PPI discontinuation and an improvement in patient satisfaction. When compared to fundoplication, MSA had a reduced operative time and length of stay, higher rates of PPI discontinuation, and improved functional outcomes such as ability to belch/emesis and less postoperative bloating. However, there were only a few high-quality studies found that directly compared MSA with fundoplication including rates of postoperative dysphagia. RCTs are therefore required to directly compare MSA with fundoplication and to assess the long-term surgical reintervention and adverse outcomes following

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MSA procedures.

Regression of Barrett's Esophagus (BE)

The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. There is limited data showing effective BE regression with MSA. There is only one small retrospective review of 87 patients (Dunn 2021).

PROFESSIONAL GUIDELINE(S)

Treatment of GERD

most current guideline from the American Society of General Surgeons (ASGS) was issued in 2014, with the following supportive statement: "Based on currently available information and the experience of our members with the procedure we do support the LINX procedure as mechanism for controlling GERD when it is placed by properly trained laparoscopic surgeons with experience in foregut surgery and the management of GERD patients."

In 2017, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Technology and Value Assessment Committee published an updated analysis of the safety and effectiveness of the LINX Reflux Management System. The Committee concluded that longer-term (three to five years) experience confirms the initial safety profile that led to FDA approval of the device and that the LINX device has been demonstrated to result in long-term GERD control, based on symptomatic outcomes, PPI utilization, and pH studies. The committee determined that the LINX device is a reasonable treatment option for appropriately selected patients with GERD who meet indications for anti-reflux surgery; however, it should be performed by surgeons familiar with the workup of and different management alternatives for GERD and should not offered in isolation.

In 2022, The American College of Gastroenterology (ACG) recommends consideration of MSA as an alternative to laparoscopic fundoplication for patients with regurgitation who fail medical management (strong recommendation, moderate level of evidence) (Katz 2022).

In 2022, the American Gastroenterology Association's (AGA) Clinical Practice Update on the evaluation and management of GERD states MSA is an effective surgical option for patients with proven GERD whose symptoms are inadequately controlled following lifestyle and pharmacotherapy optimization (Yadlapati 2022).

In 2023, the National Institute for Health and Care Excellence (NICE) updated their interventional procedure guidance (IPG) evidence-based recommendations on laparoscopic insertion of a magnetic ring for gastro-oesophageal reflux disease. Guidelines indicate that evidence on the safety and efficacy is adequate to support using the procedure and that patient selection and procedure should be done by clinicians who have specific training in the procedure. The committee commented that the procedure has evolved, and the incidence of dysphagia and oesophageal spasm has reduced, over time.

In 2023, international expert surgeons and gastroenterologists developed a multi-society consensus guideline on the treatment of GERD (Slater 2023). The panel was composed of members from the

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Society of American Gastrointestinal and Endoscopic Surgery (SAGES), American Society for Gastrointestinal Endoscopy (ASGE), American Society for Metabolic and Bariatric Surgery (ASMBS), European Association for Endoscopic Surgery (EAES), Society for Surgery of the Alimentary Tract (SSAT), and the Society of Thoracic Surgeons (STS), and published with the following panel recommendations for magnetic sphincter augmentation:

- The panel suggests that adult patients with GERD may be treated with either MSA or Nissen fundoplication based on surgeon and patient shared decision making. The choice for either procedure should be made on a patient specific basis consider other factors such as BMI and esophageal dysmotility, which are relative contraindications for MSA (Conditional recommendation based on very low certainty of evidence).
- The panel suggests that adult patients with GERD may benefit from MSA over continued PPI use. There is still a large amount unknown about this comparison. (Conditional recommendation based on moderate certainty of evidence).

Regression of Barrett's Esophagus (BE)

There is no professional guideline recommendation for use of magnetic sphincter augmentation for this indication.

REGULATORY STATUS

In 2012, the LINX Reflux Management System was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P100049) 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 required a five-year follow-up of 100 patients from the investigational device exemption (IDE) pivotal study, to evaluate the safety and efficacy of the device, which was completed in March 2016 and the results were published in 2019.

In March 2018, the FDA approved an update of the LINX Reflux Management System precautions statement (P100049/S021), 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 to remove a precautionary statement about Barrett's Esophagus (BE) from the instructions for use. The updated labeling states that the "LINX has not been proven to effectively treat BE by causing regression or preventing progression to cancer. As such, 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)."

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CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (e.g., magnetic band), including cruroplasty when performed
43285	Removal of esophageal sphincter augmentation device

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HCPCS Codes

Code	Description
No specific code(s)	

ICD10 Codes

Code	Description
K21.0	Gastro-esophageal reflux disease with esophagitis
K21.9	Gastro-esophageal reflux disease without esophagitis

REFERENCES

Aiolfi A, 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.

American Society of General Surgeons (ASGS) Board of Trustees [Internet]. Position statement: LINX statement of support from ASGS. 2014 [accessed 2025 Feb 02]. Available from: <https://theasgs.org/position-statements/linx-statement-of-support-from-asgs/>

Alicuben ET, et al. Worldwide experience with erosion of the magnetic sphincter augmentation device. J Gastrointest Surg. 2018 Aug; 22(8):1442-1447. PMID 29667094.

Ayazi S, et al. Magnetic sphincter augmentation (MSA) in patients with hiatal hernia: clinical outcome

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and patterns of recurrence. *Surg Endosc.* 2020;34(4):1835-1846.

Ayazi S, et al. Magnetic sphincter augmentation and postoperative dysphagia: characterization, clinical risk factors, and management. *J Gastrointest Surg.* 2020 Jan;24(1):39-49. Epub 2019 Aug 6.

Bell R, 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.e.1. Epub 2018 Jul 18.

Bell R, et al. Magnetic sphincter augmentation superior to proton pump inhibitors for regurgitation in a 1-year randomized trial. *Clin Gastroenterol Hepatol* 2020 Jul;18(8):1736-1743.

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.

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.

Bonavina L, et al. Three-year clinical experience with magnetic sphincter augmentation and laparoscopic fundoplication. *Surg Endosc.* 2021 Jul;35(7):3449-3458. PMID 32676727

Buckley FP 3rd, 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):1762–1868.

Callahan ZM et al., Outcomes after anti-reflux procedures: Nissen, Toupet, magnetic sphincter augmentation or anti-reflux mucosectomy? *Surg Endoscopy.* 2023 May;37(5):3944-3951. Epub 2022 Aug 23.

DeMarchi J et al. Evolution of a novel technology for gastroesophageal reflux disease: a safety perspective of magnetic sphincter augmentation. *Dis Esophagus.* 2021 Nov 11;34(11):doab036.

Dunn CP, et al. Regression of Barrett's esophagus after magnetic sphincter augmentation: intermediate-term results. *Surg Endosc.* 2021 Oct;35(10):5804-5809.

Ganz RA, et al. Long-term outcomes of patients receiving a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux. *Clin Gastroenterol Hepatol.* 2016 May;14(5):671-677. PMID 26044316

Ganz RA, et al. Esophageal sphincter device for gastroesophageal reflux disease. *N Engl J Med.* 2013 Feb 21;368(8):719-27.

Fadel MG, et al. Magnetic sphincter augmentation in the management of gastro-esophageal reflux disease: a systematic review and meta-analysis. *Int J Surg.* 2024 Oct 1;110(10):6355-6366.

Ferrari, D., et al. Six to 12-year outcomes of magnetic sphincter augmentation for gastroesophageal reflux disease. *Sci Rep* 2020. Aug 13;10(1)13753.

Hawalsli A, et al. Laparoscopic placement of the LINX system in management of severe reflux after sleeve gastrectomy. *Am J Surg.* 2019 Mar;217(3):496-499.

Katz PO, et al. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux

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Disease. Am J Gastroenterol. 2022 Jan 01;117(1):27-56. PMID 34807007.

Khaitan et al. Feasibility and efficacy of magnetic sphincter Augmentation for the management of gastroesophageal reflux disease post sleeve gastrectomy for obesity. Obesity Surgery. 2023 Dec;33:387-396.

Laird J. Magnetic sphincter augmentation device placement for treatment of gastroesophageal reflux. JAAPA. 2020 Dec;33(12):30-32.

Lee D and Chang K. Endoscopic management of GERD. Digestive Diseases and Sciences. 2022 May;67(5):1455-1468.

Leeds, S.G., et al. The role of preoperative workup in predicting dysphagia, dilation, or explantation after magnetic sphincter augmentation. Surg Endosc. 2020 Aug;34(8):3663-3668.

Lipham JC, et al. The LINX reflux management system: confirmed safety and efficacy now at 4 years. Surg Endosc. 2012;26(10):2944-2949.

Louie BE, et al. Objective evidence of reflux control after magnetic sphincter augmentation: one-year results from a post approval study. Ann Surg. 2019 Aug;270(2):302-308.

National Institute for Health and Care Excellence (NICE) [Internet]. Laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease [IPG749]. 2023 Jan 11 [accessed 2025 Feb 02]. Available from: <https://www.nice.org.uk/guidance/ipg749>

Rausa E, 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. 2023 Jan 21;408(1):52. PMID 36680602

Rettura F, et al. Refractory gastroesophageal reflux disease: A management update. Front Med (Lausanne). 2021 Nov 1;8:765061.

Riva CG, et al. Magnetic sphincter augmentation after gastric surgery. Journal of Society of Laparoendoscopic Surgeons. 2019 Oct-Dec;23(4):e2019.00035.

Rona KA, et al. Efficacy of magnetic sphincter augmentation in patients with large hiatal hernias. Surg Endosc. 2017; 31(5):2096–102.

Schizas D, 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;8(2):294-305.

Schwameis K, et al. Efficacy of magnetic sphincter augmentation across the spectrum of GERD disease severity. J Am Coll Surg. 2021 Mar;232(3):288-297. Epub 2020 Dec 30.

Skubleny D, et al. LINX magnetic esophageal sphincter augmentation versus Nissen fundoplication for gastroesophageal reflux disease: a systematic review and meta-analysis. Surg Endosco. 2017 Aug;31(8):3078-3084.

Slater BJ, et al. Multi-society consensus conference and guideline on the treatment of gastroesophageal reflux disease (GERD). Surg Endosc. 2023 Feb;37(2):781-806. Epub 2022 Dec 18.

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PMID: 36529851.

Slater BJ, et al. SAGES guidelines for the surgical treatment of gastroesophageal reflux (GERD). Surgical Endoscopy. 2021 Jul;35(9):4903-4917.

Smith CD, et al. Lower esophageal sphincter augmentation for gastroesophageal reflux disease: the safety of a modern implant. J Laparoendosc Adv Surg Tech. 2017 June;27(6):586-591.

Society of American Gastrointestinal and Endoscopic Surgeons [Internet]. LINX Reflux Management System. SAGES technology and value assessment committee (TAVAC) safety and effectiveness analysis. 2017 Mar 13 [accessed 2025 Feb 02]. Available from:

<https://www.sages.org/publications/tavac/tavac-safety-and-effectiveness-analysis-linx-reflux-management-system/>

Tatum JM, et al. Removing the magnetic sphincter augmentation device: operative management and outcomes. Surgical Endoscopy. 2019;33:2663–2669.

Torax Medical, Inc. LINX Reflux Management System – instructions for use. 2023 Jan [accessed 2025 Feb 10] Available from: https://www.jnjmedtech.com/system/files/pdf/LINX-Clasp-IFU_0.pdf

U.S. Food & Drug Administration (FDA) [Internet]. Premarket Approval (PMA). LINX Reflux Management System. P100049/S001. 2012 Jun 6 [accessed 2025 Feb 3]. Available from: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100049>

U.S. Food & Drug Administration (FDA) [Internet]. Premarket Approval (PMA). LINX Reflux Management System. P100049/S021. 2018 Mar 15 [accessed 2025 Feb 3]. Available from: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100049S021>

U.S. Food & Drug Administration (FDA) [Internet]. Premarket Approval (PMA). LINX Reflux Management System. P100049/S037. 2024 Feb 2 [accessed 2025 Feb 3]. Available from: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100049S037>

Yadlapati R, et al. AGA Clinical Practice Update on the Personalized Approach to the Evaluation and Management of GERD: Expert Review. Clin Gastroenterol and Hepatol. 2022;20:984-994.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

[Select Minimally Invasive GERD Procedures \(LCD L35080\)](#) [accessed 2025 Feb 3]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.

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- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/22/15, 01/21/16, 12/15/16, 12/21/17, 02/21/19, 02/20/20, 02/18/21, 02/17/22, 04/20/23, 04/18/24, 04/17/25	
Date	Summary of Changes
04/17/25	<ul style="list-style-type: none">• Annual review, policy intent unchanged.
01/01/25	<ul style="list-style-type: none">• Summary of changes tracking implemented.
02/20/14	<ul style="list-style-type: none">• Original effective date