# MEDICAL POLICY

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| **Medical Policy Title** | **Magnetic Sphincter Augmentation for the Treatment of Gastroesophageal Reflux Disease (GERD)** |
| **Policy Number** | **7.01.89** |
| **Current Effective Date** | **October 15, 2026** |
| **Next Review Date** | **June 2027** |

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

## POLICY STATEMENT(S)

I. Magnetic sphincter augmentation (e.g., LINX Reflux Management System) is considered **medically appropriate** to treat gastroesophageal reflux (GERD), when **ALL** of the following are met:

A. The individual is 18 years of age or older;

B. Body mass index (BMI) less than 35 kg/m$^2$;

C. Objective evidence of pathologic acid exposure confirmed by esophageal pH monitoring;

D. Persistent daily GERD symptoms despite documented adherence to at least 6 months of optimized medical therapy including **both** of the following:

1. Lifestyle modification, including weight reduction when clinically indicated; **and**
2. Maximum or maximally tolerated proton pump inhibitor (PPI) therapy;

E. For individuals with a hiatal hernia greater than 2 centimeters (cm), submitted records must indicate that the hiatal hernia will be repaired prior to or at the time of MSA;

F. Absence of **any** of the following contraindications or precautions:

1. Major esophageal motility disorder (e.g., achalasia, distal esophageal spasm, hypercontractile esophagus and absent contractility);
2. Grade C or D esophagitis (LA classification);
3. Esophageal stricture or significant anatomic abnormalities (e.g., Schatzki's ring, or obstructive lesions);
4. Esophageal or gastric varices;
5. Suspected or confirmed esophageal or gastric cancer;
6. Scleroderma; **or**
7. Suspected or known allergy to titanium, stainless steel, nickel, or iron (ferrous) materials.

II. Use of magnetic sphincter augmentation for any other indication is considered **investigational**.

## RELATED POLICIES

Corporate Medical Policy

7.01.45 Transendoscopic Therapies for Gastroesophageal Reflux Disease (GERD)

7.01.120 Peroral Endoscopic Myotomy Procedures

11.01.03 Experimental or Investigational Services

## POLICY GUIDELINE(S)

I. Prior to magnetic sphincter augmentation (MSA) surgery, patients with symptoms of GERD undergo a comprehensive pre-operative evaluation, which typically includes an endoscopy, a high-resolution esophageal manometry, pH testing, and an upper GI series (barium swallow).

II. Optimized PPI therapy requires confirmed adherence, correct pre-meal dosing, supportive lifestyle measures, and an adequate trial of an initial once-daily course followed by a subsequent trial of twice-daily dosing for refractory symptoms, unless there is documentation of a serious side effect (Katz 2022).

III. LINX device is a long-term implant. Explant (removal) or replacement may be indicated at any time.

## 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 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, now Johnson & Johnson MedTech) was developed for the treatment of GERD. The device consists of a laparoscopically implanted ring composed of interlinked titanium beads with magnetic cores that 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 (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, allowing it to pass through the LES and LINX. After the passage of the bolus, 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, now Johnson & Johnson MedTech 2023), the LINX Reflux Management System is 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 by 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 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 serious adverse events (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 ≤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 et al (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 et al (2016) published five-year results for the 100 patients in the pivotal IDE trial. 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 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.

In two separate meta-analyses by Aiolfi et al (2018) and Skubleny et al (2017), 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 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.

Buckley et al (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 et al (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.

Louie et al (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 et al (2019) conducted a randomized controlled trial (RCT) with 152 patients with GERD and moderate-to-severe regurgitation despite 8 weeks of once-daily PPI therapy, who were randomized 2:1 to treatment with twice-daily (BID) PPIs (n=102) or laparoscopic magnetic sphincter augmentation (MSA) (n=50) at 21 U.S. sites. Patients were assessed at baseline and at six months using the Foregut Symptom Questionnaire (FSQ), Reflux Disease Questionnaire (RDQ), and GERD-Health Related Quality of Life (HRQL) questionnaire. At six months, patients also underwent 24-hour impedance-pH testing evaluated by a blinded, independent laboratory. After six months, patients in the BID PPI group with persistent moderate-to-severe regurgitation and excess reflux episodes were offered crossover to MSA. At the six-month primary endpoint, 89% of MSA-treated patients reported relief of regurgitation compared with 10% of the BID PPI group per-protocol (84% vs. 10% by intention-to-treat; P < .001). MSA patients also demonstrated greater improvement in GERD-HRQL scores (81% vs. 8% achieving ≥50% improvement; P <.001), with 91% remaining off PPI therapy. Normal reflux episodes and acid exposures were observed in 91% and 89% of MSA patients, respectively, compared with 58% (P < .001) and 75% (P = .065) of BID PPI patients. After six months, BID PPI patients with persistent symptoms were offered crossover to MSA. 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.

Bell et al (2020) reported the one-year RCT follow-up, including patients who crossed over from BID PPI to MSA (total n=75 MSA-treated patients), MSA resulted in control of regurgitation in 96% (72/75) of patients, compared with 19% (8/43) of patients remaining on BID PPIs. Among the 75 MSA-treated patients, 81% had greater than 50% improvement in GERD-HRQL scores, and 91% discontinued daily PPI use. Esophageal acid exposure time decreased from 10.7% to 1.3% (P <

.001), and 70% (48/69) of patients had pH normalization at study completion. MSA was not associated with any peri-operative events, device explants, erosions, or migrations. The authors concluded that MSA provides significantly better control of moderate-to-severe regurgitation when compared with BID PPI, with relief sustained over 12 months.

DeMarch et al (2021) published the FDA MAUDE report and manufacturer complaint databases were analyzed from 2013 to 2020 to determine rates of surgical device erosion and explants Overall, 7-year cumulative risk of removal was 4.81% (95% CI, 4.31% to 5.36%). 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 ($p < 0.0001$) 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.

Bonavina et al (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 the 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.

Callahan et al (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, 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 point 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 et al (2024) conducted a systematic review and meta-analysis to assess the clinical outcomes of MSA and to provide comparison between MSA and the current gold standard treatment, fundoplication, in the management of GERD. A total of 39 studies with 8,075 patients were included (6,983 patients underwent MSA and 1,092 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 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 long-term surgical reintervention and adverse outcomes following MSA procedures.

Tade et al (2025) conducted a meta-analysis of randomized and cohort studies from 1980 to 2024, including adults with GERD who underwent fundoplication (Nissen, Toupet), MSA, or transoral incisionless fundoplication (TIF). The analysis pooled 9,516 patients with available pre- and post-operative acid exposure time (AET), DeMeester score, and/or symptom relief scores. The median follow-up was 12 months. Across procedures, AET, DeMeester scores, and symptom relief improved significantly. In multilevel meta-regression, TIF showed significantly less improvement than

Nissen in AET (p = 0.045) and DeMeester (p = 0.023), while MSA and Toupet demonstrated significantly better symptom relief than Nissen (MSA p = 0.044; Toupet p = 0.034). The authors noted study-level heterogeneity and limitations, including incomplete data on hiatal hernia characteristics/repair techniques and procedural variations, and they did not meta-analyze postoperative complications (e.g., dysphagia, bloating) as primary outcomes. Overall, Nissen fundoplication demonstrated significantly better improvement with acid exposure and DeMeester score compared to MSA and TIF. However, symptom relief scores are significantly improved with Toupet fundoplication and MSA compared to other surgical treatment options.Louie et al (2026) published long-term (>5 years) outcomes from the FDA post-approval study of MSA with the LINX Reflux Management System. The multicenter, prospective study enrolled 200 patients from 2013 to 2015 with confirmed GERD despite acid suppression therapy who underwent laparoscopic implantation of a magnetic sphincter. A total of 136 of 200 patients were available for follow-up. Clinical success, defined as a ≥50% improvement in the total GERD-HRQL score compared with baseline off PPIs, was achieved in 81.6%, with the median score improving from 26 to 4. Freedom from daily PPI use was 90.4%. Objectively, the percent time pH <4 decreased from 9.1 to 3.2, and the DeMeester score decreased from 29 to 11 in 81 patients, consistent with normalization of esophageal acid exposure. The ability to belch and vomit was retained if needed. Dysphagia occurred in 5%. There were 27 (13%) devices explanted with only 4 (2%) erosions; of these, 25 (92.6%) patients had resolution of their symptoms with removal, conversion to fundoplication, or replacement of the device. The authors concluded that MSA controls symptoms of GERD without the need for PPIs but may need explantation in 13% of patients.

Regression of Barrett's Esophagus (BE)

The evidence is insufficient to determine that 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

American Society of General Surgeons (ASGS)

The most current guideline from the 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."

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

In 2017, 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 be offered in isolation.

In 2021, SAGES published clinical practice guidelines for the surgical treatment of GERD (Slater et al. 2021). The guidelines recommend that patients being considered for antireflux surgery undergo a comprehensive preoperative evaluation including upper endoscopy, high-resolution esophageal manometry, and ambulatory pH monitoring. SAGES recommends that MSA is an appropriate surgical option for patients who meet indications for antireflux surgery, and that the choice between MSA and fundoplication should be individualized based on patient and disease characteristics. The guidelines note that partial fundoplication may be preferred in patients with esophageal hypomotility, and that MSA should be performed by surgeons with training and experience in foregut surgery.

American College of Gastroenterology (ACG)

In 2022, the 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 addition, the ACG recommends an initial 8-week trial of once-daily PPI therapy taken 30–60 minutes before a meal for adults with typical GERD symptoms and no alarm features, with maintenance at the lowest effective dose for those who respond. For individuals whose symptoms persist, the guideline advises optimization of PPI therapy as the first step, which includes verifying proper timing and adherence and considering escalation to twice-daily dosing before labeling symptoms as refractory or considering procedural therapy.

American Gastroenterology Association (AGA)

In 2022, the AGA issued a statement on the personalized approach to evaluating and managing individuals with GERD (Yadlapati 2022). The authors provided a best practice recommendation that in patients with proven GERD, laparoscopic fundoplication and magnetic sphincter augmentation are effective surgical options, and transoral incisionless fundoplication is an effective endoscopic option in carefully selected patients.

Multi-Society Consensus Conference

In 2023, a panel of 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 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:

- 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 considering other factors such as BMI and esophageal dysmotility, which are relative contraindications for MSA (Conditional recommendation based on very low certainty of evidence).

- 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).

National Institute for Health and Care Excellence (NICE)

In 2023, NICE issued an updated health tech guidance (HTG654) on laparoscopic insertion of a magnetic ring for GERD. The following recommendations were based on a comprehensive literature search and review: 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.

Regression of Barrett's Esophagus (BE)

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

## REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates MSA devices as a medical device. All MSA devices require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Mar 5]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls-and-early-alerts | FDA [accessed 2026 Mar 5]

The LINX Reflux Management System received FDA premarket approval in 2012 (P100049) for GERD in patients with abnormal pH testing and persistent symptoms despite maximal therapy. The FDA-required five-year follow-up of 100 pivotal IDE patients was completed in 2016, with results published in 2019. In 2018, labeling was updated (P100049/S021) to require repair of hiatal hernias larger than 3 cm at implantation and to add related clinical data and patient-information revisions. In February 2024, the FDA removed a precaution about Barrett's Esophagus, noting that LINX has not been proven to treat BE and that patients with BE should continue appropriate management, which may include PPIs.

## 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 |



**HCPCS Codes**

| Code | Description |
|---|---|
| Not Applicable | |

**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.

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

American Society for Gastrointestinal Endoscopy (ASGE) Standards of Practice Committee; Desai M, et al. American Society for Gastrointestinal Endoscopy guideline on the diagnosis and management of GERD: summary and recommendations. Gastrointest Endosc. 2025 Feb;101(2):267-284. Epub 2024 Dec 17.

American Society of General Surgeons (ASGS) Board of Trustees [Internet]. Position statement: LINX statement of support from ASGS. 2014 [accessed 2026 Feb 24]. Available from: https://theasgs.org/position-statements/linx-statement-of-support-from-asgs/

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.

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

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

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. 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. 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. 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):1762–1768.

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

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

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

Khaitan L, 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.

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.

Louie BE, et al.; Post-approval study investigators. Long-term (>5 years) outcomes after magnetic sphincter augmentation. Ann Surg. 2026 Jun 1;283(6):1001-1008.

National Institute for Health and Care Excellence (NICE) [Internet]. Laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease [HTG654]. 2023 Jan 11 [accessed 2026 Feb 26]. Available from: https://www.nice.org.uk/guidance/htg654

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

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.

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 2026 Feb 24]. Available from: https://www.sages.org/publications/tavac/tavac-safety-and-effectiveness-analysis-linx-reflux-management-system/

Tade Y, et al. Fundoplication significantly improves objective and subjective reflux outcomes-a meta-analysis. Surg Endosc. 2025 Jul;39(7):4496-4504.

Torax Medical, Inc. LINX Reflux Management System – instructions for use. 2023 Jan [accessed 2026 Mar 5] 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 2026 Mar 5]. 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 2026 Mar 5]. 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 2026 Mar 5]. 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.

## SEARCH TERMS

Not Applicable

## CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Select Minimally Invasive GERD Procedures (LCD L35080) [accessed 2026 Mar 5]

## 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.
- 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

02/20/14, 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, 06/18/26

| Date | Summary of Changes |
|---|---|
| 06/18/26 | • Annual review. Policy statements for diagnosis and symptom management were revised, measurement for hiatal repair was decreased to 2 cm. |
| 04/17/25 | • Annual review, policy intent unchanged. |
| 01/01/25 | • Summary of changes tracking implemented. |
| 02/20/14 | • Original effective date |