

Regence

Medical Policy Manual

Surgery, Policy No. 190

Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD)

Effective: May 1, 2024

Next Review: January 2025

Last Review: March 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

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.

MEDICAL POLICY CRITERIA

An implantable magnetic esophageal ring is considered **investigational** as a treatment of gastroesophageal reflux disease (GERD).

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. [Bariatric Surgery](#), Medical Policy Manual, Surgery, Policy No. 58
2. [Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease \(GERD\)](#), Medical Policy Manual, Surgery, Policy No. 110
3. [Gastric Reflux Surgery](#), Medical Policy Manual, Surgery, Policy No. 186

BACKGROUND

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 10-20% prevalence in developed countries. The severity of GERD is widely variable. 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's esophagus and esophageal cancer. For patients with severe disease, chronic treatment with acid blockers is one option. For some patients, medications are not adequate to control symptoms, and 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.

LINX™ PROCEDURE

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

REGULATORY STATUS

The LINX™ Reflux Management System was approved by the U.S. Food and Drug Administration (FDA) in 2012. The LINX™ device is indicated 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 5-year follow-up of 100 patients from the investigational device exemption (IDE) pivotal study to evaluate safety and efficacy of the device. 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.

EVIDENCE SUMMARY

Randomized controlled trials (RCTs) are necessary to establish the efficacy of treatments for gastroesophageal reflux disease (GERD). GERD has a variable natural history, with exacerbations and remissions, and, as a result, a control group is required to differentiate improvements in symptoms from the natural history of the disorder. A placebo control is optimal due to the subjective nature of the patient-reported outcome measures, which are prone to bias if the patient is not blinded to treatment assignment. Random assignment is important because of the multiple potential confounders of GERD outcomes, such as diet, smoking, and obesity. Randomization minimizes the chance that these confounders will be distributed unequally among treatment groups. It is also important to determine comparative

efficacy of treatments for GERD because numerous medical and surgical treatments are effective.

SYSTEMATIC REVIEWS

A systematic review with pooled analysis comparing LINX™ to fundoplication was identified,^[1] however, the follow-up duration was short (\leq one year); longer-term data are needed to evaluate the overall effect on health outcomes. Each of the four included studies are summarized in the Comparative Studies section, below.^[2-5]

Zhuang (2021) published a systematic review including 14 studies (Ten single-arm studies, one randomized controlled trial and three cohort studies) involving 1138 participants which aimed to determine the safety and efficacy of MSA in the management of GERD.^[6] Post-MSA PPI withdrawal, significant GERD-HRQL improvement and AET normalization were achieved in 87.0%, 88.0% and 75.0% of the patients, respectively. The incidence of postoperative dysphagia was 29% and endoscopic dilation was required in 7.4% of patients undergoing MSA. MSA showed a better efficacy in symptom control than PPI (PPI cessation: 91% vs 0%; GERD-HRQL improvement: 81% vs 8%) and similar effectiveness but a lower risk of gas-bloat syndrome (RR 0.69, 95% CI 0.51-0.93). The outcome for better reserved ability to belch (RR 1.48, 95% CI 0.76-2.86) compared with LNF was not significant. This review is limited by the lack of randomized trials and high risk of bias in the included studies. Additional long-term randomized trials are needed.

Schizas (2020) published a systematic review which included 35 studies with 2511 patients who received magnetic sphincter augmentation using the LINX® Reflux Management System.^[7] Post-operative proton-pump inhibitor (PPI) cessation rates reached 100%, with less bloating symptoms and a better ability to belch or vomit in comparison to laparoscopic fundoplication. Special patient groups, such as bariatric or those with large hiatal-hernias, had promising results as well. The most common postoperative complication was dysphagia ranging between 6% and 83%. Dilation due to dysphagia occurred in 8% of patients. Esophageal erosion may occur in up to 0.03% of patients. Overall, there continues to be a lack of randomized controlled trials with long-term follow up evaluating the safety and efficacy of the LINX Reflux Management System.

RANDOMIZED CONTROLLED TRIALS

Bell published results from the only randomized controlled trial of LINX™ identified in the literature in 2019 (NCT 02505945).^[8] Torax Medical, Inc., the manufacturer of LINX™ sponsored the trial, also known as the CALIBER study. Twice-daily (BID) PPI therapy (omeprazole 20 mg) (N = 102) was compared to magnetic sphincter augmentation (MSA) with the LINX™ device (N = 50) in those with moderate-to-severe regurgitation despite once-daily PPI therapy in a 2:1 randomized fashion. Participants were recruited from 21 centers across the US. Baseline characteristics were similar between groups, with the exception of DeMeester scores which were significantly higher in the MSA group. Prior to study start, 3 MSA patients withdrew, and 1 failed to start BID PPI therapy. At the 6-month endpoint, 47 of the MSA patients (100%) completed surveys, and 44 of 47 (94%) completed impedance-pH testing. Of the BID PPI patients, 13 withdrew before the 6-month visit; of the 101 patients 87 (86%) completed surveys and 79 (78%) completed impedance-pH testing. GERD–health-related quality of life scores (GERD-HRQL) were reduced by 50% or more in 81% of the MSA patients as compared to 8% of the BID PPI patients ($p < .001$). Ninety-one percent of patients in the MSA arm discontinued PPI use at 6 months. Objective measures of GERD improvement

trended towards MSA being superior, though statistical significance was only achieved in the measurement of reflux events per 24 hours. Fifteen patients (32%) in the MSA arm reported dysphagia, rated mild in 9 (19%), moderate in 4 (9%), and severe in 2 (4%). This was transient (minimal or resolved by 6 months) in 13 patients and was ongoing in 2 (4%). One rated moderate, and 1 rated severe. Conclusions are somewhat limited by the length of follow-up, and no additional study time was reported in the design.

NONRANDOMIZED STUDIES

Comparative Studies

Retrospective comparative studies have been identified on magnetic sphincter augmentation (MSA) with the LINX™ device compared with laparoscopic Nissen fundoplication (LNF) or laparoscopic Toupet fundoplication (LTF).

Bonavina (2021) published 3-year outcomes from a prospective, observational registry evaluating MSA and laparoscopic fundoplication in 631 patients (465 MSA; 166 laparoscopic fundoplication).^[9] 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 Los Angeles 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.

The largest study identified is a multi-institutional retrospective cohort study by Warren (2016) who reported on 415 patients treated with either MSA (n=201) or LNF (n=214).^[5] Eligible patients were retrospectively identified from 3 centers' prospectively collected databases, and met criteria if they had GERD at least partially responsive to proton pump inhibitor (PPI) treatment and positive pH testing. MSA-treated patients had lower DeMeester scores, and lower rates of biopsy-proven Barrett esophagus and hiatal hernia. Given the differences in baseline groups, the authors used propensity score matching to generate 114 matched pairs based on preoperative esophagitis, presence of Barrett esophagus, hiatal hernia, and body mass index (BMI). Mean follow-up differed for matched pair MSA and LNF groups (11 mo vs 16 mo, respectively, p<0.001). In quality of life analysis at follow-up, there was no significant difference in match-pair groups in Gastroesophageal Reflux Disease–Health-Related Quality of Life (GERD-HRQL) scores (6 for MSA vs 5 for LNF, p=0.54). The proportion of patients using PPIs at follow-up was higher in the MSA group (24% vs 12%, p=0.02), but more patients in the MSA group had the ability for eructation (97% vs 66%, p<0.001).

Also in 2016, Asti reported on an observational cohort study comparing MSA (n=135) and LTF (n=103), using patients identified from a prospectively collected database.^[10] Eligible patients had GERD symptoms despite PPI for at least 6 months, and normal esophageal motility. In a generalized estimating equation model for the GERD-HRQL, there was no significant difference at 1 year in GERD-HRQL scores between MSA and LTF groups (odds ratio [OR] for time-treatment interaction term, 1.04; 95% confidence interval [CI], 0.89 to 1.27; p=0.578). Similarly, there was no significant difference between the MSA and LTF groups at 1 year in PPI use (OR for time-treatment interaction term, 1.18; 95% CI, 0.81 to 1.70; p=0.389).

Reynolds (2015) reported on 1-year follow-up for 50 MSA and 50 LNF patients matched by disease severity.^[4] To be included in the study, patients had (1) objective evidence of GERD, defined as an abnormal pH study, presence of biopsy-proven Barrett esophagus, or esophagitis grade B or greater; (2) PPI therapy for a minimum of 6 months; and (3) normal esophageal motility. Some patients had been included in previous reports. At 1 year after surgery, the 2 groups had similar GERD-HRQL scores (MSA=4.2 vs LNF=4.3; maximum, 50) and PPI use (MSA=17% vs LNF=8.5%). There was no difference in the number of patients reporting mild gas and bloating (MSA=27.6% vs LNF=27.6%), but more LNF patients reported severe gas and bloating (10.6% vs 0%, p=0.028). More LNF patients were unable to belch (MSA=8.5% vs LNF=25.5%, p=0.028) or vomit when needed (MSA=4.3% vs LNF=21.3%, p<0.002).

Louie (2014) compared outcomes from 34 patients who had MSA with 32 patients who underwent LNF.^[2] Similar improvements were found for both groups on the GERD-HRQL. The DeMeester score and pH normalized in both groups, but both were lower (p=0.001) in the fundoplication group. MSA allowed belching in 67% of patients compared with 0% in the fundoplication group. Sheu (2014) retrospectively compared outcomes from 12 MSA patients with a contemporaneous case-matched cohort of patients who underwent LNF.^[3] Over half of the MSA patients were self-referred compared with none who underwent LNF. Both procedures were effective for reflux. Severe dysphagia requiring endoscopic dilation was more frequent after MSA (50% of cases), while there was a trend for a reduction in bloating, flatulence, and diarrhea in this study.

In 2015, Riegler published 1-year results from an industry-sponsored multicenter registry (NCT01624506) that included a comparison with laparoscopic fundoplication.^[11] The report included 202 MSA and 47 LNF or LTF patients from a planned enrollment of 734 patients. The choice of procedure was made by the surgeon at the time of laparoscopy, taking into account the presence of a large hiatal hernia and other factors. In addition to having a greater frequency of large hiatal hernias (>3 cm, 45.7% vs 1.6%), the fundoplication group was older and had a greater frequency of Barrett esophagus (19.1% vs 1.0%, p<0.001). Consistent with the greater severity of symptoms, patients who underwent fundoplication had greater regurgitation and fewer discontinued PPIs after treatment. Excessive gas and abdominal bloating (31.9% vs 10.0%) and inability to vomit (55.6% vs 8.7%) were significantly higher after fundoplication than after MSA. Improvements in GERD-HRQL scores were similar for the groups.

Single Arm Studies

Fletcher (2021) published a multicenter retrospective review of 144 patients undergoing dilation for dysphagia after MSA for GERD, reporting 245 dilations at a median time to dilation of 175 days.^[12] A second dilation was performed in 67 patients, a third dilation was performed

in 22 patients, and four or more dilations were performed in an additional seven patients. Overall, dysphagia prompting dilation after MSA implantation was associated with nearly a 12% risk of device explantation (17 devices).

Data submitted to the U.S. Food and Drug Administration (FDA) for the LINX® Reflux Management System included 2 single-arm, nonrandomized FDA-regulated investigational device exemption (IDE) trials with a total of 144 subjects and follow-up data between 2 and 4 years.^[13] The feasibility IDE study enrolled 44 subjects at 4 clinical sites (2 U.S. and 2 Europe) and has published data out to 4 years.^[14, 15] The pivotal IDE study included 100 subjects from 14 clinical sites (13 U.S. and 1 Europe) who had documented symptoms of gastroesophageal reflux disease for longer than 6 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 4 for 4.5% or more of the time when off GERD medications. The primary safety endpoint measured the rate of related device and procedure serious adverse events (SAEs). Efficacy endpoints were assessed off PPI therapy and measured esophageal acid exposure, total GERD-HRQL scores, and PPI usage. Subjects served as their own controls.

Results of the pivotal trial were published in 2013.^[16] In this study, 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 postoperatively, in 11% at 1 year, and in 4% at 3 years. Nineteen patients underwent esophageal dilation for dysphagia. Six patients (6%) experienced a serious adverse event (SAE) including severe dysphagia and vomiting. The device was removed in 4 of these 6 patients with a SAE and in 2 additional patients for persistent reflux and chest pain.

Five-year results from 33 of the 44 patients from the feasibility IDE trial were published in 2015.^[17] For the 33 with follow-up, the mean total GERD-HRQL score decreased from 25.7 at baseline to 2.9 at year 5 ($p < 0.001$); 93.9% had more than 50% reduction in total score versus baseline. On esophageal pH testing, the mean percentage of time that pH was less than 4 decreased from 11.9% at baseline to 4.6% at 5 years ($p < 0.001$). At 5 years, 87.8% had stopped PPIs.

Five-year results for the 100 patients in the pivotal IDE trial were published in 2016.^[18] Eighty-five patients had follow-up at 5 years. Of those 85, 83% achieved had a 50% reduction in GERD-HRQL scores (95% CI 73% to 91%) and 89.4% had a reduction of 50% or more in average daily dose of PPI (95% CI, 81% to 95%). No new major safety concerns emerged. The device was removed in 7 patients.

In 2013, Bonavina published longer follow-up from patients in the pilot and multicenter registry studies.^[19] This study included a consecutive series of 100 patients who received MSA for GERD at their institution and were followed for a median of 3 years (range, 378 days to 6 years). Thirty of the patients had data beyond 5 years. Median GERD-HRQL score improved

from 24 off PPIs to 2 ($p < 0.001$), and freedom from daily dependence on PPIs was achieved in 85% of patients. The time that esophageal pH was less than 4 decreased from 8.0% to 3.2% ($p < 0.001$). Although three patients had the device removed for persistent GERD, odynophagia, or dysphagia, no occurrences of device migrations or erosions were observed during follow-up.

In 2018, Louie reported on 1-year results from a 5-year Post Approval Study, mandated by the FDA (NCT 01940185).^[20] The FDA requires such studies in order to confirm clinical outcomes achieved in the investigational setting can also be achieved in a broader clinical context. Two hundred patients (102 males, 98 females) with characteristics similar to those in the IDE trials were enrolled between 2013 and 2015 at 17 clinical centers in the United States. The trial was designed with input from the FDA and aimed to evaluate patients with GERD before and after MSA with predefined clinical measures. At 1-year follow-up, data were available for 91% of patients (182/200). One patient had the device removed just after 1-year data collection. Four additional patients had the device removed prior to data collection; removal was performed for vomiting (11 days post implant), dysphagia (243 and 323 days post implant), device erosion (362 days post implant), or pseudo achalasia (343 days post implant). All device removals were safely performed, and no life-threatening events, deaths, or permanent disability occurred during the 1-year safety assessment. Study success was predefined as achieving a 50% or greater reduction in total GERD-HQRL score, which 84.3% of patients reached at 1 year. Objective measurement of GERD symptoms was statistically significantly improved in the 164 patients who agreed to esophageal pH monitoring. Overall, 87.4% of patients had completely discontinued PPIs, and 91.4% of patients were free from daily PPI use. The results are limited by several factors including the single-arm design, lack of generalizability to lower volume/non-academic practices, and length of follow-up. Additional results will be reported up to 5-years, though long-term randomized trial results are still warranted. Additional single-arm observational studies have reported on outcomes after MSA in sample sizes of up to 200 patients,^[21-25] some of which focused on specific subpopulations of individuals with GERD, such as those with large hiatal hernias (eg, Rona, 2017)^[24].

Alicubin (2018) published a retrospective review which identified a risk of device erosion of 0.3% at 4 years after device placement.^[26] Twenty-nine reported cases of erosion occurred among 9453 device placements. The median time to erosion was 26 months, and most cases occurred between 1 and 4 years after device placement.

ADVERSE EVENTS

In 2015, Lipham reported on adverse events for the first 1048 implanted patients (82 institutions).^[27] Of these, 144 were implanted as part of premarket clinical trials (previously described), 332 had been enrolled in the postmarket registry, and 572 were implanted outside of a postmarket registry. The three sources used to identify adverse events were the published clinical literature along with the device's Summary of Safety Effectiveness Data, the Food and Drug Administration database for device-related complications (MAUDE database), and information provided by the manufacturer. Event rates were 0.1% intra- or perioperative complications, 1.3% hospital readmissions, 5.6% endoscopic dilations, and 3.4% reoperations for device removal. The primary reason for device removal was dysphagia. Erosion of the device occurred in 1 (0.1%) patient. Median device implantation was 274 days. This study was limited by the short follow-up and the voluntary reporting of adverse events outside of the registry.

SOCIETY OF AMERICAN GASTROINTESTINAL AND ENDOSCOPIC SURGEONS

In 2017, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) updated a Technology and Value Assessment publication on the safety and effectiveness of the LINX™ Reflux Management System.^[28] The SAGES assessment stated that safety analyses of the LINX™ system at 3-5 years followup confirms the initial safety profile that led to FDA approval. The committee concluded that based on available evidence, the LINX™ device should be an option available to patients and providers for the management of medically refractory GERD; however, the available evidence is limited by the following:

- Patients are repeatedly used in some publications;
- Publication bias in favor of LINX™ as several studies are manufacturer sponsored, or performed by investigators with manufacturer affiliation;
- Selection bias, as published studies are performed in high volume centers with highly selected cohorts that may not reflect the general population, and may also lead to underreported complications;
- Existing studies lack randomization and blinding.

AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY

A 2013 report on emerging technology from the American Society for Gastrointestinal Endoscopy concluded that long-term data about the safety and efficacy of the LINX™ device are needed.^[29]

AMERICAN FOREGUT SOCIETY

The American Foregut Society (AFS) issued a statement on appropriate patient selection and use of MSA and noted that "patient selection criteria for MSA do not differ in principle from those of any other surgical procedure for reflux disease."^[30] Indications for MSA include:

- Typical GERD symptoms (ie, heartburn, regurgitation) with break-through symptoms, intolerance to medical therapy, and/or unwillingness to take anti-reflux medications long term.
- Regurgitation despite optimized medical therapy and lifestyle modification.
- Extraesophageal symptoms with objective evidence of significant reflux disease (ie, endoscopic evidence of [Los Angeles] Class C or D esophagitis, Barrett's esophagus or positive pH study.

The statement additionally notes that "MSA candidacy largely mirrors that for laparoscopic fundoplication. Low dysphagia rates for MSA have been found when performed in patients with normal esophageal motility." The AFS also recommends that a full hiatal dissection and cruroplasty be performed prior to implantation of an MSA device.

The AFS Bariatric Committee also issued a statement regarding the concurrent use of MSA at the time of primary bariatric surgery, noting that this practice "violates many basic surgical principles and is not considered judicious use by the American Foregut Society." The statement also notes that prospective trials demonstrating the safety and efficacy of concurrent MSA are needed.

AMERICAN COLLEGE OF GASTROENTEROLOGY

In 2022, the American College of Gastroenterology (ACG) published a clinical guideline on the diagnosis and management of GERD.^[31] Relevant recommendations concerning surgical management of refractory GERD include:

"For patients who have regurgitation as their primary PPI [proton pump inhibitor]-refractory symptom and who have had abnormal gastroesophageal reflux documented by objective testing, we suggest consideration of antireflux surgery or TIF [transoral incisionless fundoplication] (conditional recommendation; low level of evidence).

We recommend antireflux surgery performed by an experienced surgeon as an option for long-term treatment of patients with objective evidence of GERD, especially those who have severe reflux esophagitis (LA grade C or D), large hiatal hernias, and/or persistent, troublesome GERD symptoms (strong recommendation; moderate level of evidence).

We recommend consideration of MSA as an alternative to laparoscopic fundoplication for patients with regurgitation who fail medical management (strong recommendation; moderate level of evidence)."

The guideline also notes that due to the paucity of long-term data on MSA outcomes and lack of randomized trials directly comparing MSA with fundoplication, "it is difficult to recommend one over the other at this time."

SUMMARY

More research is needed to know how well laparoscopically-implanted magnetic esophageal ring works for the treatment of gastroesophageal reflux disease (GERD). The available evidence consists primarily of nonrandomized trials, majority of which are limited due to the lack of comparison against current gold standard treatments such as drug therapy or Nissen fundoplication surgery. High-quality data from randomized controlled trials are needed to compare the implanted magnetic esophageal ring procedure with the currently accepted treatments for GERD and to accurately assess possible adverse events associated with this procedure. Therefore, the use of laparoscopically-implanted magnetic esophageal ring is considered investigational for the treatment of GERD.

REFERENCES

1. Chen MY, Huang DY, Wu A, et al. Efficacy of Magnetic Sphincter Augmentation versus Nissen Fundoplication for Gastroesophageal Reflux Disease in Short Term: A Meta-Analysis. *Canadian journal of gastroenterology & hepatology*. 2017;2017:9596342. PMID: 28466002
2. Louie BE, Farivar AS, Shultz D, et al. Short-term outcomes using magnetic sphincter augmentation versus Nissen fundoplication for medically resistant gastroesophageal reflux disease. *The Annals of thoracic surgery*. 2014;98(2):498-504; discussion 04-5. PMID: 24961840
3. Sheu EG, Nau P, Nath B, et al. A comparative trial of laparoscopic magnetic sphincter augmentation and Nissen fundoplication. *Surgical endoscopy*. 2014. PMID: 25012804

4. Reynolds JL, Zehetner J, Wu P, et al. Laparoscopic Magnetic Sphincter Augmentation vs Laparoscopic Nissen Fundoplication: A Matched-Pair Analysis of 100 Patients. *Journal of the American College of Surgeons*. 2015;221(1):123-8. PMID: 26095560
5. Warren HF, Reynolds JL, Lipham JC, et al. Multi-institutional outcomes using magnetic sphincter augmentation versus Nissen fundoplication for chronic gastroesophageal reflux disease. *Surgical endoscopy*. 2016;30(8):3289-96. PMID: 26541740
6. 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*. 2021;22(12):695-705. PMID: 34693633
7. Schizas D, Mastoraki A, Papoutsis E, et al. LINX((R)) reflux management system to bridge the "treatment gap" in gastroesophageal reflux disease: A systematic review of 35 studies. *World journal of clinical cases*. 2020;8(2):294-305. PMID: 32047777
8. 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. *Gastrointestinal endoscopy*. 2019;89(1):14-22 e1. PMID: 30031018
9. Bonavina L, Horbach T, Schoppmann SF, et al. Three-year clinical experience with magnetic sphincter augmentation and laparoscopic fundoplication. *Surgical endoscopy*. 2021;35(7):3449-58. PMID: 32676727
10. Asti E, Bonitta G, Lovece A, et al. Longitudinal comparison of quality of life in patients undergoing laparoscopic Toupet fundoplication versus magnetic sphincter augmentation: Observational cohort study with propensity score analysis. *Medicine*. 2016;95(30):e4366. PMID: 27472725
11. Riegler M, Schoppman SF, Bonavina L, et al. Magnetic sphincter augmentation and fundoplication for GERD in clinical practice: one-year results of a multicenter, prospective observational study. *Surgical endoscopy*. 2015;29(5):1123-9. PMID: 25171881
12. Fletcher R, Dunst CM, Abdelmoaty WF, et al. Safety and efficacy of magnetic sphincter augmentation dilation. *Surgical endoscopy*. 2021;35(7):3861-64. PMID: 32671521
13. LINX™ Reflux Management System. Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee 2012. [cited 03/19/2024]. 'Available from:' https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100049B.pdf.
14. Bonavina L, DeMeester T, Fockens P, 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;252:857-62. PMID: 21037442
15. Lipham JC, DeMeester TR, Ganz RA, et al. The LINX(R) reflux management system: confirmed safety and efficacy now at 4 years. *Surgical endoscopy*. 2012;26(10):2944-9. PMID: 22538694
16. Ganz RA, Peters JH, Horgan S, et al. Esophageal sphincter device for gastroesophageal reflux disease. *The New England journal of medicine*. 2013;368(8):719-27. PMID: 23425164
17. Saino G, Bonavina L, Lipham JC, et al. Magnetic Sphincter Augmentation for Gastroesophageal Reflux at 5 Years: Final Results of a Pilot Study Show Long-Term Acid Reduction and Symptom Improvement. *Journal of laparoendoscopic & advanced surgical techniques Part A*. 2015;25(10):787-92. PMID: 26437027
18. Ganz RA, Edmundowicz SA, Taiganides PA, et al. Long-term Outcomes of Patients Receiving a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux. *Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association*. 2016;14(5):671-7. PMID: 26044316

19. Bonavina L, Saino G, Bona D, et al. One hundred consecutive patients treated with magnetic sphincter augmentation for gastroesophageal reflux disease: 6 years of clinical experience from a single center. *Journal of the American College of Surgeons*. 2013;217(4):577-85. PMID: 23856355
20. 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*. 2018. PMID: 29697454
21. 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. *Journal of the American College of Surgeons*. 2014;218(4):776-81. PMID: 24529809
22. 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. *The American surgeon*. 2014;80(10):1034-8. PMID: 25264655
23. 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*. 2017;266(1):99-104. PMID: 27464617
24. Rona KA, Reynolds J, Schwameis K, et al. Efficacy of magnetic sphincter augmentation in patients with large hiatal hernias. *Surgical endoscopy*. 2017;31(5):2096-102. PMID: 27553803
25. Antiporda M, Jackson C, Smith CD, et al. Short-Term Outcomes Predict Long-Term Satisfaction in Patients Undergoing Laparoscopic Magnetic Sphincter Augmentation. *Journal of laparoendoscopic & advanced surgical techniques Part A*. 2019;29(2):198-202. PMID: 30556776
26. Alicuben ET, Bell RCW, Jobe BA, et al. Worldwide Experience with Erosion of the Magnetic Sphincter Augmentation Device. *J Gastrointest Surg*. 2018;22(8):1442-47. PMID: 29667094
27. Lipham JC, Taiganides PA, Louie BE, et al. Safety analysis of first 1000 patients treated with magnetic sphincter augmentation for gastroesophageal reflux disease. *Diseases of the esophagus : official journal of the International Society for Diseases of the Esophagus / ISDE*. 2015;28(4):305-11. PMID: 24612509
28. Telem DA, Wright AS, Shah PC, et al. SAGES technology and value assessment committee (TAVAC) safety and effectiveness analysis: LINX((R)) reflux management system. *Surgical endoscopy*. 2017;31(10):3811-26. PMID: 28842765
29. Magnets in the GI tract. *Gastrointestinal endoscopy*. 2013;78(4):561-7. PMID: 24054738
30. Society AF. American Foregut Surgery Statement on Appropriate Patient Selection and Use of Magnetic Sphincter Augmentation (LINX). [cited 3/6/2023]. 'Available from:' <https://www.americanforegutsociety.org/wp-content/uploads/sites/21/2021/04/AFS-LINX-Final.pdf>.
31. Katz PO, Dunbar KB, Schnoll-Sussman FH, et al. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol*. 2022;117(1):27-56. PMID: 34807007

CODES

NOTE: Based on the CPT description, a hiatal hernia repair should not be reported with this procedure.

Codes	Number	Description
CPT	43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed
	43285	Removal of esophageal sphincter augmentation device
	43289	Unlisted laparoscopy procedure, esophagus
HCPCS	None	

Date of Origin: January 2014