Lower Esophageal Magnetic Sphincter Augmentation

Medicare Advantage Medical Policy #MNG-012
Original Effective Date: 01/01/2025
Current Effective Date: 01/01/2025

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan considers magnetic esophageal sphincter augmentation (MSA), also known as LINX™ Reflux Management System, medically reasonable and necessary when all of the following conditions are met:

- Patient has diagnosis of gastroesophageal reflux disease (GERD) defined by abnormal pH testing in which acid exposure time (AET) is greater than 6%.
- Patient has undergone endoscopic and esophageal manometric evaluation to rule out extragastrointestinal etiology of symptoms.
- Patient has chronic GERD symptoms despite maximum medical therapy for the treatment of reflux defined as maximum (or maximum tolerated) dose of proton pump inhibitors (PPI) for at least 6 months.
- Implantation of the device is performed by a surgeon with experience in laparoscopic anti-reflux procedures and has received product specific training.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers magnetic esophageal sphincter augmentation when the coverage criteria are not met and for all other indications to be **investigational**.*****

Because safety and efficacy has not been established, coverage is excluded for the following:

- Patients with suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials
- Patients with electrical implants such as pacemakers and defibrillators, or other metallic, abdominal implants
- Unrepaired hiatal hernia >3 cm or a paraesophageal hernia
- Barrett's Esophagus or esophagitis Los Angeles (LA) class C or D

- Scleroderma
- Suspected or confirmed esophageal or gastric cancer
- Prior esophageal or gastric surgery or endoscopic intervention
- Distal esophageal motility less than 35mmHg 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 lower esophageal sphincter (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 (body mass index (BMI) >35)
- Age < 21

Definitions:
The LA Classification of GERD2:

Grade A-One (or more) mucosal break no longer than 5 mm that does not extend between the tops of 2 mucosal folds

Grade B-One (or more) mucosal break more than 5 mm long that does not extend between the tops of 2 mucosal folds

Grade C-One (or more) mucosal break that is continuous between the tops of 2 or more mucosal folds, but which involve less than 75% of the circumference

Grade D-One (or more) mucosal break which involves at least 75% of the esophageal circumference

Summary of Evidence

Overview
The Montreal Consensus defines GERD as "a condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications". It includes a spectrum of symptoms, including heartburn, regurgitation, dysphagia, laryngitis, dental problems, adult-onset asthma, and aspiration pneumonia. The prevalence of GERD is high and increasing globally.

Lifestyle modification and medications are the mainstay of treatment for GERD. Despite proper medical therapy, 10 to 40% of patients continue to have significant symptoms. Surgical intervention is generally reserved for patients who have persistent symptoms or develop complications despite optimal medical therapy. Fundoplication is a well-established surgical intervention that dates to the 1950's. Since then, multiple variations of the fundoplication have been established. The laparoscopic

fundoplication (LF) and its variations are considered highly effective and durable but also associated with significant potential for adverse effects, including dysphagia, difficulty in vomiting, and gas bloating.

Since the advent of fundoplication, other less invasive options that do not alter the gastric fundus have been developed. MSA is 1 of those options. It is performed using the LINX® Reflux Management System. This device treats GERD by augmenting the LES with an extraluminal ring consisting of a series of magnets. The magnetic attraction increases the LES closure pressure but permits food passage when swallowing.

Safety and efficacy

Since FDA approval in 2012, numerous studies have evaluated the safety and efficacy of MSA using the LINX® device. Multiple short to moderate-term studies (6 months to 5 years) have demonstrated reduced GERD symptoms, improved GERD-related quality of life scores, cessation of PPI use, and normalization of objective GERD measurements. More recently, studies have been published with data extending beyond 5 years.

In 2012, Lipham JC et al. performed a multicenter, prospective, single-arm study of 44 patients who underwent laparoscopic placement of the LINX® System. The AET reduced from 11.9% at baseline to 3.8% at 3 years, with 80% (18/20) of patients achieving pH normalization. At ≥ 4 years, 100% of the patients reported improved quality-of-life measures for GERD, and 80% had complete cessation of PPIs. There were no reported deaths or long-term device-related complications such as migration or erosion.

A retrospective case-control study was done in 2014 by Louie BE et al. It involved consecutive patients undergoing either laparoscopic Nissen fundoplication (LF) or MSA who had chronic GERD and a hiatal hernia of less than 3 cm.9 Sixty-six patients underwent operations (34 MSA and 32 LF) and were followed for at least 6 months. The groups were similar in reflux characteristics and hernia size. MSA resulted in less gassy and bloated feelings and enabled belching in 67% compared with none of the LF patients. The AET normalized in both groups but was statistically better in the LF group. MSA resulted in similar objective control of GERD, symptom resolution, and improved quality of life compared with LF.

Saino G et al. (2015) evaluated the safety and efficacy of the MSA for 5 years during a prospective, multicenter study.10 Forty-four patients (ages 18-75 years) had a LINX® device implanted by laparoscopy, and 33 patients were followed to 5 years. At 5 years, GERD Health-Related Quality of Life (HRQL) questionnaire score, esophageal pH, PPI use, and complications were evaluated. Complete discontinuation of PPIs was achieved by 87.8% of patients. No device erosions or migrations were reported. However, 11 (25%) of the study patients were not followed to the 5-year endpoint. Three patients had device removal.

A 2015 prospective, multicenter study by Riegler M et al. compared MSA and LF in clinical practice.11 Two hundred forty-nine patients (202 MSA patients and 47 LF patients) had completed one-year follow-up. Discontinuation of PPIs was achieved by 81.8% of patients after MSA and 63.0% after LF. Excessive gas and abdominal bloating were reported by 10.0% of patients after MSA and 31.9% following LF. Following MSA, 91.3% of patients were able to vomit if needed, compared with 44.4% of those undergoing LF. The reoperation rate was 4.0% following MSA and 6.4% following LF.

Ganz RA et al. (2016) performed a prospective study on 100 subjects ages (18-75) that underwent the LINX® placement, 85 of which were followed for 5 years to evaluate quality of life, reflux control, use of PPIs, and side effects.12 All patients used PPIs at baseline; this decreased to 15.3% at 5 years. Moderate or severe regurgitation occurred in 57% of subjects before the procedure and 1.2% at 5 years post-surgery. All patients reported the ability to belch and vomit if needed. Bothersome dysphagia was present in 5% at baseline and 6% at 5 years. No device erosions, migrations, or malfunctions were reported in this study. Device removal occurred in 7 patients.

Bell R et al. (2019) prospectively studied 152 patients with GERD and moderate-to-severe regurgitation despite 8 weeks of once-daily PPI therapy.13 These results indicate 89% (42/47) of treated patients with MSA reported relief of regurgitation compared with 10% (10/101) of the BID PPI group at the 6-month primary endpoint. The same authors published another study in 2020 that offered MSA to patients in the PPI arm of the study who had persistent moderate to severe regurgitation and excess reflux episodes during impedance or pH testing on medication.14 In this study, 70% (48/69) of patients had pH normalization at study completion. MSA was not associated with peri-operative events, device explants, erosions, or migrations.

The 2019 multicenter, prospective study by Louie BE et al. evaluated patients with pathologic acid reflux confirmed by esophageal pH testing undergoing MSA.15 A total of 200 patients, ages ranging from 19.7-71.6 years. At 1 year, the mean total AET decreased from 10.0% at baseline to 3.6% and 74.4% of patients had normal esophageal AET. The device removal rate at 1 year was 2.5%. One erosion was reported.

In a long-term retrospective study, Ferrari D et al. (2020) reported on the course of 335 patients, 124 of which were followed from 6 to 12 years after surgery (median 9 years).16 The mean total GERD-HRQL score significantly improved from 19.9 to 4.01, and PPI use was discontinued by 79% of patients. The mean total percent time with pH < 4 decreased from 9.6% at baseline to 4.1%, with 89% of patients achieving pH normalization. The rate of procedure-related adverse events was 11.6%, with 2.4% requiring a single endoscopic pneumatic dilation due to persistent dysphagia. Thirty-one patients (9.2%) required laparoscopic device removal for the following reasons: erosion (6), regurgitation (6), heartburn (5), dysphagia (5), foreign body sensation (2), odynophagia (1), pharyngodynia (1), chronic cough (1), need for Magnetic Resonance Imaging (MRI) (1).

Addressing postoperative dysphagia, Ganz RA et al. (2013) prospectively assessed 100 patients with GERD before and after sphincter augmentation.17 The study did not include a concurrent control group. The most frequent adverse event was dysphagia (in 68% of patients postoperatively, in 11% at 1 year, and 4% at 3 years). Serious adverse events occurred in 6 patients, and the device was removed in 6 patients. Ayazi S et al. (2020) performed a retrospective review of prospectively collected data of patients who underwent MSA over 5 years.18 The preoperative objective evaluation included upper endoscopy, esophagram, high-resolution impedance manometry, and esophageal pH testing. A total of 380 patients underwent MSA; at a mean follow-up of 11.5 months, 15.5% of patients were experiencing persistent dysphagia. The overall response rate to dilation therapy was 67%, and the efficacy of dilation reduced with each subsequent procedure.

Regarding the risk of erosion, Alicuben ET et al. (2018) examined data for all devices placed worldwide from February 2007 through July 2017 using the device registry.19 In total, 9453 devices were placed, and there were 29 reported cases of erosion. The median time to presentation of erosion was 26 months, most occurring between 1 and 4 years after placement. The risk of erosion was 0.3% at 4 years after device implantation. In this series, smaller devices were associated with higher rates of erosion. Notably, the smaller 12-bead device was responsible for 18/29 (62%) of erosions.

Effectiveness compared to fundoplication

In a systematic review and meta-analysis of 688 patients (273 fundoplication and 415 MSA), Skubleny D et al. (2017) found MSA was statistically superior to LF in preserving patient's ability to belch and vomit.20 There was no statistically significant difference between MSA and LF in gas/bloating, postoperative dysphagia, and PPI elimination.

Aiolfi A et al. (2018) examined 7 observational cohort studies, including 1211 patients, 686 MSA and 525 LF.21 Postoperative morbidity ranged from 0 to 3% in the MSA group and from 0 to 7% in the LF group, and there was no mortality reported. Dysphagia requiring endoscopic dilatation occurred in 9.3% of MSA and 6.6% of LF patients. Postoperative PPI use, dysphagia requiring dilatation, and quality of life are similar in the 2 patient groups. MSA was associated with less gas/bloat symptoms and an increased ability to vomit and belch.

Chen M-Y et al. (2017) conducted a meta-analysis of 4 trials that included 624 patients and aimed to evaluate the differences in PPI use, complications, and adverse events.22 MSA had a shorter operative time and length of stay. Similar PPI use, complication rate, and severe dysphagia for dilation were shown in both groups. Although there was no difference between the MSA and LF in the number of adverse events, the incidence of postoperative gas or bloating favored the MSA group. There was no significant difference in the ability to belch and vomit.

The systematic review by Guidozzi N et al. (2019) identified 6 comparative studies of MSA versus fundoplication and 13 single-cohort studies.23 Collectively, the study included 1099 patients, 632 receiving MSA and 467 receiving fundoplication. Following MSA, only 13.2% required

postoperative PPI therapy, 7.8% dilatation, 3.3% device removal or reoperation, and esophageal erosion was seen in 0.3%. There was no significant difference between the groups in the requirement for postoperative PPI therapy, GERD-HRQOL score, dysphagia, and reoperation. However, when compared to fundoplication, MSA was associated with significantly less gas bloating and a greater ability to belch. Regarding safety, 3.3% of the MSA patients required device removal.

Patient Selection

Rona KA, et al. performed a retrospective review of 192 patients.24 Median follow-up was 20 months (ranging from 3-75 months). Fifty-two patients had a hiatal hernia >3cm. This study reports MSA in patients with large hiatal hernias showed decreased postoperative PPI requirement and mean GERD-HRQL scores compared to patients with smaller hernias.

Buckley FP 3rd et al. (2018) conducted a 3-year multicenter, prospective study of consecutive patients undergoing MSA with the LINX® device with concurrent repair of paraesophageal and hernias over 3 cm.25 Non-permanent mesh reinforcement of hiatal repair was performed in 83% of the patients. At 9-month median follow up, complete PPI independence was achieved in 94%, 9.5% required dilation, GERD-HRQL scores improved from 26 preoperatively to 2 postoperatively. There were no device explants, erosions, or migrations reported.

In a retrospective review, Dunn CP et al. (2021) evaluated 79 patients with GERD and hiatal hernias ≥ 3 cm who underwent MSA and hiatal hernia repair over a 7-year period.26 Seventy-nine patients, with a median age of 65.56 years were included, median follow up was 2.98 years. Five (6.3%) hiatal hernia recurrences occurred, and 1 required re-operation. Median GERD-HRQL scores improved from 21 to 2.

Alicuben ET et al. (2019) and Dunn CP et al. (2021) published very similar retrospective studies showing MSA to be effective at preventing progression of metaplasia/Barrett's esophagus to dysplasia or neoplasia.27,28 The studies involved 86 and 87 patients, respectively. In both studies, the effect remained consistent even after 2 years of follow-up.

Warren HF et al. (2018) retrospectively studied clinical, endoscopic, manometric, pH data, and intraoperative factors of 170 patients.29 Manometric data pre- and post-MSA demonstrated that LESs with 1 defective component were restored to normal in 77% of patients; however, those with 2 or 3 defective components can only be restored to normal in 56%. MSA appears to provide less control of GERD in patients with LES with multiple defects. Using a multivariable analysis, BMI >35, structurally defective LES, and preoperative LES residual pressure were independent negative predictors of excellent/good outcome.

In a 3-year retrospective cohort study, James TJ et al. (2022) evaluated the outcomes of 621 consecutive patients who underwent laparoscopic MSA.30 Patients were grouped into 4 cohorts according to the World Health Organization body mass index (BMI) classification: BMI < 25

(normal weight), BMI 25-29.9 (overweight), BMI 30-34.9 (obese class I), and BMI > 35 (obese class II-III). Follow-up with endoscopy or video esophagram was available for 361 patients (58%) with a median follow-up of 15.4 months. There were no significant differences in outcomes between normal weight, overweight, and obese patient groups undergoing MSA.

Analysis of Evidence (Rationale for Determination)

With fundoplication considered the gold standard for surgical treatment of GERD refractory to medical management, numerous studies have evaluated MSA versus fundoplication. Current evidence shows MSA to have similar safety and efficacy when used in appropriately selected patients. The data shows similar quality-of-life improvement scores and rates of PPI cessation in both groups. In contrast, more fundoplication patients are unable to belch and vomit. Compared to fundoplication, MSA generally has shorter operative times and duration of hospital stay.

Dysphagia is a common adverse symptom that generally decreases over time and has been successfully treated with dilation therapy.17, 18 The risk of erosion was addressed in a large 2018 study, which found the incidence to be 0.3%.19 Persistent or recurrent adverse effects such as heartburn, regurgitation, dysphagia, chest pain, and device erosion have resulted in explantation. The likelihood of explantation generally ranges from 3-7% and should be included in the preoperative risk/benefit discussion.

The criteria for patient selection undergoing MSA are primarily based on the manufacturer's FDA-approved instructions for use, as these guidelines have been used in the majority of studies. Although use outside these parameters is reported, it has only been evaluated in a small number of studies, has limited objective data, and lacks adequate long-term follow-up.

There is limited study in patients with an unrepaired hiatal hernia >3m. However, there are multiple studies that show the effective use of MSA in patients who have a hiatal hernia concurrently repaired at the time of placement.

Thus far, there is limited data regarding use in patients with more severe GERD including esophagitis LA class C or D and Barrett’s esophagus. Two small retrospective studies evaluated the outcomes of MSA in patients with Barrett’s and showed promising results.27-28 However, these studies were from the same institutions, had nearly identical numbers, and occurred over a similar timeframe. Although published separately, the results appear consistent with data used from an overlapping patient population. Authors involved in both articles disclosed a paid consulting relationship with the manufacturer, adding limitation to the studies.

The literature suggests that endoscopy and esophageal manometry are valuable in the preoperative evaluation to rule out alternative pathology including cancer, motility disorders, stricture, and anatomic abnormalities. The 2018 Warren study showed structurally defective LES and preoperative LES residual pressure were independent negative predictors of excellent/good outcome.

The initial trials that led to the approval of the LINX® device excluded patients with a BMI > 35, and most studies since then have followed this criterion. James et al. examined the effect of preop BMI on outcomes and found no significant differences between normal-weight patients, overweight, and different classes of obesity.30 However, the 2018 study by Warren et al. suggests a higher BMI may be a negative predictor.29 Currently, there is not sufficient evidence for use outside this parameter.

It is important to note that patients >75 years old were excluded from the original FDA trials. Since then, no significant study has addressed its use for patients >75 years old. Although studies have suggested that younger age is a predictor of positive outcomes19, age is not listed as an exclusionary criterion. Careful patient selection is critical for both success and safety.

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Exclusions: None.

Policy History

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Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	43284, 43285
HCPCS	No codes
ICD-10 Diagnosis	K21.00, K21.9

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services

at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-bene-help.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.