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Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD)

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Related Policies (if applicable)
MED201.016: Device Therapies for Gastroesophageal Reflux Disease (GERD)

Disclaimer

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Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

A laparoscopically implantable magnetic esophageal ring (LINX® Reflux Management System) **is considered medically necessary** as a treatment alternative to surgical fundoplication, when the individual has chronic gastroesophageal reflux disease (GERD) symptoms (reflux symptoms that occur two or more times per week) AND symptoms are refractory to maximum medical therapy.

The safety and effectiveness of a laparoscopically implantable magnetic esophageal ring (LINX® Reflux Management System) has not been established and/or is contraindicated and therefore **considered experimental, investigational and/or unproven** for individuals with any other indication including, but not limited to, the following conditions:

1. Suspected or known allergies to metals such as iron, nickel, titanium, or stainless steel,
2. Barrett's esophagus or Grade C or D (Los Angeles [LA] classification) esophagitis,
3. Scleroderma,

4. Suspected or confirmed esophageal or gastric cancer,
5. Prior esophageal or gastric surgery or endoscopic intervention,
6. Distal esophageal motility less than 35 mmHg peristaltic amplitude on wet swallows or <70% (propulsive) peristaltic sequences or a known motility disorder (e.g., achalasia, nutcracker esophagus, and diffuse esophageal spasm or hypertensive lower esophageal sphincter [LES]),
7. Symptoms of dysphagia more than once per week within the last 3 months,
8. Esophageal stricture or gross esophageal anatomic abnormalities (Schatzki's ring, obstructive lesions, etc.),
9. Esophageal or gastric varices,
10. Lactating, pregnant or plan to become pregnant,
11. Morbid obesity (body mass index [BMI] >35), or
12. Age <21.

Removal of an esophageal sphincter augmentation device **may be considered medically necessary** when all the following criteria are met:

- Individual met all the criteria for initial placement of the device, AND
- There are complications such as erosion, device migration, or difficulty swallowing.

Policy Guidelines

None.

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.

Gastroesophageal Reflux Disease
Gastroesophageal reflux disease 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.

Regulatory Status
In 2012, the LINX® Reflux Management System (Ethicon; formerly 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 (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. (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

This medical policy has been updated regularly with searches of the PubMed database. The most recent literature update was performed through September 13, 2023.

Medical policies 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, two domains are examined: the relevance, and 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 (MSA) in individuals who have gastroesophageal reflux disease (GERD) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

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 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 two 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 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. 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 individuals resume a normal diet within 24 hours post-surgery. 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 individuals with severe disease, chronic treatment with acid suppressive therapies is an option. For some individuals, medications are inadequate to control symptoms; other individuals prefer to avoid the use of indefinite, possibly lifelong medications. Surgical treatments are available for these individuals, 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 MED201.016.

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
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 Gastroesophageal Reflux Disease-Health-Related Quality of Life (GERD-HRQL), a scale with 11 items focusing on heartburn symptoms, dysphagia, medication effects, and the individual'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 four subscales: daily activity, treatment effect, diet, and psychological well-being. The total score of this questionnaire is the average of the four subscale scores. The final score can range from 0 to 100, with a higher score indicating a better QOL.

<u>Study Selection Criteria</u>
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.

Systematic Reviews

Four systematic reviews compared MSA to laparoscopic Nissen fundoplication (LNF) in patients with GERD (Table 1). (4-7) Three meta-analyses 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).

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

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Rausa et al. (2023) (7)	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) (6)	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 al. (2019) (4)	1987-2013	6 comparative observational 13 single-arm cohort	Patients with GERD	Comparative observational studies: 1099 (24-415)	Comparative observational	Range 6-44 months
Aiolfi et al. (2018) (5)	2000-2015	6	Patients with GERD	2561 (23-335)	Comparative observational (1 prospective, 5 retrospective cohort)	Up to 1 year

APF: anterior partial fundoplication; GERD: gastroesophageal reflux disease; LTF, laparoscopic Toupet fundoplication; LNF: laparoscopic Nissen fundoplication; MSA: magnetic sphincter augmentation; NR: not reported; PPI: proton pump inhibitor; RCT: randomized controlled trial; RFA: radiofrequency ablation; TIF: transoral incisionless fundoplication.

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
Rausa et al. (2023) (7)		Bloating		
Total N	MSA, n=50 (comparisons to LNF referent group n=1740)	MSA, n=50 (comparisons to LNF referent group n=1740)	MSA, n=50 (comparisons to LNF referent group n=1740)	
Pooled effect (95% CI)	Value not reported, but authors state LTF, LNF, APF, MSA, RFA and TIF had 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) (6)	At 1-year post-operation	≥50% reduction in GERD-HRQL at 1-year post-operation	Post-operative dysphagia	
Total N	6 studies (NR)	4 studies (395)	5 studies (543)	
Pooled effect (95% CI)	OR: 0.15 (0.11 to 0.21), favoring MSA	RD: 0.88 (0.84 to 0.92), favoring MSA	RD: 0.29 (0.13 to 0.46), favoring MSA	
I^2 (p)	43%	40%	96%	
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=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) (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=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)

APF: anterior partial fundoplication; LTF: laparoscopic Toupet fundoplication; LNF: laparoscopic Nissen fundoplication; MSA: magnetic sphincter augmentation; NR: not reported; 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; RFA: radiofrequency ablation; TIF: transoral incisionless fundoplication.

Randomized Controlled Trials

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. (8)

Table 3. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
Bell et al. (2020) (9) 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)

				Median age: 46 Sex: Male, 58% Race: White, 88%; Hispanic, 5%; Black, 3%; Asian, 3%; Other, 1%. Mean length of PPI use: 8.4 years		

MSA: magnetic sphincter augmentation; PPI: proton pump inhibitor; NCT: National Clinical Trial Identifier.

Table 4a. Summary of Key RCT Results

Study	Symptoms	Quality of Life		PPI Discontinuation
Bell et al. (2020) (8, 9) NCT02505945				
N	134	134	134	
	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*	
MSA	42/47 (89%)	18	38/47 (81%)	43/47 (91%)
Omeprazole	10/101 (10%)	1	7/87 (8%)	NR
P value for difference	<.001	<.002	<.001	

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

Table 4b. Summary of Key RCT Results

Study	Impedance-pH Testing				Withdrawals
Bell et al. (2020) (8, 9) NCT02505945					
N	123	123	123	123	148
	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	22.5 (IQR, 13.0 to 40.5)	2%	40/44 (91%)	39/44 (89%)	0/47 (0%)

Omeprazole	49.0 (IQR 31.0 to 76.78)	5%	46/79 (58%)	59/79 (75%)	13/101 (12.9%)
P value for difference	<.001	.065	<.001	.065	NR

IQR: interquartile range; MSA: magnetic sphincter augmentation; NR: not reported; PPI: proton pump inhibitor.

The relevance and study design and conduct limitations of the RCT conducted by Bell et al. (2020) are shown in Tables 5 and 6.

Table 5. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Bell et al. (2020) NCT02505945 (9)	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		

NCT: National Clinical Trial Identifier.
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. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[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. (2020) (9) NCT02505945	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; NCT: National Clinical Trial Identifier; 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 and 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%).

Asti et al. (2023) published data from an observational, retrospective cohort study comparing MSA and laparoscopic Toupet 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).

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, 46 MSA, 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 2-year follow-up, but at 5 years MSA patients had worse GERD-HRQL scores compared to the Toupet fundoplication group (17.8 vs 4.9; p=.024). All groups had similar scores at all time points follow-up for gas bloating and dysphagia symptoms.

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 to 14) in the MSA group and 7.5 (IQR, 2.5 to 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).

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. (14) The feasibility IDE trial enrolled 44 subjects at 4 clinical sites (2 U.S., 2 Europe) and had published data out to 4 years. (15, 16) 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 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. 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). (18) 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. (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 reported on outcomes after MSA in sample sizes ranging from 30 to 500 patients, (15, 16, 22-31) some of which 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]) or with prior bariatric and anti-reflux surgery (Leeds et al. [2021]). (23, 26, 32, 33) Other studies have highlighted independent predictors of favorable outcomes, (24, 25) such as age of intervention <40 to 45 years, male sex, abnormal DeMeester scores, and baseline GERD-HRQL scores >15.

The FDA Manufacturer and User Facility Device Experience (MAUDE) reports and manufacturer complaint databases were analyzed from 2013-2020 by DeMarchi and colleagues (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 gastroesophageal reflux disease (GERD) who receive magnetic sphincter augmentation (MSA), the evidence includes one randomized controlled (RCT) trial comparing MSA to proton pump inhibitor (PPI) therapy, four nonrandomized studies comparing

MSA to laparoscopic Nissen fundoplication (LNF), laparoscopic Toupet fundoplication (LTF), or anti-reflex mucosectomy (ARM), single-arm cohort studies, and systematic reviews comparing MSA to LNF. Relevant outcomes are 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 quality of life (QOL) at 6 months. Four non-randomized comparative studies of MSA to laparoscopic fundoplication showed mixed outcomes, with some studies indicating similar improvements in QOL, satisfaction, and PPI use. In the 2 single-arm, uncontrolled pivotal trials submitted to the U.S. Food and Drug Administration (FDA) with materials for device approval, subjects showed improvements in GERD-HRQL scores and reduced PPI use. Similarly, observational comparative studies included in systematic reviews, most often comparing MSA with LNF, generally have shown that GERD-HRQL scores do not differ significantly between fundoplication and MSA, and patients can reduce PPI use after MSA. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

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 antireflux 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."

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, (38) 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 Gastroenterological Association

The American Gastroenterological Association (AGA) issued a statement on the personalized approach to evaluating and managing individuals with GERD in 2022. (39) The authors provided a best practice recommendation: "In patients with proven GERD, laparoscopic fundoplication and magnetic sphincter augmentation are effective surgical options, and transoral incisionless fundoplication is an effective endoscopic option in carefully selected patients."

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. (40) The SAGES indicated that "review of published studies suggests that magnetic sphincter augmentation is safe with no reported deaths and a 0.1% rate of intra/perioperative complications. Long-term efficacy of LINX appears good for typical GERD symptoms with reduced acid exposure, improved GERD symptoms, and freedom from PPI in 85-88% at 3-5 years."

Multi-society Consensus Conference

A multi-society consensus guideline on the treatment of GERD was issued by the Society of American Gastrointestinal and Endoscopic Surgeons (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. (41) 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. (42) 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."

Ongoing and Unpublished Clinical Trials

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

Table 7. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
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)
NCT02923362	Registry of Outcomes From AntiReflux Surgery (ROARS)	2500	May 2025
NCT04695171	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
Unpublished			
NCT01940185[a]	A Post-Approval Study of the Lynx® Reflux Management System	200	Jun 2023

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	43284, 43285
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
10/15/2024	Document updated with literature review. Coverage unchanged. References added: 6, 7, 11-13, 28-31, 33, 35, 39, and 41; others updated/revised.
09/15/2023	Document updated with literature review. The following change was made to Coverage: Removed “Hiatal hernias greater than 3 cm in size” from experimental, investigational and/or unproven list. Added references 22, 23, 28, and 32.
06/15/2022	Document updated with literature review. Coverage unchanged. The following references were added: 1-3, 7, 8, 14-16, 19-22, and 24-27; others removed.
09/15/2021	Reviewed. No changes.
01/01/2021	Document updated with literature review. Coverage unchanged. Added references 1, 2, and 21.
04/01/2019	Reviewed. No changes.
05/01/2018	Document updated with literature review. Coverage unchanged. References 1-2, 11-12 and 15-19.
12/01/2017	Reviewed. No changes.
06/01/2017	Document updated with literature review. The following statement was added to the coverage section of the medical policy: Removal of an esophageal sphincter augmentation device may be considered medically necessary when all the following criteria are met: 1) Patient met all the criteria for initial placement of the device, AND 2) Complications such as erosion, device migration, or difficulty swallowing.
04/01/2016	New medical document originating from a topic previously addressed on medical policy MED201.016. Coverage has changed to the following: 1) A laparoscopically implantable magnetic esophageal ring (LINX™ Reflux

	Management System) is considered medically necessary as a treatment alternative to laparoscopic Nissen fundoplication when the patient has chronic gastroesophageal reflux disease (GERD) symptoms refractory to maximum medical therapy, 2) The safety and effectiveness of a laparoscopically implantable magnetic esophageal ring (LINX™ Reflux Management System) has not been established and/or is contraindicated and therefore considered experimental, investigational and/or unproven for patients with the following conditions: Suspected or known allergies to metals such as iron, nickel, titanium, or stainless steel; Hiatal hernias greater than 3 cm in size; Barrett's esophagus or Grade C or D (LA classification) esophagitis; Scleroderma; Suspected or confirmed esophageal or gastric cancer; Prior esophageal or gastric surgery or endoscopic intervention; Distal esophageal motility less than 35 mmHg peristaltic amplitude on wet swallows or <70% (propulsive) peristaltic sequences or a known motility disorder (e g. Achalasia, Nutcracker Esophagus, and Diffuse Esophageal Spasm or Hypertensive LES); Symptoms of dysphagia more than once per week within the last 3 months; Esophageal stricture or gross esophageal anatomic abnormalities (Schatzki's ring, obstructive lesions, etc.); Esophageal or gastric varices; Lactating, pregnant or plan to become pregnant; Morbid obesity (BMI >35), or Age <21.