7.01.137	Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease		
Original Policy Date:	June 28, 2013	**Effective Date:**	January 1, 2022
Section:	7.0 Surgery	**Page:**	Page 1 of 15

Policy Statement

Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease (GERD) is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

There are specific CPT category I codes for this procedure:

- **43284**: Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed
- **43285**: Removal of esophageal sphincter augmentation device

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 maximal medical therapy.

Related Policies

- Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 2012, the LINX® Reflux Management System (Torax Medical) 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 maximal therapy for the treatment of reflux. The FDA initially required a 5-year follow-up of 100 patients from the investigational device exemption pivotal study to evaluate the safety and efficacy of the device, which was completed in March 2016. In 2018,the manufacturer initiated a device recall due to a possible separation of the bead

component with the adjacent wire link causing a potential discontinuous or open LINX device.[1] This recall was terminated on November 4, 2020. FDA product code: LEI.

In March 2018, the FDA approved an update of the LINX® Reflux Management System precautions statement, stating that the use of the system "in patients with a hiatal hernia larger than 3 cm should include hiatal hernia repair to reduce the hernia to less than 3 cm and that the LINX Reflux Management System has not been evaluated in patients with an unrepaired hiatal hernia greater than 3 cm, add a hiatal hernia clinical data summary in the instructions for use, update the instructions for use section to highlight the recommendation to repair a hiatal hernia, if present, at the time of the LINX Reflux Management System implantation, and update the patient information booklet to align with the instructions for use and include 5 year clinical study results."[2]

Rationale

Background

Gastroesophageal Reflux Disease

Gastroesophageal reflux disease (GERD) is defined as the reflux of stomach acid into the esophagus that causes symptoms and/or mucosal injury. GERD is a common medical disorder, with estimates of 10% to 20% prevalence in developed countries.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Clinical Context and Therapy Purpose

The purpose of magnetic sphincter augmentation (MSA) in patients who have gastro-esophageal reflux disease (GERD) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of MSA improve the net health outcome in individuals with GERD who have not responded to optimal medical management?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with GERD who have not responded to optimal medical management.

The severity of GERD varies widely. Many patients have mild, intermittent symptoms that do not require treatment or only require episodic use of medications. Other patients have chronic, severe GERD that can lead to complications such as Barrett esophagus and esophageal cancer.

The Los Angeles (LA) classification system is used to describe the endoscopic appearance of reflux esophagitis and grade its severity. Esophagitis is confirmed by endoscopy according to a 5 grading severity scale.

- Not present: No breaks (erosions) in the esophageal mucosa (edema, erythema, or friability may be present).
- Grade A: One or more mucosal breaks confined to the mucosal folds, each not more than 5 mm in maximum length.
- Grade B: One or more mucosal breaks more than 5 mm in maximum length, but not continuous between the tops of 2 mucosal folds.
- Grade C: Mucosal breaks that are continuous between the tops of 2 or more mucosal folds, but which involve less than 75% of the esophageal circumference.
- Grade D: Mucosal breaks which involve at least 75% of the esophageal circumference.

Interventions

The therapy being considered is MSA. The LINX Reflux Management System is composed of a small flexible band of 10 to 18 interlinked titanium beads with magnetic cores. Using standard laparoscopic techniques, the band is placed around the esophagus at the level of the gastro-esophageal junction. The magnetic attraction between the beads is intended to augment the lower esophageal sphincter to prevent gastric reflux into the esophagus, without compressing the esophageal wall. It is proposed that swallowing food or liquids creates sufficient pressure to overcome the magnetic bond between the beads, allowing the beads to separate and temporarily increase the size of the ring. Magnetic sphincter augmentation is a 30-minute surgical procedure performed under general anesthesia that includes testing of the esophageal sphincter. This is a minimally invasive procedure conducted in an inpatient surgical center and requires an overnight stay. The device manufacturer claims patients resume a normal diet within 24 hours postsurgery. The device can be removed by a laparoscopic procedure if severe adverse events occur or if magnetic resonance imaging is needed for another condition.

Comparators

The following therapies and practices are currently being used to treat GERD that has not responded to optimal medical therapy: lifestyle modifications, continued medical therapy, and interventions to strengthen the lower esophageal sphincter.

Lifestyle modifications may include weight loss, elevation of the head of the bed, avoidance of meals close to bedtime, and elimination of dietary triggers. For patients with severe disease, chronic treatment with acid suppressive therapies is an option. For some patients, medications are inadequate to control symptoms; other patients prefer to avoid the use of indefinite, possibly lifelong medications. Surgical treatments are available for these patients, primarily a Nissen fundoplication performed either laparoscopically or by open surgery.

In patients who continue to have symptoms despite once daily proton pump inhibitors (PPIs) (e.g., omeprazole 20 mg), guideline based recommendations include increasing and/or splitting the PPI dose, and switching to a different PPI to optimize pharmacologic treatment.

Outcomes

Relevant outcomes of interest are a reduction in symptoms such as heartburn and regurgitation, reduction in acid suppression medication use, QOL, treatment-related adverse events, device failure, device erosion, the need to explant if magnetic resonance imaging is necessary, and progression to Barrett esophagus and esophageal cancer. Additional outcomes of interest include objective measures such as the DeMeester score or percent time esophageal pH < 4

based on impedence-pH findings. Objective measures are of special interest as a lack of correlation between subjective and objective measures of GERD have been reported in the literature.[3]

A variety of scales have been developed to measure patient and investigator-reported GERD symptoms. Frequently used measures of QOL include the GERD-health-related QOL (GERD-HRQL), a scale with 11 items focusing on heartburn symptoms, dysphagia, medication effects, and the patient's present health condition. Each item is scored from 0 to 5, with a higher score indicating a better QOL, and GERD-QOL, a scale with 16 items clustered into the following 4 subscales: daily activity, treatment effect, diet, and psychological well-being. The total score of this questionnaire is the average of the 4 subscale scores. The final score can range from 0 to 100, with a higher score indicating a better QOL.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Two recent systematic reviews compared MSA to laparoscopic Nissen fundoplication (LNF) in patients with GERD (Table 1).[4,5] Both conducted meta-analyses of comparative observational studies and concluded that MSA and LNF had similar effects on symptoms and QOL (Table 2). The body of evidence was limited, however, by the retrospective design of most studies, and the reviewers concluded that RCT evidence was needed.

Table 1. Characteristics of Systematic Reviews of Magnetic Sphincter Augmentation Compared to Laparoscopic Nissen Fundoplication

Study	Dates	Trials	Participants1	N (Range)	Design	Duration
Guidozzi et al (2019)[4]	1987 to 2013	6 comparative observational 13 single-arm cohort	Patients with GERD	Comparative observational studies: 1099 (24 to 415)	Comparative observational	Range 6 to 44 months
Aiolfi et al (2018)[5]	2000 to 2015	6	Patients with GERD	2561 (23 to 335)	Comparative observational (1 prospective, 5 retrospective cohort)	Up to 1 year

GERD: gastroesophageal reflux disease.

Table 2. Results of Systematic Reviews of Magnetic Sphincter Augmentation Compared to Laparoscopic Nissen Fundoplication

Study	Need for PPI	GERD-HRQL	Dysphagia	Need for Reoperation
Guidozzi et al (2019)[4]				
Total N	5 studies (861)	3 studies (760)	4 studies (795)	4 studies (754)
Pooled effect (95% CI)	OR 1.08 (0.40 to 2.95); p=.877	WMD 0.34 (-0.70 to 1.37); p=.525	OR 0.94 (0.57 to 1.55); p=.822	OR 1.23 (0.26 to 5.8); p=.797
I^2 (p)	72% (.007)	70.6% (.033)	20.4% (.288)	48.5% (.12)

Study	Need for PPI	GERD-HRQL	Dysphagia	Need for Reoperation
Aiolfi et al (2018)[5]	*PPI suspension*		*Dysphagia requiring endoscopic dilatation*	
Total N	6 studies (1098)	6 studies (1083)	5 studies (535)	3 studies (1187)
Pooled effect (95% CI)	OR 0.81 (0.42 to 1.58); p=.548	MD -0.48 (-1.05 to 0.09); p=.101	OR 1.56 (0.61 to 3.95); p=.119	OR 0.54 (0.22 to 1.34); p=.183
I^2 (p)	63.9% (.016)	0% (.82)	35% (.19)	0% (.814)

CI: confidence interval; GERD-HRQL: gastroesophageal reflux disease health-related quality of life scale; MD: mean difference; OR: odds ratio; PPI: proton pump inhibitor; WMD: weighted mean difference.

Randomized Controlled Trial

There are no RCTs of MSA compared to LNF. There is 1 open-label RCT comparing MSA to twice-daily omeprazole 20 mg in 152 patients with regurgitation symptoms despite once daily omeprazole 20 mg (Table 3). The primary endpoint was the percent of patients who achieved elimination of moderate-to-severe regurgitation at 6 months, as reported by patients on the Foregut Symptom Questionnaire. The Foregut Symptom Questionnaire evaluates the severity of regurgitation symptoms: none, mild (after straining or large meals), moderate (predictable with position change, lying down, straining), and severe (constant). Esophageal reflux parameters (number of reflux episodes and percentage of time with pH <4 and PPI use were secondary endpoints. At 6 months, significantly more patients who received MSA reported improvements in symptoms and QOL than those in the control group (Table 4). Ninety-one percent of those who received the surgery were able to maintain discontinuation of PPIs at 6 months. Patients who received MSA testing had less reflux, as measured by impedance-pH testing. Follow-up in randomized arms continued for 6 months after which patients in the medical therapy arm could elect to receive MSA; results for patients who crossed over to MSA were similar to those who were randomized to MSA.[6]

Relevance and study design and conduct limitations of the RCT conducted by Bell et al (2019) are shown in Tables 5 and 6. A major limitation of the trial was that the patients had not received optimal medical treatment prior to enrollment. Additional limitations included the use of subjective outcome measures along with an open-label design, although this is less of a concern because results were supported by better results for MSA on some objective measures (Table 4). For patients who have not responded to optimal medical treatment, an appropriate comparator would be Nissen fundoplication.

Table 3. Summary of Key Randomized Controlled Trial Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
Bell et al (2019)[7]; NCT02505945	U.S.	21	2015 to 2017	152 patients with moderate to severe regurgitation symptoms while on once-daily PPIs and actively seeking alternative, surgical treatment for regurgitation symptoms	Laparoscopic MSA (N=50)	Omeprazole 20 mg twice daily (N=102)

MSA: magnetic sphincter augmentation; PPI: proton pump inhibitor.

Table 4. Summary of Key Randomized Controlled Trial Results

Study	Symptoms	Quality of Life		PPI Discontinuation	Impedance-pH Testing				Withdrawals
Bell et al (2019)[7,6] NCT02505945									
N	134	134	134		123	123	123	123	148
	Resolution of moderate-to-severe regurgitation (FSQ) at 6 months	*Mean decrease in GERD-HRQL score at 6 months*	*≥50% decrease in GERD-HRQL score at 6 months*		*Number of reflux events per 24 hours*	*Percentage of time with pH<4 per 24 hours*	*Normal number of reflux episodes*	*Normal acid exposure*	
MSA	42/47 (89%)	18	38/47 (81%)	43/47 (91%)	22.5 (IQR,13.0 to 40.5)	2%	40/44 (91%)	39/44 (89%)	0/47 (0%)
Omeprazole	10 /101 (10%)	1	7/87 (8%)	NR	49.0 (IQR 31.0 to 76.78	5%	46/79 (58%)	59/79 (75%)	13/101 (12.9%)
p value for difference	<.001	<.002	<.001		<.001	.065	<.001	.065	NR

FSQ: Foregut Symptom Questionnaire; GERD-HRQL: gastroesophageal reflux disease health-related quality of life scale; IQR: interquartile range; MSA: magnetic sphincter augmentation; NR: not reported; PPI: proton pump inhibitor.

Table 5. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Bell et al (2019)[7] NCT02505945	4. Patients did not receive optimal medical therapy prior to study enrollment		2. Did not compare the intervention to Nissen fundoplication		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 6. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Bell et al (2019)[7] NCT02505945	1. Differences between	1. Not blinded		1. Differential loss to follow-up (12.9% in PPI		4. CIs for treatment effects not calculated

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
	groups at baseline			group vs. 0 in MSA group)		

CI: confidence interval; MSA: magnetic sphincter augmentation; PPI: proton pump inhibitor.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Nonrandomized Comparative Studies

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 2009-2014 across 22 medical centers in Europe.[8] 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 (e.g., 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. It is unclear to what extent study results are generalizable to U.S. populations and broader settings of care. Additionally, the minimal dissection protocol for MSA implantation utilized in this study has since evolved to include full crural and gastroesophageal junction dissection.

Single-Arm Studies

Data submitted to the U.S. Food and Drug Administration (FDA) for the LINX Reflux Management System included 2 single-arm FDA regulated investigational device exemption (IDE) trials (N=144 subjects) and follow-up data between 2 and 4 years.[9] The feasibility IDE trial enrolled 44 subjects at 4 clinical sites (2 U.S., 2 Europe) and had published data out to 4 years.[10,11] The pivotal IDE trial included 100 subjects from 14 clinical sites (13 U.S., 1 Europe) who had documented symptoms of GERD for more than 6 months (regurgitation or heartburn that responds to acid neutralization or suppression), required daily PPI or other antireflux 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.[12] The primary safety endpoint measured the rate of related device and procedure serious adverse events. 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.

Five-year results for the 100 patients in the pivotal IDE trial were published by Ganz et al (2016).[13] 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 7 patients.

Louie et al (2019) published 1-year outcomes from a 5-year FDA-mandated multicenter post-approval study.[14] A total of 200 patients (51% male) with a mean age of 48.5 years were treated with MSA between March 2013 and August 2015. At 1 year, GERD-HRQL score, esophageal pH monitoring, medication use, and safety assessments were available for 91% of patients. The predefined clinically significant primary endpoint of ≥50% improvement in total GERD-HRQL score was attained by 84.3% of patients at 1 year (95% CI, 78.0% to 89.4%). Median scores improved from 26.0 ± 6.5 to 4.0 ± 9.7. Data on esophageal pH monitoring was available in 164 patients, with mean percent time pH < 4 decreasing from 10.0% at baseline to 3.6% at 1 year (p<.001) and 74.4% (95% CI, 67.7% to 81.1%) achieving normal esophageal acid exposure. Overall, 87.4% of patients discontinued PPIs. Post-MSA dilation was required in 13 patients with symptoms of dysphagia at 1-year follow-up. The device was removed in 5 (2.5%) patients and 1 patient presented with device erosion.

Alicubin et al (2018) published a retrospective review, which identified a risk of device erosion of 0.3% at 4 years after device placement. [15] 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.

Ayazi et al (2020) published a retrospective review of 380 patients treated with MSA with a mean follow-up duration of 11.5 ± 8.7 months.[16] Persistent dysphagia was reported in 59 (15.5%) patients with 31% requiring at least 1 dilation for dysphagia or chest pain. The overall response rate to dilation was 67%, with 7 (1.8%) patients requiring device removal for dysphagia. Independent predictors of persistent dysphagia included the absence of a large hiatal hernia (p=.035), the presence of preoperative dysphagia (p=.037), and having less than 80% peristaltic contractions on high-resolution impedance manometry (p=.031).

Additional single-arm observational studies have reported on outcomes after MSA in sample sizes ranging from 79 to 500 patients,[17,10,11,18,19,20,21] some of which focused on specific sub-populations of individuals with GERD, such as those with large hiatal hernias (e.g., Rona et al [2017] and Dunn et al [2021]).[18,21] Other studies have highlighted independent predictors of favorable outcomes,[19,20] such as age of intervention <40-45 years, male sex, abnormal DeMeester scores, and baseline GERD-HRQL scores >15.

FDA Manufacturer and User Facility Device Experience (MAUDE) reports and manufacturer complaint databases were analyzed from 2013-2020 by DeMarchi and coworkers (2021) to determine rates of surgical device erosion and explants.[22] 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. Smaller device size was found to be associated with increased removal and erosion rates.

Summary of Evidence

For individuals who have GERD who receive MSA, the evidence includes 1 RCT comparing MSA to PPI therapy, a single nonrandomized registry study comparing MSA to laparoscopic fundoplication, single-arm cohort studies, and systematic reviews of observational studies comparing MSA to LNF. Relevant outcomes are symptoms, change in disease status, medication

use, and treatment-related morbidity. A RCT comparing MSA to omeprazole 20 mg twice daily found significantly more patients who received MSA reported improvements in symptoms and QOL at 6 months. A major limitation of the trial was that the patients had not received optimal medical treatment prior to enrollment. A prospective, observational registry study comparing MSA to laparoscopic fundoplication found similar improvements in QOL, satisfaction, and medication use. Limitations of the study included lack of randomization and blinding, heterogeneity in fundoplication techniques, use of an outdated MSA protocol, and selection bias as patients with less severe symptoms received MSA. In the 2 single-arm, uncontrolled pivotal trials submitted to the FDA with materials for device approval, subjects showed improvements in GERD-health-related QOL scores and reduced PPI use. Similarly, observational comparative studies included in systematic reviews, most often comparing MSA with LNF, generally have shown that GERD-health-related QOL scores do not differ significantly between fundoplication and MSA, and patients can reduce PPI use after MSA. However, the comparative studies are retrospective and nonrandomized, and may be affected by selection bias. Randomized comparisons of MSA with LNF are needed to evaluate the relative risk-benefit of these 2 procedures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Society of American Gastrointestinal and Endoscopic Surgeons
The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES, 2013; updated in 2017) published a Technology and Value Assessment Committee (TAVAC) analysis on the safety and effectiveness of the LINX Reflux Management System.[23.] The SAGES indicated that safety analyses of the LINX system suggested the procedure is associated with few serious adverse events and no reported mortality, and that currently available data demonstrated a reasonable assurance as to the efficacy of the system. The report concluded that direct comparative studies between the LINX procedure and Nissen fundoplication would be needed, although, based on the available evidence, the LINX device should be an option available to patients and providers for the management of medically refractory GERD.

In April 2021, guidelines for the surgical treatment of GERD were reviewed and approved by the Board of Governors of the SAGES based on a systematic review of the evidence.[24.] Key questions presented in these guidelines do not address the use of MSA.

National Institute for Health and Care Excellence
In July 2017, the National Institute for Health and Care Excellence (NICE) issued an interventional procedures guidance on laparoscopic insertion of a magnetic titanium ring for GERD.[25.] While the recommendations conclude that there are no major safety concerns with the device, they note limited evidence of short-term efficacy with inadequate quality and quantity of evidence for long-term efficacy. Accordingly, "this procedure should only be used with special arrangements for clinical governance, consent, and audit or research," and note that "long-term outcome data and comparative trials with other anti-reflux surgery would be helpful."

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." Indications for MSA include:[26.]

- "Typical GERD symptoms (i.e., 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 (i.e., 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,[27.] 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 Society for Gastrointestinal Endoscopy

In 2013, a report from the American Society for Gastrointestinal Endoscopy concluded that long-term data on the safety and efficacy of the LINX device were needed.[28.] The document indicated that the LINX band is currently being deployed laparoscopically; however, a natural orifice transluminal endoscopic surgery approach could be explored.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 7.

Table 7. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02923362	Registry of Outcomes From AntiReflux Surgery (ROARS)	2500	May 2025 (recruiting)
NCT01940185[a]	A Post-Approval Study of the Lynx® Reflux Management System	200	Oct 2025 (ongoing)
NCT04695171	Cohort Registry on LINX Reflux Management System or Fundoplication Clinical Study in Patients With Hiatal Hernia >3 cm	450	Jan 2028 (recruiting)
NCT04253392[a]	RETHINK REFLUX Registry (RETHINK REFLUX)	500	July 2032 (recruiting)
Unpublished			
NCT02429830[a]	RELIEF Study: A Prospective, Multicenter Study of REflux Management With the LINX® System for Gastroesophageal REFlux Disease After Laparoscopic Sleeve Gastrectomy	30	Jun 2021 (completed)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. U.S. Food and Drug Administration (FDA). Class 2 Device Recall LINX Reflux Management System. May 31, 2018. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=163589. Accessed October 11, 2021.
2. U.S. Food & Drug Administration (FDA). Premarket Approval: Linx Reflux Management System [P100049/S021]. March 15, 2018; accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100049S021. Accessed October 12, 2021.
3. Kothari BL, Borgert AJ, Kallies KJ, et al. Lack of Correlation Between Subjective and Objective Measures of Gastroesophageal Reflux Disease: Call for a Novel Validated Assessment Tool. Surg Innov. Jun 2021; 28(3): 290-294. PMID 32867603
4. Guidozzi N, Wiggins T, Ahmed AR, et al. Laparoscopic magnetic sphincter augmentation versus fundoplication for gastroesophageal reflux disease: systematic review and pooled analysis. Dis Esophagus. Nov 13 2019; 32(9). PMID 31069388
5. Aiolfi A, Asti E, Bernardi D, et al. Early results of magnetic sphincter augmentation versus fundoplication for gastroesophageal reflux disease: Systematic review and meta-analysis. Int J Surg. Apr 2018; 52: 82-88. PMID 29471155
6. Bell R, Lipham J, Louie BE, et al. Magnetic Sphincter Augmentation Superior to Proton Pump Inhibitors for Regurgitation in a 1-Year Randomized Trial. Clin Gastroenterol Hepatol. Jul 2020; 18(8): 1736-1743.e2. PMID 31518717
7. Bell R, Lipham J, Louie B, et al. Laparoscopic magnetic sphincter augmentation versus double-dose proton pump inhibitors for management of moderate-to-severe regurgitation in GERD: a randomized controlled trial. Gastrointest Endosc. Jan 2019; 89(1): 14-22.e1. PMID 30031018
8. Bonavina L, Horbach T, Schoppmann SF, et al. Three-year clinical experience with magnetic sphincter augmentation and laparoscopic fundoplication. Surg Endosc. Jul 2021; 35(7): 3449-3458. PMID 32676727
9. U.S. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED): LINX Reflux Management System (P100049). 2012; https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100049B.pdf. Accessed October 10, 2021.
10. Reynolds JL, Zehetner J, Bildzukewicz N, et al. Magnetic sphincter augmentation with the LINX device for gastroesophageal reflux disease after U.S. Food and Drug Administration approval. Am Surg. Oct 2014; 80(10): 1034-8. PMID 25264655
11. Warren HF, Louie BE, Farivar AS, et al. Manometric Changes to the Lower Esophageal Sphincter After Magnetic Sphincter Augmentation in Patients With Chronic Gastroesophageal Reflux Disease. Ann Surg. Jul 2017; 266(1): 99-104. PMID 27464617
12. Ganz RA, Peters JH, Horgan S, et al. Esophageal sphincter device for gastroesophageal reflux disease. N Engl J Med. Feb 21 2013; 368(8): 719-27. PMID 23425164
13. Ganz RA, Edmundowicz SA, Taiganides PA, et al. Long-term Outcomes of Patients Receiving a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux. Clin Gastroenterol Hepatol. May 2016; 14(5): 671-7. PMID 26044316
14. Louie BE, Smith CD, Smith CC, et al. Objective Evidence of Reflux Control After Magnetic Sphincter Augmentation: One Year Results From a Post Approval Study. Ann Surg. Aug 2019; 270(2): 302-308. PMID 29697454
15. Alicuben ET, Bell RCW, Jobe BA, et al. Worldwide Experience with Erosion of the Magnetic Sphincter Augmentation Device. J Gastrointest Surg. Aug 2018; 22(8): 1442-1447. PMID 29667094
16. Ayazi S, Zheng P, Zaidi AH, et al. Magnetic Sphincter Augmentation and Postoperative Dysphagia: Characterization, Clinical Risk Factors, and Management. J Gastrointest Surg. Jan 2020; 24(1): 39-49. PMID 31388888

17. Smith CD, DeVault KR, Buchanan M. Introduction of mechanical sphincter augmentation for gastroesophageal reflux disease into practice: early clinical outcomes and keys to successful adoption. J Am Coll Surg. Apr 2014; 218(4): 776-81. PMID 24529809
18. Rona KA, Reynolds J, Schwameis K, et al. Efficacy of magnetic sphincter augmentation in patients with large hiatal hernias. Surg Endosc. May 2017; 31(5): 2096-2102. PMID 27553803
19. Ferrari D, Asti E, Lazzari V, et al. Six to 12-year outcomes of magnetic sphincter augmentation for gastroesophageal reflux disease. Sci Rep. Aug 13 2020; 10(1): 13753. PMID 32792508
20. Ayazi S, Zheng P, Zaidi AH, et al. Clinical Outcomes and Predictors of Favorable Result after Laparoscopic Magnetic Sphincter Augmentation: Single-Institution Experience with More than 500 Patients. J Am Coll Surg. May 2020; 230(5): 733-743. PMID 32081749
21. Dunn CP, Zhao J, Wang JC, et al. Magnetic sphincter augmentation with hiatal hernia repair: long term outcomes. Surg Endosc. Oct 2021; 35(10): 5607-5612. PMID 33029733
22. DeMarchi J, Schwiers M, Soberman M, et al. Evolution of a novel technology for gastroesophageal reflux disease: a safety perspective of magnetic sphincter augmentation. Dis Esophagus. Nov 11 2021; 34(11). PMID 34117494
23. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Technology and Value Assessment Committee (TAVAC) Safety and Effectiveness Analysis: LINX Reflux Management System. 2017; https://www.sages.org/publications/tavac/tavac-safety-and-effectiveness-analysis-linx-reflux-management-system/. Accessed October 12, 2021.
24. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Guidelines for the Surgical Treatment of Gastroesophageal Reflux (GERD). April 2021; http://www.sages.org/publications/guidelines/guidelines-for-the-surgical-treatment-of-gastroesophageal-reflux-gerd/. Accessed October 11, 2021.
25. National Institute for Health and Care Excellence (NICE). Laparoscopic insertion of a magnetic titanium ring for gastro-esophageal reflux disease [IPG585]. July 26, 2017; https://www.nice.org.uk/guidance/ipg585/. Accessed October 12, 2021.
26. American Foregut Society (AFS). American Foregut Surgery Statement on Appropriate Patient Selection and Use of Magnetic Sphincter Augmentation (LINX). n.d.; https://www.americanforegutsociety.org/wp-content/uploads/sites/21/2021/04/AFS-LINX-Final.pdf. Accessed October 12, 2021.
27. Khaitan L, Abu Dayyeh BK, Lipham J, et al. American Foregut Society (AFS) Committee Statement on Combined Magnetic Sphincter Augmentation and Bariatric Surgery. n.d.; https://www.americanforegutsociety.org/wp-content/uploads/sites/21/2021/04/AFS_MSA_Bariatric_Surgery_Final-1.pdf. Accessed October 10, 2021.
28. Gottlieb KT, Banerjee S, Barth BA, et al. Magnets in the GI tract. Gastrointest Endosc. Oct 2013; 78(4): 561-7. PMID 24054738
29. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 7.01.137 (November 2021).

Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may

include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed
	43285	Removal of esophageal sphincter augmentation device
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
06/28/2013	BCBSA Medical Policy adoption
10/31/2014	Policy revision without position change
01/30/2015	Coding update
12/01/2016	Policy title change from Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD). Policy revision without position change.
10/01/2017	Policy revision without position change
01/01/2018	Policy revision without position change
12/01/2018	Policy revision without position change
01/01/2019	Policy revision without position change
02/01/2020	Annual review. No change to policy statement. Literature review updated.
02/01/2021	Annual review. No change to policy statement. Literature review updated.
01/01/2022	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease 7.01.137 **Policy Statement:** Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease (GERD) is considered **investigational**.	**Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease 7.01.137** **Policy Statement:** Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease (GERD) is considered **investigational**.