KAISER PERMANENTE® Mid-Atlantic States	**Laparoscopic Magnetic Sphincter Augmentation for Gastroesophageal Reflux Disease (LINX Reflux Management System) Medical Coverage Policy**

2024 New Policy

UTILIZATION * ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- For Medicare members, please consult the Medicare Coverage Database.
- Note: After searching the Medicare Coverage Database, if no NCD/LCD/LCA is found, then use the policy referenced above for coverage guidelines

I. Procedure: **Laparoscopic Magnetic Sphincter Augmentation (MSA) for Gastroesophageal Reflux (GERD) or LINX Reflux Management System**

II. Diagnosis**: Gastroesophageal Reflux (GERD)**

III. **Clinical Indication for Referral**

Laparoscopic Magnetic Sphincter Augmentation is considered medically necessary for patients with **all** of the following:

A. Diagnosis of Gastroesophageal Reflux Disease (GERD) with acid exposure time (AET) greater than 6%; **and**

B. Presence of 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; **and**

C. Have undergone appropriate endoscopic and esophageal manometric evaluation to rule out extra-gastrointestinal etiology of symptoms; **and**

D. Implantation of the device is performed by a surgeon with experience in laparoscopic anti-reflux procedures and has received product specific training.

IV. **Contraindication, Exclusion, Risks and Adverse Events**

A. Contraindication

LINX Reflux Management System is contraindicated with **all** of the following:

1. Suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials.
2. Exposure to MRI after implantation of LINX Reflux Management System as the MRI environment can interfere with the magnetic strength and the function of the device and/or can cause serious

injury to the patient.
3. Exposure of the device to temperatures above 212 Fahrenheit (100 centigrade) as this could adversely affect the magnets and the function of the device.

B. Exclusion

The **Laparoscopic MSA** for GERD is not medically indicated as safety and efficacy has not been established on **any** of the following condition:

1. Age <21;
2. Pregnancy or plan to become pregnant;
3. Lactating;
4. Morbid obesity: Body Mass Index (BMI) >35);
5. Unrepaired hiatal hernia >3 cm or a para-esophageal hernia;
6. Barrett's esophagus or esophagitis Los Angeles (LA) classification Grade class C or D);
7. Patients with electrical implants such as pacemakers and defibrillators, or other metallic, abdominal implants;
8. Major motility disorders;
9. Scleroderma;
10. Suspected or confirmed esophageal or gastric cancer;
11. Prior esophageal or gastric surgery or endoscopic intervention;
12. 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;
13. Symptoms of dysphagia more than once per week for the last 3 months;
14. Esophageal stricture or gross esophageal anatomic abnormalities (such as obstructive lesions, Schatzki's ring etc.); **and**
15. Esophageal or gastric varices.

C. Risks

The risks associated with the Laparoscopic MSA for GERD are the following:

1. Death;
2. Bleeding;
3. Injury to esophagus, spleen, or stomach;
4. Peritonitis;
5. Pneumothorax;
6. Pain;
7. Worsening of preoperative symptoms (including but not limited to dysphagia or heartburn);
8. Device migration;
9. Organ damage caused by device migration;
10. Erosion of the device;

11. Device failure;
12. Device explant/re-operation;
13. Early satiety;
14. Decreased appetite;
15. Achalasia;
16. Dysphagia;
17. Odynophagia;
18. Esophageal spasms;
19. Nausea;
20. Vomiting,
21. Hiccups;
22. Inability to belch or vomit;
23. Increased belching;
24. Regurgitation;
25. Stomach bloating;
26. Impaired gastric motility;
27. Food impaction;
28. Flatulence;
29. Diarrhea;
30. Infection; **and**
31. Weight loss

D. Adverse Events

The adverse events associated with laparoscopic magnetic sphincter augmentation is any of the following:

1. Anaphylaxis;
2. Cardiac arrest;
3. Death;
4. Diarrhea;
5. Fever;
6. Hypotension;
7. Hypoxemia;
8. Infection;
9. Myocardial infarction;
10. Perforation;
11. Pneumonia;
12. Pulmonary embolism;
13. Respiratory distress;
14. Thrombophlebitis;
15. Symptoms after anti-reflux surgery procedures (such as nausea, dysphagia, odynophagia,

retching, vomiting and bloating); **and**

16. Adverse reaction to anesthesia (like headache, muscle pain, nausea)

Description

Magnetic Sphincter Augmentation (MSA) for Gastroesophageal Reflux Disease (GERD) or LINX Reflux Management System, is a magnetic gastrointestinal sizing class II device, approved by FDA in 2012 for treatment of GERD though laparoscopic placement of a flexible interlinked band of magnetic titanium beads around the esophagus. The magnetic attraction from the device increases the closure of lower esophageal sphincter (LES), preventing reflux.

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Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
11/21/2024	11/21/2024

*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.