Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease (GERD)

Description/Background

GASTROESOPHAGEAL REFLUX DISEASE

Gastroesophageal reflux disease (GERD) is defined as reflux of stomach acid into the esophagus that causes symptoms and/or mucosal injury. GERD is a common medical disorder, with estimates of 10% to 20% prevalence in developed countries. The severity of GERD varies widely. Many patients have mild, intermittent symptoms that do not require treatment or only require episodic use of medications. Other patients have chronic, severe GERD that can lead to complications such as Barrett esophagus and esophageal cancer.

Treatment

For patients with severe disease, chronic treatment with acid blockers is one option. For some patients, medications are not adequate to control symptoms; other patients prefer to avoid the use of indefinite, possibly lifelong medications. Surgical treatments are available for these patients, primarily a Nissen fundoplication performed either laparoscopically or by open surgery. A number of less invasive procedures are also being evaluated as an intermediate option between medical therapy and surgery.

The LINX™ Reflux Management System (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 is needed for another condition.

Regulatory Status:

The LINX™ Reflux Management System (Torax Medical, Shoreview, MN) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P100049) for patients diagnosed with GERD, as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximum therapy for the treatment of reflux. The FDA initially required 5-year follow-up of 100 patients from the investigational device exemption (IDE) pivotal study to evaluate 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. Device recall was lifted November 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.]

Medical Policy Statement

Magnetic esophageal sphincter insertion for the treatment of gastroesophageal reflux (GERD) is experimental/investigational. The use of this device has not been scientifically shown to improve patient clinical outcomes.

Removal of an implanted magnetic esophageal sphincter device may be considered established for patients who experience side effects or complications of the device of such severity as to disrupt the patient’s normal quality of life.

Inclusionary and Exclusionary Guidelines

Inclusions-for the removal of the magnetic esophageal sphincter device only:

Must have documentation in the medical record of complications of the implanted device, including, but not limited to:

- Ring erosion
- Ring migration

- Infection
- Severe dysphagia

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

**43285

***May be considered established only if done for medical complications.*

Other codes (investigational, not medically necessary, etc.):

43284

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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. RCTs 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 in individuals who have GERD is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICOs** were used to select literature to inform this review.

Populations
The relevant population of interest are individuals with GERD.

The severity of GERD varies widely. Many individuals have mild, intermittent symptoms that do not require treatment or only require episodic use of medications. Other individuals 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 magnetic sphincter augmentation (MSA).

MSA is a 30-minute surgical procedure performed under general anesthesia that includes testing of the esophageal sphincter. MSA is a minimally invasive procedure conducted in an inpatient surgical center and requires an overnight stay. The device manufacturer claims individuals resume a normal diet within 24 hours post-surgery.

Comparators
The following therapies and practices are currently being used to treat GERD: lifestyle modifications, continued medical therapy (e.g., proton pump inhibitors) 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. A number of less invasive procedures are also being evaluated as an intermediate option between medical therapy and surgery (see review 2.01.38 on endoscopic procedures).

In individuals 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

The general outcomes of interest are reduction in symptoms and medication use, quality of life (QOL), treatment related adverse events, device failure 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

- To assess efficacy outcomes, we sought comparative controlled prospective trials, with a preference for RCTs and systematic reviews of these studies.
- In the absence of such trials, we sought comparative observational studies, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, we also sought single-arm studies that captured longer periods of follow-up and/or larger populations.

Systematic Reviews

Four recent systematic reviews compared MSA to laparoscopic Nissen fundoplication (LNF) in patients with GERD (Table 1).[4-7] Three conducted meta-analyses and concluded that MSA and LNF had similar effects on symptoms and QOL and one meta-analysis found superior reductions in need for a PPI, GERD-HRQL, and post-operative dysphagia (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 MSA compared to LNF

Study	Dates	Trials	Participants[1]	N (Range)	Design	Duration
Rausa et al (2023)	Inception to 2022	33	Patients with GERD	LTF, n=1120; LNF,n=1740; APF,n=322; MSA,n=50; Stretta,n=50; TIF, n=188;PPI, n=819;Sham, n=63	RCTs	NR
Zhuang et al (2021)	Inception to 2020	14 1 RCT, 3 cohort studies, and 10 single-arm	Patients with GERD	1138 (32 to 214)	RCTs,comparative observational studies, and single-arm studies	Range, 6 to 60 months
Guidozzi et	1987-	6 comparative	Patients with	Comparative	Comparative	Range 6-44

al (2019)	2013	observational 13 single-arm cohort	GERD	observational studies: 1099 (24-415)	observational	months
Aiolfi et al (2018)	2000-2015	6	Patients with GERD	2561 (23-335)	Comparative observational (1 prospective, 5 retrospective cohort)	Up to 1 year

MSA: magnetic sphincter augmentation; LNF laparoscopic Nissen fundoplication; GERD: gastroesophageal reflux disease.

Table 2. Results of Systematic Reviews of MSA Compared to LNF

Study	Need for PPI	GERD-HRQL	Dysphagia	Reoperation
Rausa et al (2023)		Bloating		
Total N	MSA, n=50 (comparisons toLNF referent group n=1740)	MSA, n=50 (comparisons toLNF referent group n=1740)	MSA, n=50 (comparisons toLNF referent group n=1740)	
Pooled effect (95% CI)	Value not reported, butauthors state LTF, LNF,APF, MSA, RFA and TIFhad similar rates of post-operative PPI discontinuation.	RR, 2.3 (0.7 to 6.9); p=NS	RR, 1.7 (0.66 to 4.5); p=NS	
I^2(p)	NR	NR	NR	
Zhuang et al (2021)	At 1 year post-operation	≥50% reduction in GERD-HRQL at 1 year post-operation	Post-operative dysphagia	
Total N	6 studies (NR)	6 studies (NR)	6 studies (NR)	
Pooled effect (95% CI)	OR: 0.15 (0.11 to 0.21),favoring MSA	OR: 0.15 (0.11 to 0.21),favoring MSA	OR: 0.15 (0.11 to 0.21),favoring MSA	
I^2(p)	43%	43%	43%	
Guidozzi et al (2019)				
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=0.877	WMD 0.34 (-0.70 to 1.37); P=0.525	OR 0.94 (0.57 to 1.55); P=0.822	OR 1.23 (0.26 to 5.8); P=0.797
I^2 (p)	72% (0.007)	70.6% (0.033)	20.4% (0.288)	48.5% (0.12)
Aiolfi et al (2018)	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=0.548	MD -0.48 (-1.05 to 0.09); P=0.101	OR 1.56 (0.61 to 3.95); P=0.119	OR 0.54 (0.22 to 1.34); P=0.183
I^2 (p)	63.9% (0.016)	0% (0.82)	35% (0.19)	0% (0.814)

MSA: magnetic sphincter augmentation; LNF laparoscopic Nissen fundoplication; PPI: proton pump inhibitor; GERD-HRQL: gastroesophageal reflux disease health-related quality of life scale; N: sample size; CI: confidence interval; OR: odds ratio; WMD: weighted mean difference; MD: mean difference.

Randomized Controlled Trial

There are no RCTs of MSA compared to LNF. There is one 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). At six 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 six 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.[8]

Relevance and study design and conduct limitations of the RCT conducted by Bell et al (2019) are shown in Tables 5 and 6. Limitations included the use of subjective outcome measures along with an open-label design. At baseline, more patients in the MSA group had grade B esophagitis (18.4% vs. 10.0), and more had a hiatal hernia (58% vs. 49%). There were more withdrawals in the PPI group (12.9% vs. 0). It is unclear whether twice-daily omeprazole 20mg is an appropriate comparator. Although an increased dose is sometimes recommended, 20 mg twice daily is not a FDA-approved dose for patients with GERD.

Table 3. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
Bell et al (2020)	U.S.	21	2015-2017	152 patients with moderate to Severe regurgitation symptoms while on once-daily PPIs and actively seeking alternative, surgical treatment for regurgitation symptoms Median age: 46 Sex: Male, 58% Race: White, 88%;Hispanic, 5%; Black,3%; Asian, 3%;Other, 1%. Mean length of PPIuse: 8.4 years	Laparoscopic MSA (N=50)	Omeprazole 20 mg twice daily (N=102)

RCT: randomized controlled trial; MSA magnetic sphincter augmentation; PPI: proton pump inhibitor.

Table 4. Summary of Key RCT Results

Study	Symptoms	Quality of Life		PPI Discontinuation	Impedance-pH Testing				Withdrawals
Bell et al (2020)									
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

RCT: randomized controlled trial; N: sample size; FSQ: Foregut Symptom Questionnaire; GERD-HRQL: gastroesophageal reflux disease health-related quality of life scale; NR: not reported; PPI: proton pump inhibitor.

Table 5. Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Bell et al (2020)	3. Patients did not receive optimal medical therapy prior to study enrollment. 4. Enrolled populations do not reflect relevant diversity.		2. Did not compare the intervention to Nissen fundoplication		

BID: twice daily; GERD: gastroesophageal reflux disease.
[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	Data	Power[e]	Statistical[f]

			Reporting[c]	Completeness[d]		
Bell et al (2020)	1.Differences Between groups at baseline	1.Not blinded		1. Differential loss to follow-up (12.9% in PPI group vs. 0 in MSA group)		4. CIs for treatment effects not calculated

CI: confidence interval; MSA: magnetic sphincter augmentation; PPI: proton pump inhibitor.
[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.[10,] 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.

Asti et al (2023) published data from an observational, retrospective cohort study comparing MSA and laparoscopic Toupe fundoplication (LTF) in patients with refractory GERD at a single tertiary-care center in Italy.[11] Patients underwent laparoscopic anti-reflux surgery for GERD and/or large hiatal hernias from January 2014 to December 2021 in 199 patients [130 MSA; 69 toupet fundoplication). All patients included had persistent GERD symptoms despite PPI therapy for at least 6 months with abnormal acid exposure at the time of esophageal pH monitoring and initial hernia < 3cm. Patients with previous esophageal or gastric surgeries were excluded. Both groups had a median follow-up time of 12 months. The morbidity rate in the MSA group was 0.8% and 2.9% after LTF, with no post-operative deaths in either group. A

significant decrease in GERD-HRQL score was noted in both patient groups (p<.001), but when adjusted for age, sex, and baseline GERD scores no significant differences in the change from baseline were observed between groups (-12.39 in LTF vs. -15.47 in MSA, p=.73). Patients in the MSA group had a greater incidence of grade > 2 dysphagia (35.5%) compared to the LTF group (7.7%; p=.0009). No significant differences were observed in the rate of severe or persistent bloating between groups (12.9% LTF vs. 35.9% in MSA; p=.7604) or continued PPI therapy (21.9% LTF vs. 18.7% in MSA; p=.6896). Limitations of the study include lack of randomization and blinding and imbalance of baseline patient characteristics including GERD-HREQL score, duration of PPI therapy, hernia size, gender and age. It is unclear to what extent study results are generalizable to U.S. populations and broader care settings.

Callahan et al (2023) published a retrospective review of a prospective database evaluating patients who underwent LNF, MSA, or anti-reflux mucosectomy (ARMs).[12] 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, 46MSA, and 40 ARMs procedures. These groups were imbalanced on several baseline characteristics including age, 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<.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 Toupet 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 2year follow-up, but at 5 years MSA patients had worse GERD-HRQL scores compared to the Toupet fundoplication group (17.8vs 4.9; p=.024). All groups had similar scores at all time points follow-up for gas bloating and dysphagia symptoms. Limitations of the study include lack of randomization and blinding, imbalance of baseline patient characteristics, and changes in secular trends over the study period which resulted in predominantly younger patients with normal manometry receiving LNF.

O'Neil et al (2023) published a retrospective cohort study of patients undergoing MSA (n=25) compared to LNF (n=45) for the management of symptomatic GERD from a single center from 2013 to 2015 with the intent of comparing long-term follow-up outcomes at 5 years.[13]
At baseline, patients were imbalanced on gender, with LNF having more females, BMI with LNF patients being more overweight, and baseline GERD-HRQL scores with LNF having worse symptoms. In the short term, both groups experienced improvements in GERD-HRQL and gastroesophageal reflux symptom scale (GERSS) scores and reductions in PPI usage from baseline levels, but no significant between-group differences were observed. The median long-term follow-up was 65 months for LNF (range 51 to 85 months) and 68 months for MSA (range 57 to 87 months); 5 patients in the MSA group and 4 patients in the LNF group did not have long-term outcomes reported. At the last available follow-up, between-group comparisons of outcomes were equivalent for all reported outcomes. Patients in the MSA group had a rate of PPI use of 40% compared to 33% in the LNF group (p=.62). Median GERD-HRQL scores were 9 (interquartile range [IQR], 4-14) in the MSA group and 7.5(IQR, 2.5-14; p=.068) in the LNF group; median overall GERSS scores also did not vary significantly (10 vs 11; p=.89). Rates of revision were 20% in the MSA group and 7% in the LNF group (p=.32). A within-group

longitudinal comparison of pre-operative, to post-operative, and long-term follow-up values showed both groups had significant reductions in PPI usage, improvements in GERD-HRQL and GERSS overall scores (p<.01). Limitations of the study include lack of randomization and blinding as well as an imbalance of baseline patient characteristics.

Single-Arm Studies

Data submitted to the 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 2 and 4 years[14] 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.[15,16] 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.[17] 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-Health Related Quality of LIFE (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 in 2016.[18] Eighty-five patients had follow up at five years. Of those 85, 83% achieved had a 50% reduction in GERD-HRQL (95% CI 73% to 91%) and 89.4% had a reduction in 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 seven patients.

Louie et al (2019) published 1-year outcomes from a 5-year FDA-mandated multicenter post-approval study.[19] 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. [20] 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.[21] 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 been reported on outcomes after MSA in sample sizes ranging from 30 to 500,[22-31] some of which have focused on specific subpopulations of individuals with GERD, such as those with large hiatal hernias (e.g., Rona et al, 2017 and Dunn et al, 2021). Other studies have highlighted independent predictors of favorable outcomes,[24,25] 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.[34] 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.

Fletcher et al (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.[35,] A second dilation was performed in 67 patients, a third dilation was performed in 22 patients, and 4 or more dilations were performed in an additional 7 patients. Overall, dysphagia prompting dilation after MSA implantation was associated with nearly a 12% risk of device explantation (17 devices).

SUMMARY OF EVIDENCE

For individuals who have GERD who receive MSA, the evidence includes one RCT comparing MSA to PPI therapy, four nonrandomized registry studies comparing MSA to laparoscopic fundoplication, comparative observational studies of MSA vs. LNF, single-arm cohort studies, and systematic reviews of comparing MSA to LNF. The relevant outcomes include symptoms, change in disease status, medication use, and treatment-related morbidity. An 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. 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.

Ongoing and Unpublished Clinical Trials

Some currently 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			
NCT01940185[a]	A post-approval study of the Lynx® reflux management system	200	Oct 2025
NCT05238636	The Effect of Anti-reflux Procedures (Stretta, LINX, and Fundoplication) on Physiological Parameters Contributing to Symptom Resolution in Adults With Gastro-oesophageal Reflux at a Single UK Tertiary Centre (GASP)	60	Jan 2024 (recruiting)
NCT04695171	Cohort Registry on LINX Reflux Management System or Fundoplication Clinical Study in Patients With Hiatal Hernia >3 cm	450	Jan 2028
NCT02923362	A post-approval study of the LINX® Reflux Management System	2500	May 2025
NCT04253392[a]	RETHINK REFLUX Registry	500	Jul 2032
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

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

Multi-society Consensus Conference

A multi-society consensus guideline on the treatment of GERD was issued by the 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) in 2023.[40] Based on a review of the available evidence the consensus panel determined the following recommendations:

- The panel suggests that adult patients with GERD may be treated with either MSA or Nissen fundoplication based on surgeon and patient shared decision-making. (Conditional recommendation based on very low certainty of evidence)
- The panel suggests that adult patients with GERD may benefit from MSA over continued PPI use. (Conditional recommendation based on moderate certainty of evidence)

National Institute for Health and Care Excellence

In 2023, the NICE issued an interventional procedure guidance on laparoscopic insertion of a magnetic ring for GERD.[41] The following recommendations were based on a comprehensive literature search and review:

- "Evidence on the safety and efficacy of laparoscopic insertion of a magnetic ring for GERD is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent, and audit."
- "Patient selection and the procedure should be done by clinicians who have specific training in the procedure and experience in upper gastrointestinal laparoscopic surgery and managing GERD."

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:[37]

- "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,[31] 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 January 2022, the American College of Gastroenterology (ACG) published a clinical guideline on the diagnosis and management of GERD.[36] 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 anti-reflux surgery or TIF [transoral incisionless fundoplication] (conditional recommendation; low level of evidence).
- We recommend anti-reflux 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."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Government Regulations
National/Local:

No national or local coverage decisions were identified for the LINX® Reflux Management System.

Codes 43284 &43285 are assigned a fee schedule according to CMS.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Transesophageal Endoscopic Therapies for GERD

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/13	8/20/13	9/10/13	Joint policy established
1/1/15	10/21/14	11/3/14	Routine review of non-established service. References added. No change in policy status.
7/1/15	4/24/15	5/8/15	Code update. No change in policy status. Added information regarding removal of the device for medical reasons.
7/1/16	4/19/16	4/19/16	Routine maintenance
5/1/17	2/21/17	2/21/17	Deleted 0392T and 0393T, added 43284 and 43285 effective 1/1/17. Updated rationale and references (1,2,11,12,15-18).
5/1/18	2/20/18	2/20/18	Routine policy maintenance. No change in policy status.
5/1/19	2/19/19		Routine policy maintenance. No change in policy status.
5/1/20	2/18/20		Routine policy maintenance. Updated rationale, added references #21-23. No change in policy status.
11/1/20	8/18/20		Routine policy maintenance. No change in policy status.
11/1/21	8/17/21		Routine policy maintenance. No change in policy status.
11/1/22	8/16/22		Rationale section updated, references 3, 8, 16, 20-22, 25-26, added. No change in policy status.
11/1/23	8/15/23		Rationale updated, added references 22,23,25 and 33. No change in policy status. Vendor managed: N/A. (ds)
11/1/24	8/20/24		Updated rationale, added references 6, 7, 11-13. No change in policy status. Vendor managed: N/A (ds)

Next Review Date: 3rd Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: MAGNETIC ESOPHAGEAL SPHINCTER AUGMENTATION TO TREAT GASTROESOPHAGEAL REFLUX DISEASE (GERD)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Insertion of magnetic esophageal sphincter is not covered. Removal of magnetic esophageal sphincter is covered with prior authorization documenting complications related to the implanted ring.
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.