MEDICAL COVERAGE POLICY

SERVICE:	**Magnetic Sphincter Augmentation (Linx) for GERD**
Policy Number:	**233**
Effective Date:	**05/01/2024**
Last Review:	**04/08/2024**
Next Review:	**04/08/2025**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business.*
Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.

SERVICE: Magnetic Sphincter Augmentation (LinxTM) for GERD

PRIOR AUTHORIZATION: No prior authorization requirement.

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

Note: Unless otherwise indicated (see below), this policy will apply to all lines of business.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). Check for local coverage guidance. Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use the criteria set forth below.

(Although there are no applicable NCDs or TX LCDs, there is a non-Texas LCD L35080 Minimally Invasive GERD Procedures which states that the LINX and similar procedures are not covered for GERD for that jurisdiction.)

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM). If there are no applicable criteria to guide medical necessity decision making in the TMPPM, use the criteria set forth below.

BSWHP may consider a laparoscopically implanted magnetic esophageal ring (LINX Reflux Management System) medically necessary as a treatment alternative to surgical fundoplication when **ALL** of the following criteria are met:

1. The member has chronic gastroesophageal reflux disease (GERD) symptoms that occur two or more times per week; **AND**
2. Are refractory to maximum medical therapy; **AND**
3. **DO NOT** have **ANY** of the following:
   a. Erosive esophagitis grades C or D
   b. BMI > 35
   c. Electrical implants or metallic abdominal implants
   d. Major motility disorders
   e. Scleroderma
   f. Esophageal or gastric cancer

g. Distal amplitude < 35 mmHg or < 70% peristaltic sequences
h. Esophageal stricture or gross anatomic abnormality
i. Lactating, pregnant or plan to become pregnant

BACKGROUND:

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 GERD 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: None

CODES:

Important note:
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	

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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
Reviewed	10/27/2022	Formatting changes, added hyperlinks to NCD and TMPPM, beginning and ending note sections updated to align with CMS requirements and business entity changes.
Reviewed	04/08/2024	Added language to utilize this policy for all lines of business unless otherwise indicated. Corrected the “For Medicaid Plans” section to utilize this Medical Policy if TMPPM does not have medical necessity guidance.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP 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 BSWHP 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.

1. Bonavina L, Saino G, Bona D, Sironi A, Lazzari V. One hundred consecutive patients treated with magnetic sphincter augmentation for gastroesophageal reflux disease: 6 years of clinical experience from a single center. J Am Coll Surg. 2013b;217(4):577-585.
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.
4. Reynolds JL, Zehetner J, Wu P, Shah S, Bildzukewicz N, Lipham JC. Laparoscopic magnetic sphincter augmentation vs laparoscopic Nissen fundoplication: a matched-pair analysis of 100 patients. J Am Coll Surg. 2015a;221(1):123-128.
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.
6. Saino G, Bonavina L, Lipham JC, Dunn D, Ganz RA. Magnetic sphincter augmentation for gastroesophageal reflux at 5 years: final results of a pilot study show long-term acid reduction and symptom improvement. J Laparoendosc Adv Surg Tech A. 2015;25(10):787-792.

7. Society of American Gastrointestinal and Endoscopic Surgeons, "Linx Reflux Management System" https://www.sages.org/wiki/linx-reflux-management-system/ viewed 3/2/2017.
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.Dunn et al. Regression of Barrett's esophagus after magnetic sphincter augmentation: intermediate-term results. Surg Endosc. 2020 Oct 8. Online ahead of print.
12. 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.

***Note**:*
Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs.