Gastroesophageal Reflux: Magnetic Esophageal Ring

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SCOPE: Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☒ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

I. An implantable magnetic esophageal ring (e.g., LINX® Reflux Management System) is considered **not medically necessary** as a treatment of gastroesophageal reflux (GERD).

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

The LINX® Reflux Management System is intended to treat chronic gastroesophageal reflux disease (GERD). The device is composed of a series of titanium beads with magnetic cores connected by wires that are implanted around the outside of the esophagus at the lower esophageal sphincter(LES) (where the esophagus meets the stomach).[1,2]

The magnetic attraction between the beads is designed to keep the LES closed, which helps prevent reflux of bile and acid from the stomach into the esophagus.[3,4] The pressure of swallowing breaks the magnetic attraction, allowing for food and liquid to pass, and then the magnetic attraction between the beads re-closes the LES.[3,4]

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

Indications for Use:

- Patients with diagnosed Gastroesophageal Reflux Disease (GERD) as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximum medical therapy for the treatment of reflux.

Contraindications:

- Patients with suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials.

Warnings:

- The LINX Implant is considered MR Unsafe. After implantation, the patient should not be exposed to an MRI environment. The MRI environment could cause serious injury to the patient and/or interfere with the magnetic strength and the function of the device. A recommendation should be made to patients receiving the LINX device to register their implant with the MedicAlert Foundation (www.medicalert.org) or equivalent organization. In the event alternative diagnostic procedures cannot be used and MRI is required, the LINX device can be safely removed utilizing a laparoscopic technique that does not compromise the option for traditional anti-reflux procedures.

Precautions:

- The LINX device has not been evaluated in patients with a hiatal hernia larger than 3 cm. Use of LINX device in patients with a hiatal hernia larger than 3cm should be considered on the basis of each patient's medical history and severity of symptoms.
- The safety and effectiveness of the LINX device has not been evaluated in patients with Barrett's esophagus or Grace C or D (LA classification) esophagitis.
- The safety and effectiveness of the LINX device has not been evaluated in patients with electrical implants such as pacemakers and defibrillators, or other metallic, abdominal implants.
- The safety and effectiveness of the LINX device has not been evaluated in patients with major motility disorders.
- The safety and effectiveness of the LINX Reflux Management System has not been established for the following conditions:
    - 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 such as 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)
- Age <21

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of the LINX® Reflux Management System as a treatment for Gastroesophageal Reflux Disease (GERD). Below is a summary of the available evidence identified through May 2022.

Systematic Reviews

- In 2018 (updated 2021 and archived 1/2022), Hayes published an evidence review evaluating magnetic sphincter augmentation (MSA) (LINX® Reflux Management System) for the treatment of gastroesophageal reflux disease (GERD).[5] Hayes searched the literature through December 2019 according to predefined inclusion criteria, which excluded case series and studies with fewer than 50 participants. Seven studies were ultimately included for review: 1 manufacturer-funded RCT comparing MSA to twice-daily proton pump inhibitor (PPI) medication (omeprazole), and 6 cohort studies comparing MSA to laparoscopic fundoplication (LF) – gold standard GERD surgical treatment. Hayes judged the RCT to be "fair quality," 4 of the 6 cohort studies to be "poor" quality, and 2 of the 6 cohort studies to be "very poor" quality. Sample sizes ranged from 66 to 415 patients and follow-up varied from 6 months to 44 months. The review's primary outcomes of interest were GERD-related symptom improvement, symptom improvement comparative with current standard treatments for GERD, adverse events and patient selection criteria.

  Quality of Life

  Each of the seven included studies assessed GERD health-related quality of life (GERD-HRQL) to measure GERD symptoms before and after treatment. While both MSA and LF were associated with substantial improvements in GERD-HRQL scores, these improvements were not significant different between MSA and LF groups (all analyses; $p>0.1$). One cohort study analyzed a minority of subjects at 7-years post-treatment and found no statistically significant difference in GERD-HRQL scores between treatment groups (OR=1.04 [95% CI, 0.89-1.27]; $p=0.578$), with both groups reporting continued improvements ($p<0.001$). Follow-up among each of the six cohort studies for all subjects was brief, ranging from 6 months to 1 year.

  The included RCT reported that MSA significantly improved GERD-HRQL scores compared to twice-daily PPI ($p<0.002$). At baseline, MSA patients scored 24 points compared to 25 points for PPI-only patients, improving to 6 points compared 24 points at 6-month follow-up ($p<0.002$). Furthermore, 81% of MSA patients experienced a ≥ 50% reduction (i.e. improvement) in GERD-HRQL score compared with 8% of twice-daily PPI patients ($p<0.001$).

PPI Use

All 7 studies reported substantial reductions in PPI use among MSA patients. In 4 of 6 studies, there was no statistically significant difference in PPI use between MSA and LF groups at follow-ups ranging from 6-months to 1-year. Across six cohort studies, 0% to 19% of MSA patients used PPI compared to 3% to 37% of LF patients at 1-year follow-up. One study reported higher PPI use among MSA patients versus LF patients at 1 year (24% versus 12% of patients; p=0.02) following a propensity score-matched analysis. Alternatively, a large, multicenter prospective cohort study (n=249) reported significantly lower PPI use among MSA patients versus LF patients (18.2% versus 37%; p=0.009), also at 1-year follow-up. In the RCT, PPI use decreased among MSA patients from 100% at baseline to 9% at 6-months post-surgery.

Patient-reported GERD Symptoms

Each of the 4 studies assessing patient-reported GERD symptoms reported a positive association between MSA and improved symptoms at 6-month and 1-year follow-ups. The largest, multicenter prospective cohort study (n=249) reported a significantly lower incidence of moderate or severe regurgitation at 1 year compared with LF (3.1% versus 13%; compared to 58.2% versus 60% of patients at baseline; p=0.014). Investigators reported no inter-group differences in proportion of patients with reflux affecting extraesophageal symptoms, sleep quality or sleep position (p>0.2). A second cohort study found symptom improvement among 97.8% among both MSA and LF groups, with complete resolution in 51.1% of MSA patients and 48.9% of LF patients (p=0.978 between groups). A third cohort study reported significant improvement in GERD symptoms in both groups (e.g. heartburn, regurgitation, cough, aspiration, chest pain, or ear, nose and throat issues) (P≤0.001). In the RCT comparing MSA to twice-daily PPI, 89% of MSA patients experienced regurgitation resolution versus 10% in the PPI group (p<0.001) at 6-month follow-up.

Esophageal pH

Two studies (one small, retrospective cohort and one RCT) evaluated esophageal pH parameters, with both reporting improvement following MSA surgery. In the retrospective cohort study, LF patients experienced significantly greater improvement in both DeMeester score and time spent with a pH < 4 (p=≤0.0001) compared to MSA patients. In the RCT, MSA patients achieved more normal esophageal pH outcomes than PPI patients. The statistical significance of these findings was not reported.

Summary

Hayes ultimately assigned a “C” rating (potential but unproven benefit) for MSA in the treatment of GERD, concluding that the “low-quality body of consistent evidence suggest[ed] that MSA is associated with improved QOL and GERD symptoms, with similar effectiveness and potentially superior safety compared with laparoscopic fundoplication.”[5] The report noted the lack of long-term data demonstrating safety and efficacy and undefined patient selection criteria. Limitations in reviewed studies included small sample sizes, a lack of long-term follow-up (6-months to 1-year), a lack of power analyses and significant differences in baseline characteristics between treatment groups.

- In 2021 Zhuang and colleagues completed a systematic review and meta-analysis to determine the efficacy and safety of magnetic sphincter augmentation (MSA) in the management of refractory gastroesophageal reflux disease (rGERD).[6] Ten single-arm studies, one randomized controlled trial and three cohort studies containing 1138 participants were included. Post procedure PPI withdrawal, significant GERD-HRQL improvement and normalization of acid exposure times were achieved in 87%, 88%, and 75% of patients, respectively. Incidence of the most common adverse event, dysphagia, was 29% and 7.4% of patients that underwent MSA procedure required endoscopic dilation. MSA showed better efficacy in symptom control than PPI (PPI cessation: 91% vs 0%; GERD-HRQL improvement: 81% vs 8%) and similar effectiveness but a lower risk of gas-bloat syndrome and better reserved ability to belch when compared with laparoscopic Nissen fundoplication. The authors conclude that well-designed randomized trials comparing the efficacy of MSA with other therapies are needed.

- In 2020 (updated in 10/2021), ECRI published an evidence review evaluating the safety and effectiveness of magnetic sphincter augmentation (MSA) in the treatment of GERD.[7] The review searched the published and gray literatures through March 2020 and included 4 studies for review (2 systematic reviews of nonrandomized studies, 1 RCT and 1 pre-post study and 2 economic studies) reporting on 13,437 patients. The primary outcomes evaluated were GERD symptoms, quality of life (QOL), proton-pump inhibitor (PPI) medication use, endoscopic or surgical retreatment for GERD symptoms and adverse events. One meta-analysis of 6 studies found no differences between LINX and fundoplication groups in PPI use, GERD-health-related quality of life (GERD-HQOL) scores, dysphagia, and retreatments up to 4 years.[8] The same study reported PPI use in 13.2% of patients, LINX removal in 3.3%, and esophageal erosion in 0.3% at up to 5-year follow-up across 13 case series (n = 11,598). The review concluded, however, that there remains "an urgent need for randomized data directly comparing fundoplication with MSA for the treatment of GERD to truly evaluate the efficacy of this treatment approach."[8] Another systematic review found that patients receiving LINX experienced less bloating (OR: 0.34, 95% CI: 0.16 to 0.71) and better belching ability (OR: 12.34, 95% CI: 6.43 to 23.70), and improvements in GERD-HRQOL (mean 35.2 to 5.6 points) at 2-year follow-up in patients who underwent MSA after gastric surgery.[9] One RCT reported greater patient satisfaction (81% versus 2%) and improvement in GERD-HRQOL scores (18 versus 1 points) with LINX at 6-month follow-up, and >50% GERD-HRQOL improvement with LINX in 81% of patients, less PPI use in 91%, less regurgitation in 96%, and less bloating in 25% at 6-month to 1-year follow-up.[10]
  Results from the two systematic reviews were limited by reviewed studies' small sample sizes, retrospective design, single-center focus and lack of randomization. Patient-reported outcomes of QOL and patient satisfaction were at also risk of bias as blinding was not feasible in patients or clinicians. Despite these limitations, ECRI deemed evidence sufficient to support the safety and efficacy of MSA given the consistency of results across studies and their validation in a meta-analysis of controlled studies and an independent RCT. While indicating that studies with longer follow-up and comparisons of LINX with other GERD devices "would be useful," ECRI concluded that evidence supporting MSA is overall "very favorable."[7]

- In 2020, Schizas and colleagues conducted a systematic review evaluating the safety and efficacy of MSA for the treatment of GERD.[11] Independent investigators systematically searched the literature through August 2019, identified eligible studies, assessed study quality and extracted data. In total, 35 studies assessing 2,511 patients were included for review. Median follow-up was 12 months. Post-operative proton-pump inhibitor (PPI) cessation rates reached 100%, with fewer bloating

symptoms and a better ability to belch or vomit compared to patients receiving LF. Common complications included dysphagia, with rates ranging between 6% and 83%. Dilation due to dysphagia occurred in 8% of patients with typical inclusion criteria. Esophageal erosion may occur in up to 0.03% of patients. Investigators concluded that MSA may serve as a bridge treatment between conventional medical treatment and LF, yet called for additional studies with longer follow-up to validate results reported to date.

- In 2020, Kirkham and colleagues conducted a systematic review evaluating the safety and efficacy of MSA for the treatment of GERD.[12] Independent investigators systematically searched the literature through December 2019, identified eligible studies, assessed study quality and extracted data. In total, 39 full-text papers were included (1 RCT 5 cohort, 3 case-control, 25 case series, 5 case reports). Sample sizes ranged from 24 to 415. Follow-up ranged from 4 weeks to 5 years; however, in 14 studies, it was less than 1 year. Of the nine comparative studies, including one RCT, eight were limited by different selection criteria and unmatched patients at baseline. Information about ethical approval, patient consent and conflicts of interest was often missing. Investigators concluded that evidence is insufficient to support the use of MSA given the lack of information about patient selection, governance, expertise, techniques, and outcomes. Authors called for additional, high-quality studies to validate positive results.

- In 2019, Guidozzi and colleagues completed a systematic review and pooled analysis of laparoscopic magnetic sphincter augmentation versus fundoplication for gastroesophageal reflux disease.[8] Six comparative studies and 13 single-cohort studies met pre-defined inclusion criteria with sample sizes ranging from 32 to 202. The authors confirmed that MSA is safe, with minimal postoperative complications identified throughout the available literature. Only 0.3% of the study subjects experiencing device erosion and 3.3% of patients requiring device removal/reoperation. The analysis also concluded that MSA is equally as effective as fundoplication in controlling symptoms of GERD measured by used of PPIs after intervention and similar GERD-HRQOL scores between both intervention groups postoperatively. One comparative study also evaluated postoperative pH and found normalization in post groups after intervention. Guidozzi et al. listed potential bias concerns and weaknesses including underreporting of complications, identification of both early and late complications, small recruitment populations, reporting bias, variations in follow-up protocols/length of follow-up, and lack of randomized controlled trials.

- In 2018, Stanak and colleagues performed a systematic review evaluating GERD-health-related quality of life (GERD-HRQL) among magnetic sphincter augmentation (MSA) patients.[13] Six studies (n=249) met pre-defined inclusion criteria (5 prospective case series and one prospective registry study). Patients were heterogeneous at baseline in terms of age, length of GERD symptoms, proton-pump inhibitor (PPI) (i.e. medication) resistance, and confirmation of reflux by pH monitoring. Only one study[14] (discussed below) met inclusion criteria for effectiveness analysis of MSA. The study reported improvements in patients' symptoms, GERD-HRQL scores, and PPI use at one year follow-up. Investigators concluded that the overall quality of evidence was "very low" due to the one included study's case series design, and high risk of bias from potential confounders.

- In 2018, Aiolfi and colleagues performed a systematic review and meta-analysis evaluating magnetic sphincter augmentation (MSA) in the treatment of GERD compared to laparoscopic fundoplication (LF).[15] The review included seven observational cohort studies, six of which were also included in Hayes' systematic review above.[5] Sample sizes ranged from 12 to 185 and follow-up was 1 year.

Investigators calculated pooled effect measures, evaluated heterogeneity using I^2- index and Cochrane Q-test, and addressed potential confounders via meta-regression. The meta-analysis reported no statistically significant difference between MSA and LF in GERD health-related quality of life scores, proton-pump inhibitor (i.e. medication) use, and dysphagia requiring endoscopic dilation. However, MSA patients experienced significant lower incidence of gas/bloat symptoms (OR=0.39 [95% CI, 0.25-0.61]; *p*<0.001); and improved ability to vomit (OR=10.10 [95% CI, 5.33-19.15]; *p* <0.001) and belch (OR=5.53 [95% CI, 3.73-8.19]; *p* <0.001). Investigators nonetheless concluded that "the difference in outcomes between the two patient groups need[s] to be interpreted with caution since no comparative randomized clinical trials exist to provide strong evidence [of comparative efficacy]."[15]

- In 2017, Hillman and colleagues published a systematic review of anti-reflux procedures for GERD.[16] Reviewers searched the literature through 2015 according to pre-defined inclusion criteria and extracted data. Primary outcomes of interest were improvement in GERD symptoms, esophageal acid exposure (EAE), DeMeester score, reflux events and erosive esophagitis (EE) healing. In total, 6 studies evaluating magnetic sphincter augmentation (MSA) were included (5 prospective cohort studies and 1 observational comparison study, all of which are either included in the ECRI review[7] above or evaluated elsewhere in this policy (i.e. Lipham et al.).[17] Investigators concluded that MSA appeared to be an effective alternative to laparoscopic fundoplication (LF) in patients who previously failed to respond to proton-pump inhibitor medication, based on superior improvements to GERD symptoms relative to LF. Limitations of this review include the lack of reviewer assessment of individual study outcomes (e.g. no *p*-values or confidence intervals provided for reported results); the non-randomized design of studies included for review; and the lack of long-term follow-up among included studies.

- In 2017, Skubleny et al. published the first systematic review and meta-analysis comparing the LINX magnetic sphincter augmentation (MSA) to laparoscopic Nissen fundoplication (LNF) for Gastroesophageal Reflux Disease (GERD).[18] Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. The outcomes of interest were GERD-Health Related Quality of Life (GERD-HRQL), DeMeester score, operative time, ability to belch, ability to emesis, discontinuation of proton pump inhibitors, need for endoscopic dilation, procedural satisfaction, and presence of gas/bloating and dysphagia.

  Three primary studies (2 retrospective case-controls and 1 prospective case-control) met inclusion criteria for review and meta-analysis; thus producing a sample size of n=688 (n=273 LNF, n=415 MSA). Mean follow-up duration ranged from 7 to 12 months for MSA and 7 to 16 months for LNF. The results of the systematic review indicated MSA was statistically better at maintaining the patient's ability to belch (95.2% vs. 65.9%, *p*<0.00001) and vomit (93.5% vs. 49.5%, *p*<0.0001). There was no statistically significant difference between the two procedures for gas/bloating (26.7% vs. 53.4%, *p*=0.06), postoperative dysphagia (33.9% vs. 47.1%, *p*=0.43), and proton pump inhibitor elimination (81.4 vs. 81.5%, *p*=0.68). MSA patients required more post-implant esophageal dilations compared to LNF patients (23.4% MSA vs. 3.3% LNF). Both MSA and LNF groups showed improvement in GERD-HRQL and DeMeester scores. Adverse events reported in the MSA group included pleural injury, two episode of intraoperative bleeding, one pneumothorax, and one gastroesophageal junction obstruction. Two MSA device removals were reported due to treatment failure and dysphagia secondary to device erosion.

Strengths of this study include the systematic review of literature following a pre-defined protocol and evaluation of methodological quality by two independent reviewers. Strength was also found in the assessment of heterogeneity to determine the appropriateness of conducting a meta-analysis. A significant limitation of this systematic review is the poor quality of selected studies and lack of randomized controlled trials. Also, there are very few studies with long-term follow-up data of MSA versus LNF. The study also indicated "the validity of many of the primary outcomes was decreased due to their subjective nature and lack of clear medical definition."[18] The authors concluded MSA may be an effective treatment for GERD, but long-term comparative outcome data past 1 year is needed in order to further understand the efficacy of MSA.

Nonrandomized Studies

- In 2020, Ayazi and colleagues conducted a retrospective review reporting on clinical outcomes and predictors of favorable results after LINX treated at a single institution.[19] In total, data from 553 patients were collected over a 5-year period. Investigators conduced a regression multivariable analysis to determine the factors predicting a favorable outcome, defined as freedom from proton pump inhibitors and at least 50% improvement in Gastroesophageal Reflux Disease-Health-Related Quality of Life (GERD-HRQL) total score. At a mean (SD) follow-up of 10.3 (10.6) months after MSA, 92.7% of the patients were free of proton pump inhibitor use and 84% reported at least 50% improvement in their GERDHRQL total score. The GERD-HRQL total score was improved from a mean (SD) baseline value of 33.8 (18.7) to 7.2 (9.0) ($p < 0.001$) and 76.1% of the patients had normalization of their esophageal acid exposure. Independent predictors of a favorable outcome after MSA included age younger than 45 years, male sex, GERD-HRQL total score >15, and abnormal DeMeester score. Limitations include the study's retrospective design, short duration of follow-up (10 months) and the senior author's conflict of interest with the device manufacturer.

- In 2020, Bonavina and colleagues evaluated outcomes a 3-years follow-up for MSA and LFin patients with GERD.[20] In total, 631 patients (465 MSA and 166 LF) were enrolled in the registry. Both MSA and LF resulted in improvements in total GERD-HRQL score (mean reduction in GERD-HRQL from baseline to 3 years post-surgery: MSA 22.0 to 4.6 and LF 23.6 to 4.9) and in satisfaction (GERD-HRQL satisfaction increase from baseline to 3 years: MSA 4.6% to 78.2% and LF 3.7% to 76.5%). Most patients were able to belch as needed with both therapies (MSA 97.6% and LF 91.7% at 3 years). MSA allowed a higher percentage of patients the ability to vomit as needed (MSA 91.2% and LF 68.0% at 3 years). PPI usage declined from baseline to 3 years for both groups after surgery (MSA 97.8% to 24.2% and LF 95.8% to 19.5%). Investigators concluded that MSA and LF are comparably effective treatment strategies for patients with GERD. Study limitations included lack of randomization, lack of long-term follow-up, lack of surgeries conducted in the United States, author conflicts of interest with the device manufacturer and a lack of uniform procedures within the LF group. Moreover, the MSA procedure now includes full crural and gastroesophageal junction dissection as opposed to the minimal dissection utilized in this investigation.

- In 2020, Ferrari and colleagues evaluated outcomes at long-term follow-up (6 to 12 years) of MSA for the treatment of GERD.[21] The study was a single-center, retrospective single-arm study. In total, 335 patients met the study inclusion criteria, 124 of which were followed from 6 to 12 years after surgery. At median follow-up of 9 years, mean total GERD-HRQL score significantly improved from 19.9 to 4.01 ($p < 0.001$), and PPI were discontinued by 79% of patients. The mean total percent time

with pH< 4 decreased from 9.6% at baseline to 4.1% ($p < 0.001$), with 89% of patients achieving pH normalization. Independent predictors of a favorable outcome were age at intervention< 40 years (OR 4.17) and GERD-HRQL score > 15 (OR 4.09). Limitations included the study' retrospective design, lack of comparator groups and heterogeneous patient selection criteria and treatment parameters.

- In 2018, Louie and colleagues published preliminary results, at 1-year follow-up, from their multi-center, prospective, observational study to be conducted over five years.[22] This is the second of two post-approval studies,(the other being Ganz et al. (2016)),[14] conducted as part of the FDA approval process to assess the long-term effectiveness and incidence of adverse events for magnetic sphincter augmentation (MSA). A total of 200 patients (102 males, 98 females) were treated across 17 sites (mean age: 48.5 years old; mean body mass index: 27.4; average duration of GERD symptoms: 11.9 years; average proton-pump inhibitor (PPI) utilization: 8.5 years). GERD was confirmed via ambulatory esophageal pH testing. Outcomes of interest were GERD-Health related quality of life (GERD-HRQL), PPI use, esophageal pH level, regurgitation, extra-esophageal symptoms and serious adverse events. At one-year follow-up, data were available for 91% of patients (n=181). Median GERD-HRQL scores improved from 26.0 to 4.0 among patients. Post-surgery patient approval was also high: 80% reported "satisfaction" with their present condition, 15% reported "neutral" and 5% reported "dissatisfied." Predefined success criteria of 50% or greater reduction (i.e. improvement) in total GERD-HRQL score was achieved by 84.3% of patients (95% CI), with improvements in symptoms of gas/bloating, difficulty swallowing and painful swallowing. At 1-year follow up, 87.4% of patients no longer used PPIs, and moderate/severe regurgitation and extra-esophageal symptoms declined from 61.5% of patients at baseline to 5.4%. Post-surgery, 36.6% of patients (n=30) experienced difficulty swallowing (i.e. dysphagia), only 1 of whom experienced daily symptoms sufficient to affect daily activities. Five patients (2.5%) had the device removed. Limitations of the study include the lack of control group receiving maximal medical therapy (e.g. PPI or LF) and short-term follow-up. Results at the five-year follow-up will better clarify MSA's efficacy and safety profile.

- In 2018, an expert panel of 14 esophagologists applied the RAND/UCLA Appropriateness Method to evaluate management options for patients with GERD refractory to medication (PPIs).[23] The majority of panelists agreed that the LINX device would be an inappropriate management strategy in seven of the nine hypothetical scenarios. There was "equivocal" agreement among panelists in the setting of breakthrough acid (esophageal acid exposure > 6.0%) with large hiatal hernia (> 3cm); and majority agreement (77%) that LINX would be appropriate for patients with breakthrough acid with a small/absent hiatal hernia (< 3cm). Limitations include a lack of any evidence in support of these determinations and industry support from LINX's manufacturer to half (n=7) of the panelists. The panel concluded that randomized control trials with long-term follow-up and were necessary before clinicians should consider the LINX device over fundoplication.

- In 2016, Ganz and colleagues reported safety and efficacy outcomes for 85 patients receiving MSA for the treatment of GERD at 5-year follow-up.[14] Outcomes of interest included quality of life, reflux control, use of proton-pump inhibitors (PPIs) and side effects. At follow-up, no device erosions, migrations, or malfunctions were reported. Median GERD-related quality of life score improved significantly from baseline among patients not already on PPIs, although it is unclear if this improvement was significant among patients already on PPIs. Bothersome gas-bloat decreased significantly from 52% at baseline to 8.3%, as did rates of regurgitation, constipation and nausea/vomiting. Rates of bothersome dysphagia, difficulty swallowing and diarrhea did not

significantly improve. Limitations included the study's lack of a comparator group receiving gold-standard treatment (i.e. laparoscopic fundoplication), high attrition (15%) and authors' conflicts of interest with the device manufacturer.

- In 2015, Reynolds et al. conducted a retrospective matched-pair analysis of 100 patients to evaluate laparoscopic magnetic sphincter augmentation (MSA) (e.g., LINX) versus laparoscopic Nissen fundoplication (LNF).[24] A prospectively collected database was used to identify patients who had a confirmed diagnosis of GERD (defined by an abnormal pH study), underwent MSA or NSF between April 2007 and October 2013, Barret's esophagus or esophagitis grade B or greater (confirmed with biopsy), documented history of PPI therapy for at least 6 months, and normal esophageal motility. MSA and LNF patients were matched 1:1 using the best-fit model, resulting in 50 MSA patients and 50 LNF patients. Postoperative one year follow-up data was collected for the outcomes of GERD-Health Related Quality of Life (GERD-HRQL), symptom improvement, and complications.

  Follow-up data was not available for 6% of patients in each group. Of the MSA group, 97.8% reported improved symptoms and 51.1% reported complete resolution of symptoms. The LNF group also showed similar rates of improved symptoms (97.8%) and complete resolution of symptoms (48.9%) resulting in no statistically significant difference between groups. There were also no statistically significant differences between groups for improvement in GERD-HRQL and Proton Pump Inhibitor use at 1-year follow-up. In regards to complications, both groups reported gas bloat, dysphagia, inability to belch, inability to vomit, and endoscopic dilation; however, only inability to vomit resulted in a statistically significant difference between groups (4% MSA, 21% LNF). No MSA patients experienced device erosions or removals and no LNF patients required reoperation.

  Strengths of this study include the comparison of MSA to LNF and the use of best-fit analysis for matching patients. Significant methodological limitations and potential for selection bias exist in the retrospective design with lack of randomization. Other limitations include the small sample size, short follow-up period, no objective outcome measures (e.g., esophageal pH measurements), and high attrition with 12% of patients lost to follow-up. Also, there are potential conflicts of interest due to authors being consultants for the device manufacturer (Torax Medical Inc.). The authors concluded "the results support the use of MSA as first-line therapy in patients with mild to moderate GERD"[24]; however, the reliability and validity of these results is questionable due to substantial study limitations.

  In 2015, Saino and colleagues reported on the 5 year results of a pilot study evaluating magnetic sphincter augmentation (MSA) for the treatment of gastroesophageal reflux disease (GERD). [25] The prospective, multicenter, single-arm study enrolled 44 patients with diagnosed GERD to undergo MSA. Outcomes of interest included GERD-Health Related Quality of Life (GERD-HRQL) score, esophageal pH, PPI use, and complications. Of the 44 patients who underwent MSA, 33 patients (75%) had 5-year follow-up data. All patients had significant reductions in esophageal pH and significant improvements in GERD-HRQL scores. Complete discontinuation of PPIs at 5 years was achieved by 87.8% of patients. During the course of 5-year follow-up, 6.8% of patients reported serious adverse events requiring hospitalizations. The most common adverse event was dysphagia reported by 43% of MSA patients. Three devices required removal due to persistent dysphagia, magnetic resonance imaging, and ongoing GERD symptoms. Although the long-term results of this study are encouraging, significant limitations are present in the very small sample size, lack of a comparator group, and very high attrition (25% of patients were lost to follow-up by 5 years). Due to

the lack of high-quality long-term data, there is insufficient evidence to support the long-term clinical utility and safety of MSA compared to LNF.

- Six additional observational studies comparing magnetic sphincter augmentation (MSA) using the LINX technology to the gold-standard laparoscopic Nissen fundoplication (LNF) for the treatment of Gastroesophageal Reflux Disease (GERD) were identified.[3,4,14,24,26,27] All of the comparison studies had significant methodological limitations including but not limited to the following:

    - short follow-up periods,
    - small sample sizes,
    - highly selective inclusion criteria,
    - significant losses to follow-up,
    - retrospective nonrandomized study designs,
    - significant between-group differences at baseline,
    - lack of objective outcome measures (i.e., pH evaluation at follow-up).

    Also of note, 5 of the 7 comparative studies disclosed conflicts of interest involving the device manufacturer, Torax Medical Inc., calling into question the reliability of the study results. No severe adverse events or deaths were reported in the studies; however, some did report high rates of dysphagia in MSA patients (44%-68%) which frequently resulted in post-implantation endoscopic esophageal dilation (19%-50%).

Evaluation of Safety

- Each of the studies included in the 2018 Hayes review reported technology-related complications (i.e. inability to belch or vomit, dysphagia, endoscopic dilation for dysphagia, gas bloat, and explanations/reoperations). Hayes also analyzed adverse events reported to the U.S. FDA's Manufacturer and User Facility Device Experience (MAUDE) database from August 1, 2017 (the final cutoff date of the Alicuben et al. (2018) analysis discussed below[28]) through October 30, 2018.[5] During this timeframe, the FDA database received reports of 228 injuries, 5 malfunctions and 0 deaths.[29]

- A continuation of the magnetic sphincter augmentation (MSA) safety evaluation was conducted using the FDA Manufacturer and User Facility Device Experience (MAUDE) database from October 30, 2018 (the final cutoff date of the Hayes review) through December 19, 2018.[29] The FDA database received 16 safety reports within these dates, all of which resulted in device explant.

- In 2018, Alicuben and colleagues retrospectively assessed the risk of esophageal erosion among magnetic sphincter augmentation devices implanted worldwide.[28] Investigators analyzed 9453 implantation cases that were reported to the database of either the manufacturer or the U.S. FDA's Manufacturer and User Facility Device Experience (MAUDE) between February 2007 to July 2017. In total, there were 29 reported cases of erosion (0.3%), presenting between 1 to 4 years (median, 26 months) after device implantation. Dysphagia and chest pain were the most common presenting symptoms. Investigators also found a higher rate of erosion among smaller devices compared to larger devices (18/365 [4.93%] for 12-bead versus 0/674 [0%] for 17-bead devices). Investigators assessed risk of erosion over time to be 0.05% at 1 year, increasing to 0.3% at 4 years. Investigators

hypothesized that patients with connective tissue disorders, poorly controlled diabetes and immunosuppression may be more predisposed to esophageal erosion.

- In 2017, Smith and colleagues assessed magnetic sphincter augmentation-related reports in the FDA's Manufacturer and User Facility Device Experience (MAUDE) database from March 22, 2012 (the date of FDA approval) to May 31, 2016.[30] In total, investigators found 89 device removals among an estimated 3283 implantations (2.7%), with most devices (57%) explanted in the first year of implantation. Dysphagia and persistent GERD symptoms were the most common reasons for removal. No deaths, serious adverse events or device malfunctions were reported.

- In 2015, Lipham et al., conducted a safety review of the first patients implanted with the magnetic sphincter augmentation device (MSA) through July 1, 2013.[17] The authors evaluated safety events from clinical research studies, the FDA's Manufacturer and User Facility Device Experience (MAUDE) database, and the manufacturer's database of the first 1000 patients implanted with MSA. The analysis of events included complications during or after surgery, the inability to complete the implantation of the device, a device malfunction causing harm to the patient, a device-related event that required an intervention, and a hospital readmission or reoperation. A total of 111 adverse events were identified, including 36 device removals, 59 esophageal dilations, 14 hospital readmissions, 1 device erosion, and 1 intra/perioperative complication. Hospital readmissions were most commonly due to dysphagia, pain, nausea, and vomiting. The most common reason for device removal was persistent dysphagia.

CLINICAL PRACTICE GUIDELINES

Oregon Health Evidence Review Commission (HERC)

In 2020, HERC included magnetic sphincter augmentation (CPT: 43284) among its list of "unproven interventions," citing "insufficient evidence of effectiveness."[31]

National Institute for Health and Care Excellence (NICE)

In 2017, NICE published an interventional procedures guidance (IPG575) evaluating laparoscopic insertion of a magnetic titanium ring for GERD. [32] The guidance does not specifically mention the LINX device. NICE concluded that while there were no major safety concern associated with comparable devices, long-term efficacy data remained limited in quantity and quality.

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

In 2017, SAGES updated its 2013 safety and effectiveness analysis, publishing a consensus opinion regarding the use of the LINX Reflux Management System as a treatment of GERD.[33] The statement suggested that " the LINX® device is reasonably safe and efficacious for the management of medically refractory GERD." [33] However, this guideline is an expert panel recommendation, which was not based in a systematic review of evidence and was not published in a peer-reviewed journal. MSA is not included within any of the GERD treatment guidelines.

American College of Gastroenterology (ACG)

The 2022 ACG clinical guideline regarding the LINX® Reflux Management System (MSA) concluded that MSA seems to be a safe and effective alternative to laparoscopic fundoplication. Clinical outcomes of the two procedures are similar, and both have unique advantages and disadvantages. However, with no randomized trials comparing the two procedures, it is difficult to recommend one procedure over the other at this time. [34]

American Society of General Surgeons (ASGS)

The 2014 ASGS position statement regarding the LINX® Reflux Management System "supports the use of the device as a mechanism for controlling GERD when performed by properly trained laparoscopic surgeons with experience in foregut surgery and the management of GERD patients."[35] However, this recommendation was based on poor quality evidence that was not obtained through a systematic review process. In addition, the ASGS recommendation was not published in a peer-reviewed journal.

EVIDENCE SUMMARY

There is not enough evidence to determine the clinical utility and safety of magnetic sphincter augmentation (MSA) relative to other established treatments of GERD. Studies have reported similar results to laparoscopic fundoplication (LF) for GERD-Health Related Quality of Life scores and esophageal pH. Nonetheless, the comparability and superiority of MSA to LF has yet to be demonstrated as there is a need for comparative randomized control trials. To date, there have been limited studies that included long-term follow up, and follow up procedures differ greatly between, and sometimes within, studies. Additional limitations to current studies include, but are not limited to, small sample sizes, lack of a comparator group, and high attrition. Dysphagia is the most common reported adverse event following MSA and there has been inconsistent and conflicting reports. While recent studies have reported low risk of device erosion, additional randomized control trials are required to evaluate the long-term safety and reliability of MSA. Evidence-based clinical practice guidelines continue to call for additional studies evaluating MSA.

MEDICARE ADVANTAGE

Note: The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

As of [last review date], no specific Medicare coverage policy or guidance (e.g., manual, national coverage determination [NCD], local coverage determination [LCD] article [LCA], etc.) was identified which addresses XXX for XXX. In the absence of a NCD, LCD, or other Medicare policy, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)* Thus, the Company medical policy criteria may be applied for medical necessity decision-making.

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is

not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5). For Medicare, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are "not medically reasonable or necessary" for Medicare Plan members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*

BILLING GUIDELINES AND CODING

CODES*		
CPT	43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed
	43285	Removal of esophageal sphincter augmentation device
	43289	Unlisted laparoscopy procedure, esophagus
	43499	Unlisted procedure, esophagus
	43999	Unlisted procedure, stomach
HCPCS	None	

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.