MEDICAL COVERAGE POLICY	
SERVICE:	**Magnetic Sphincter Augmentation (Linx) for GERD**
Policy Number:	**233**
Effective Date:	**12/01/2021**
Last Review:	**10/28/2021**
Next Review Date:	**10/28/2022**

Important note:
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Magnetic Sphincter Augmentation (Linx™) for GERD

PRIOR AUTHORIZATION: No prior authorization requirement.

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for coverage details.

For Medicare plans, please refer to appropriate Medicare LCD (Local Coverage Determination). If there is no applicable LCD, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM

A laparoscopically implanted magnetic esophageal ring (LINX™ Reflux Management System) may be considered medically necessary as a treatment alternative to surgical fundoplication, when the patient has chronic gastroesophageal reflux disease (GERD) symptoms (reflux symptoms that occur two or more times per week) AND are refractory to maximum medical therapy AND do NOT have:

- erosive esophagitis grades C, or D,
- BMI > 35
- Electrical implants or metallic abdominal implants
- Major motility disorders
- Scleroderma
- Esophageal or gastric cancer
- Distal amplitude < 35 mmHg or < 70% peristaltic sequences
- Esophageal stricture or gross anatomic abnormality
- Lactating, pregnant or plan to become pregnant

OVERVIEW:

Magnetic sphincter augmentation (MSA) for the treatment of GERD uses a surgical device (LINX Reflux Management System; Torax Medical Inc.) as a minimally invasive alternative to fundoplication. The MSA device consists of an expandable, bracelet of magnetic titanium beads linked together. When implanted around the distal esophagus at the gastroesophageal junction, magnetic forces attract the beads to each another, holding the junction closed. Unlike fundoplication, minimal dissection is required to implant the

MSA. The natural anatomy and innervation of the esophagus are preserved, and the device can be easily removed without damaging the esophagus.

The MSA device is manufactured in sizes from 10 to 18 beads; a laparoscopic sizing tool is introduced through a surgical port to measure the esophagus and determine the proper size. Each bead is independent of the other beads in the device, allowing physiological movement of the esophagus without tension. The diameter of the device nearly doubles when the beads are maximally separated.

Implantation requires approximately 30 minutes and may be performed on an outpatient basis. Patients can immediately begin a normal diet and discontinue use of PPIs.

The available medical literature is of low quality with all having significant methodological limitations such as small sample sizes; high attrition; retrospective nonrandomized study designs. The evidence suggests that treatment with MSA consistently improves symptoms of GERD in patients with PPI-refractory GERD. However, there is substantial inconsistency among studies comparing MSA with the current standard surgical treatment, laparoscopic Nissen fundoplication. Substantial uncertainty also remains regarding the long-term safety and comparative effectiveness of MSA due to the lack of rigorous, comparative trials of this technology.

Mixed evidence from comparative studies suggests that MSA may be a viable alternative to Nissen fundoplication; however, substantial uncertainty exists: dysphagia was a common adverse event, available studies all have significant methodological limitations, optimal patient selection criteria for MSA as treatment for GERD has not been established. On the other hand, a majority of patients (87% to 93%) generally reported satisfaction with MSA.

The National Institute for Health and Care Excellence (NICE) updated its Interventional Procedure Guidance for this procedure in 2017:

1.1 There are no major safety concerns about laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease (GORD). There is limited evidence of short-term efficacy, but evidence of long-term efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to do laparoscopic insertion of a magnetic titanium ring for GORD should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's long-term efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having the procedure (see section 7.1).

1.3 This procedure should only be done by a clinician trained in upper gastrointestinal laparoscopy and with expertise in plication procedures.

1.4 NICE encourages further research into laparoscopic insertion of a magnetic titanium ring for GORD, and may update the guidance on publication of further evidence. Long-term outcome data and comparative trials with other anti-reflux surgery would be helpful.

The American College of Gastroenterology published this statement in the web-based management guidelines: “Sphincter augmentation using the LINX Reflux system constructed of titanium beads has shown efficacy up to 4 years in the reduction of the amount of pathologic esophageal acid exposure in a

small number of subjects (99). This device has been approved by the FDA based on a clinical study in 100 GERD patients. This study found that performance of LINX resulted in consistent symptom relief and pH control with markedly fewer side effects than traditional laparoscopic fundoplication in well-selected patients. More data are required before widespread usage can be recommended."

MANDATES:

CODES:

Important note:
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	43284 - Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), 43285 - Removal of esophageal sphincter augmentation device
CPT Not Covered:	
ICD10 codes:	K21.0 Gastro-esophageal reflux disease with esophagitis K21.9 Gastro-esophageal reflux disease without esophagitis
ICD10 Not covered:	

CMS: There are no applicable NCDs or LCDs.

POLICY HISTORY:

Status	Date	Action
New	03/28/2017	New policy
Reviewed	02/27/2018	Changed status to medically necessary without PA
Reviewed	07/25/2019	Updated Overview
Reviewed	09/24/2020	Re-formatted for SWHP/FirstCare
Reviewed	10/28/2021	Removed hiatal hernia restriction

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP/FirstCare will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP/FirstCare so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

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2. Ganz RA, Edmundowicz SA, Taiganides PA, et al. Long-term outcomes of patients receiving a magnetic sphincter augmentation device for gastroesophageal reflux. Clin Gastroenterol Hepatol. 2015. Epub June 1, 2015. Available at: http://www.cghjournal.org/article/S1542-3565%2815%2900763-6/abstract. Accessed December 8, 2015.

3. Louie BE, Farivar AS, Shultz D, Brennan C, Vallières E, Aye RW. Short-term outcomes using magnetic sphincter augmentation versus Nissen fundoplication for medically resistant gastroesophageal reflux disease. Ann Thorac Surg. 2014;98(2):498-504; discussion 504-505.
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5. Riegler M, Schoppman SF, Bonavina L, Ashton D, Horbach T, Kemen M. Magnetic sphincter augmentation and fundoplication for GERD in clinical practice: one-year results of a multicenter, prospective observational study. Surg Endosc. 2015;29(5):1123-1129.
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8. National Institute for Health and Clinical Excellence (NICE). Laparoscopic insertion of a magnetic bead band for gastro-oesophageal reflux disease. Interventional Procedures Guidance 431. London, UK: NICE; September 2012.
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10. American College of Gastroenterology: Guideline/Diagnosis and Management of Gastroesophageal Reflux Disease. http://gi.org/guideline/diagnosis-and-managemen-of-gastroesophageal-reflux-disease/ Viewed 3/33/2017.
11. Rona et al. Hiatal hernia recurrence following magnetic sphincter augmentation and posterior cruroplasty: intermediate-term outcomes. Surg Endosc. 2018 Jul;32(7):3374-3379.
12. Dunn et al. Regression of Barrett's esophagus after magnetic sphincter augmentation: intermediate-term results. Surg Endosc. 2020 Oct 8. Online ahead of print.
13. Buckley FP et al. Favorable results from a prospective evaluation of 200 patients with large hiatal hernias undergoing LINX magnetic sphincter augmentation. Surg Endosc. 2018 Apr;32(4):1762-1768.