KAISER PERMANENTE®

Kaiser Foundation Health Plan

Clinical Policy for Medical Necessity Criteria for Surgical Treatment of Gastroesophageal Reflux Disease

Department: Gastroenterology/General Surgery **Effective:** 6/24/26

Policy #: NCP 120 **Last Reviewed:** 6/24/26

Overview/Definitions

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

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.

Coverage Determinations

Line of Business	Determination Name/Number & Contractor	Revision Date
For Medicare Members		
NCD	None	
LCD	None- policy 120 applies to Medicare lines of business. Use the criteria below.	11/06/2025
For Medicaid Members		
OR Medicaid	This policy does not apply.	
WA Medicaid	This policy does not apply.	
For Commercial and Self-Funded Plans		
OR Commercial	This policy applies.	
WA Commercial	This policy applies.	
Self-Funded	This policy applies.	

Clinical Indications for Non-Medicare Members

Esophyx Transoral Incisionless Fundoplication procedure is indicated when ALL of the following are met:

1. Typical symptomatic GERD (e.g., heartburn, regurgitation, dental erosions)
2. Confirmation of diagnosis of GERD using 1 or more of the following testing:
    - ambulatory pH monitoring with acid exposure time (AET) > 6%
    - barium swallow study
    - Endoscopy (EGD)
3. Symptoms are unresponsive to lifestyle modification including 1 or more of the following:
    - weight loss
    - avoidance of trigger foods
    - avoidance of late meals
    - elevation of the head of the bed
4. Failure, contraindication or intolerance of an adequate trial of medical therapy, as shown by 4 continuous months of Proton Pump Inhibitor (PPI) use.
5. The patient does not have any of the following conditions:
    - Prior transoral incisionless fundoplication
    - Hiatal hernia greater than 2 cm
    - Esophagitis LA grade >B
    - Barrett's esophagus > 2 cm
    - Achalasia
    - Esophageal ulcer
    - BMI > 35

LINX® Magnetic Sphincter Augmentation (MSA) for Gastroesophageal Reflux (GERD) is medically necessary when ALL of the following are met:

1. Typical symptomatic GERD (e.g., heartburn, regurgitation, dental erosions)
2. Confirmation of diagnosis of GERD using 1 or more of the following testing:
    - ambulatory pH monitoring with acid exposure time (AET) > 6%
    - barium swallow study
    - Endoscopy (EGD)
3. Symptoms are unresponsive to lifestyle modification including 1 or more of the following:
    - weight loss
    - avoidance of trigger foods

    - avoidance of late meals
    - elevation of the head of the bed
4. Failure, contraindication or intolerance of an adequate trial of medical therapy, as shown by 4 continuous months of Proton Pump Inhibitor (PPI) use.
5. Documentation supports the need for LINX® versus traditional fundoplication procedures.
6. The patient does not have any of the following conditions:
    - Complete failure of the lower esophageal sphincter
    - Dysphagia
    - Previous endoluminal anti-reflux procedure
    - Barrett's esophagus

Exclusions

The following procedures are considered investigational/experimental and are not covered at this time:

- Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta)
- Endoscopic Suturing System (EndoCinch, Endoluminal Plication, Plicator, SomaphyX)
- Endoscopic Placement of Bulking Material (Enteryx, PMMA beads, Gatekeeper system, Durasphere)

LINX Magnetic Sphincter Augmentation for GERD is not medically indicated for ANY of the following:

- Suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials.
- 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.
- Exposure of the device to temperatures above 212 Fahrenheit (100 centigrade) as this could adversely affect the magnets and the function of the device

LINX Magnetic Sphincter Augmentation for GERD is not medically indicated as safety and efficacy has not been established on ANY of the following conditions:

- Age <21
- Pregnancy or plan to become pregnant
- Lactating
- Morbid obesity: Body Mass Index (BMI) >35)

- Unrepaired hiatal hernia >3 cm or a para-esophageal hernia
- Barrett's esophagus or esophagitis Los Angeles (LA) classification Grade class C or D)
- Patients with electrical implants such as pacemakers and defibrillators, or other metallic, abdominal implants
- Major motility disorders
- 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 hypertensive LES
- Symptoms of dysphagia more than once per week for the last 3 months
- Esophageal stricture or gross esophageal anatomic abnormalities (such as obstructive lesions, Schatzki's ring etc.)
- Esophageal or gastric varices.

Coding

LINX® Reflux Management System

CPT Codes	Description
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed, and Removal of esophageal sphincter augmentation device
43285	Removal of esophageal sphincter augmentation device

Transoral (Endoluminal) Gastroplication or Suturing/Transoral incisionless fundoplication (TIF)(Ex: Esophyx)

CPT Codes	Description
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed

Discussion/General Information

References

1. Afaneh C, Costa R, Pomp A, et al. A prospective randomized controlled trial assessing the efficacy of omentopexy during laparoscopic sleeve gastrectomy in reducing postoperative gastrointestinal symptoms. Surgical endoscopy. 2015;29(1):41-7. PMID: 24962864

2. Allaix ME, Fisichella PM, Noth I, et al. Idiopathic pulmonary fibrosis and gastroesophageal reflux. Implications for treatment. J Gastrointest Surg. 2014;18(1):100-4; discussion 04-5. PMID: 24002768

3. Anvari M, Allen C, Marshall J, et al. A randomized controlled trial of laparoscopic nissen fundoplication versus proton pump inhibitors for treatment of patients with chronic gastroesophageal reflux disease: One-year follow-up. Surgical innovation. 2006;13(4):238-49. PMID: 17227922

4. Anvari M, Allen C, Marshall J, et al. A randomized controlled trial of laparoscopic Nissen fundoplication versus proton pump inhibitors for the treatment of patients with chronic gastroesophageal reflux disease (GERD): 3-year outcomes. Surgical endoscopy. 2011;25(8):2547-54. PMID: 21512887

5. Chiu S, Birch DW, Shi X, et al. Effect of sleeve gastrectomy on gastroesophageal reflux disease: a systematic review. Surgery for obesity and related diseases : official journal of the American Society for Bariatric Surgery. 2011;7:510-5. PMID: 21130052
Dent J, El-Serag HB, Wallander MA, et al. Epidemiology of gastro-oesophageal reflux disease: a systematic review. Gut.2005;54(5):710-7. PMID: 15831922

6. Emken BG, Lundell LR, Wallin L, et al. Effects of omeprazole or anti-reflux surgery on lower oesophageal sphincter characteristics and oesophageal acid exposure over 10 years. Scandinavian journal of gastroenterology. 2017;52(1):11-17. PMID: 27593706
Galvez-Valdovinos R, Cruz-Vigo JL, Marin-Santillan E, et al. Cardiopexy with Ligamentum Teres in Patients with Hiatal Hernia and Previous Sleeve Gastrectomy: An Alternative Treatment for Gastroesophageal Reflux Disease. Obesity surgery.2015;25(8):1539-43. PMID:

7. Garg Sushil K, Gurusamy Kurinchi S. Laparoscopic fundoplication surgery versus medical management for gastro-oesophageal reflux disease (GORD) in adults. Cochrane Database of Systematic Reviews: John Wiley & Sons, Ltd, 2015.

8. Grant A, Wileman S, Ramsay C, et al. The effectiveness and cost-effectiveness of minimal access surgery amongst people with gastro-esophageal reflux disease - a UK

collaborative study. The REFLUX trial. Health Technol Assess. 2008;12(31):1-181, iii-iv. PMID: 18796263
9. Hayes. Hayes Technology Assessment. Laparoscopic Surgery for Gastroesophageal Reflux Disease Refractory to Medical Therapy. Dallas, TX: Hayes; April 21, 2023. https://evidence.hayesinc.com/report/earb.laparoscopic1509
10. Kahrilas PJ, Shaheen NJ, Vaezi MF, et al. American Gastroenterological Association Medical Position Statement on the management of gastroesophageal reflux disease. Gastroenterology. 2008;135(4):1383-91, 91 e1-5. PMID: 18789939
11. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol. 2013;108:308-28; quiz 29. PMID: 23419381
12. Kohn GP, Price RR, DeMeester SR, et al. Guidelines for the management of hiatal hernia. Surgical endoscopy. 2013;27(12):4409-28. PMID: 24018762
13. Lacy A, Ibarzabal A, Pando E, et al. Revisional surgery after sleeve gastrectomy. Surg Laparosc Endosc Percutan Tech. 2010;20:351-6. PMID: 20975509
14. Langer FB, Bohdjalian A, Shakeri-Leidenmuhler S, et al. Conversion from sleeve gastrectomy to Roux-en-Y gastric bypass—indications and outcome. Obesity surgery. 2010;20(7):835-40. PMID: 20393810
15. Lee JS, Ryu JH, Elicker BM, et al. Gastroesophageal reflux therapy is associated with longer survival in patients with idiopathic pulmonary fibrosis. American journal of respiratory and critical care medicine. 2011;184(12):1390-4. PMID: 21700909
16. Li G, Jiang N, Chendaer N, et al. Laparoscopic Nissen Versus Toupet Fundoplication for Short- and Long-Term Treatment of Gastroesophageal Reflux Disease: A MetaAnalysis and Systematic Review. Surgical innovation. 2023;30(6):745-57. PMID:
17. Linden PA, Gilbert RJ, Yeap BY, et al. Laparoscopic fundoplication in patients with endstage lung disease awaiting transplantation. J Thorac Cardiovasc Surg. 2006;131:438-46. PMID: 16434276
18. Lundell L, Attwood S, Ell C, et al. Comparing laparoscopic antireflux surgery with esomeprazole in the management of patients with chronic gastro-oesophageal reflux disease: a 3-year interim analysis of the LOTUS trial. Gut. 2008;57(9):1207-13. PMID: 18469091
19. Lundell L, Miettinen P, Myrvold HE, et al. Comparison of outcomes twelve years after antireflux surgery or omeprazole maintenance therapy for reflux esophagitis. Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association. 2009;7(12):1292-8; quiz 60. PMID: 19490952
20. Lundell L, Miettinen P, Myrvold HE, et al. Long-term management of gastrooesophageal reflux disease with omeprazole or open antireflux surgery: results of a prospective, randomized clinical trial. The Nordic GORD Study Group. European journal of

gastroenterology & hepatology. 2000;12(8):879-87. PMID: 10958215.
21. Mahon D, Rhodes M, Decadt B, et al. Randomized clinical trial of laparoscopic Nissen fundoplication compared with proton-pump inhibitors for treatment of chronic gastrooesophageal reflux. The British journal of surgery. 2005;92(6):695-9. PMID: 15898130
22. Morehead RS. Gastro-oesophageal reflux disease and non-asthma lung disease. Eur Respir Rev. 2009;18:233-43. PMID: 20956148 Mori T, Nagao G, Sugiyama M. Paraesophageal hernia repair. Ann Thorac Cardiovasc Surg. 2012;18:297-305. PMID: 22850094
23. Muller-Stich BP, Achtstatter V, Diener MK, et al. Repair of Paraesophageal Hiatal Hernias-Is a Fundoplication Needed? A Randomized Controlled Pilot Trial. Journal of the American College of Surgeons. 2015;221(2):602-10. PMID: 25868406
24. Oor JE, Roks DJ, Unlu C, et al. Laparoscopic sleeve gastrectomy and gastroesophageal reflux disease: a systematic review and meta-analysis. American journal of surgery. 2016;211(1):250-67. PMID: 26341463
25. Page MP, Kastenmeier A, Goldblatt M, et al. Medically refractory gastroesophageal reflux disease in the obese: what is the best surgical approach? Surgical endoscopy. 2014;28(5):1500-4. PMID: 24310740
26. Pallati PK, Shaligram A, Shostrom VK, et al. Improvement in gastroesophageal reflux disease symptoms after various bariatric procedures: review of the Bariatric Outcomes Longitudinal Database. Surgery for obesity and related diseases : official journal of the American Society for Bariatric Surgery. 2014;10(3):502-7. PMID: 24238733
27. Pashinsky YY, Jaffin BW, Litle VR. Gastroesophageal reflux disease and idiopathic pulmonary fibrosis. The Mount Sinai journal of medicine, New York. 2009;76(1):24-9. PMID: 19170215.
28. Patti MG, Tedesco P, Golden J, et al. Idiopathic pulmonary fibrosis: how often is it really idiopathic? J Gastrointest Surg. 2005;9:1053-6; discussion 56-8. PMID: 16269375 Raghu G, Yang ST, Spada C, et al. Sole treatment of acid gastroesophageal reflux in idiopathic pulmonary fibrosis: a case series. Chest. 2006;129:794-800. PMID: 16537884
29. Richter JE, Kumar A, Lipka S, et al. Efficacy of Laparoscopic Nissen Fundoplication vs Transoral Incisionless Fundoplication or Proton Pump Inhibitors in Patients With Gastroesophageal Reflux Disease: A Systematic Review and Network Meta-analysis. Gastroenterology. 2018. PMID: 29305934
30. Stefanidis D, Hope WW, Kohn GP, et al. Guidelines for surgical treatment of gastroesophageal reflux disease. Surgical endoscopy. 2010;24(11):2647-69. PMID: 20725747
31. Wileman SM, McCann S, Grant AM, et al. Medical versus surgical management for gastro-oesophageal reflux disease (GORD) in adults. Cochrane Database Syst Rev. 2010(3):CD003243. PMID: 20238321 13.

History Details

Type	Action	Date
Review/Revised	Reviewed at UM Quality Oversight Committee	7/21/26