Letter to Insurance carriers regarding: Insurance coverage for the LINX® Reflux Management System procedure for gastroesophageal reflux disease.

Dear Medical Director,

INTRODUCTION*:* Gastroesophageal reflux disease (GERD) is one of the most common medical conditions in the United States, affecting millions of patients. The impact of this disease burden is significant for patients, payors and the healthcare community. Nissen fundoplication has been considered the "gold standard" for the surgical treatment of GERD. There are now innovative surgical options for patients suffering from GERD which have been proven to be safe and effective.

LINX™ DEVICE DESCRIPTION: LINX is a first line, minimally invasive surgical treatment option for GERD. LINX is indicated for patients diagnosed with GERD as defined by abnormal pH testing, and who are seeking an alternative to continuous acid suppression therapy (i.e. proton pump inhibitors or histamine-2 receptor antagonists) in the management of their GERD. Furthermore, based on recent evidence, FDA updated the IFU precaution in 2018 to establish effectiveness of LINX in patients with hiatal hernia > 3 cm.

EVIDENCE: The first LINX device was implanted in 2007 and FDA approval occurred five years later in March 2012 as a premarket approved device (PMA) which required both Feasibility and Pivotal clinical trials approved by FDA to establish safety and efficacy defined by prospective primary and secondary efficacy endpoints and safety endpoints. The long-term results of the pivotal study initially published in the New England Journal of Medicine[31] were published in Clinical Gastroenterology and Hepatology.[54] There have been over 30,000 LINX procedures performed worldwide to date.

Currently, the supportive literature for LINX includes more than 100 publications with over fifty peer-reviewed articles which have been published on LINX®. These include 2 randomized controlled trials (RCT),[1,2] 8 meta-analyses/systematic reviews,[4, 8-14] 28 cohort studies on safety and efficacy, [3,5,6, 15-40] 10 non-randomized comparative therapy outcomes studies, [4, 8-14, 42-49] 3 health economic studies,[42, 48, 50] and 3 long-term safety studies (including registries).[4, 51,52] Importantly, the recent RCT, from Bell and colleagues, comparing LINX to twice-daily (BID) PPI patients reported that a statistically significant number of patients experienced improvement in GERD Health-Related Quality of Life (GERD-HRQL) as well as vastly superior relief of moderate-to-severe regurgitation (89% Linx vs 10% double-dose PPI, $p<0.001$).[2] The Ferrari et al study published in 2020 is the longest clinical published experience study on LINX to date, which followed patients with LINX over a 6-12 year period and shows that LINX provides effective long-term control of GERD, eliminating the need for daily reflux medications in 79% of patients and significantly improving their quality of life. Importantly, there were very few device related complications among the patients in the study. Patient satisfaction was 93.8% after 10 years. [3]

In appropriately selected patients, LINX is as effective as laparoscopic fundoplication for the treatment and control of GERD. There are certain features of LINX which may be advantageous in certain patients, specifically due to lower rates of gas bloat. The two most recent meta-analyses summarized up to 7 studies and 1,211 patients and found no differences in GERD-HRQL, postoperative PPI use,

dysphagia, or reoperation between LINX® and LNF.[4,10] Both studies demonstrated an advantage with LINX® in preserving the ability to belch and vomit and incurring less gas bloat.

Given the high prevalence and broad impact of GERD in the population, it is imperative that we have multiple treatments at our disposal. There is no single treatment that will work effectively across the spectrum of patients that are affected by this disease. For patients that are not well controlled with medical therapy, surgical options are critical. Fundoplication alone is not adequate to meet the needs of all of these patients. The LINX device and procedure represent an important and necessary addition to our armamentarium for the treatment of patients with GERD.

REIMBURSEMENT: The LINX procedure was granted a Category 1 CPT code by the CPT Editorial Panel of AMA based on strong clinical data and with broad multi-specialty support including the Society of American Gastrointestinal and Endoscopic Surgeon (SAGES), the American College of Surgeons (ACS). The most recent analysis by SAGES states: "implantation of the LINX device should be covered and reimbursed by insurance for appropriate patients". [53]

The American Foregut Society (AFS) Board has concluded that there are sufficient data supporting LINX as a safe and effective treatment option in appropriately selected patients. The literature clearly supports that LINX should no longer be considered as investigational or experimental. We believe that ensuring patient access to safe and effective treatments for disease is a policy imperative, and coverage should be extended for this procedure by all payor entities.

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Source list

1. Bell R, Lipham J, Louie B, et al. Laparoscopic magnetic sphincter augmentation versus double-dose proton pump inhibitors for management of moderate-to-severe regurgitation in GERD: a randomized controlled trial. *Gastrointest Endosc.* 2019;89(1):14-22, e11.
2. Bell R, Lipham J, Louie BE, et al. Magnetic Sphincter Augmentation Superior to Proton Pump Inhibitors for Regurgitation in a 1-year Randomized Trial. *Clin Gastroenterol Hepatol.* 2019
3. Ferrari D, Asti E, Lazzari V, Siboni S, Bernardi D, Bonavina L. Six to 12-year outcomes of magnetic sphincter augmentation for gastroesophageal reflux disease. *Sci Rep.* 2020;10(1):13753.
4. Guidozzi N, Wiggins T, Ahmed AR, Hanna GB, Markar SR. Laparoscopic magnetic sphincter augmentation versus fundoplication for gastroesophageal reflux disease: systematic review and pooled analysis. *Dis Esophagus.* 2019
5. Buckley FP, 3rd, Bell RCW, Freeman K, Doggett S, Heidrick R. Favorable results from a prospective evaluation of 200 patients with large hiatal hernias undergoing LINX®magnetic sphincter augmentation. *Surg Endosc.* 2018;32(4):1762-1768.
6. Ayazi S, Zheng P, Zaidi AH, et al. Magnetic Sphincter Augmentation and Postoperative Dysphagia: Characterization, Clinical Risk Factors, and Management. *J Gastrointest Surg.* 2019.
7. Warren HF, Reynolds JL, Lipham JC, et al. Multi-institutional outcomes using magnetic sphincter augmentation versus Nissen fundoplication for chronic gastroesophageal reflux disease. *Surg Endosc.* 2016;30(8):3289-3296.
8. Skubleny D, Switzer NJ, Dang J, et al. LINX®((R)) magnetic esophageal sphincter augmentation versus Nissen fundoplication for gastroesophageal reflux disease: a systematic review and meta-analysis. *Surg Endosc.* 2017;31(8):3078-3084.
9. Chen MY, Huang DY, Wu A, et al. Efficacy of Magnetic Sphincter Augmentation versus Nissen Fundoplication for Gastroesophageal Reflux Disease in Short Term: A Meta-Analysis. *Can J Gastroenterol Hepatol.* 2017;2017:9596342.
10. Aiolfi A, Asti E, Bernardi D, et al. Early results of magnetic sphincter augmentation versus fundoplication for gastroesophageal reflux disease: Systematic review and meta-analysis. *Int J Surg.* 2018;52:82-88.
11. Stanak M, Erdos J, Hawlik K, Birsan T. Novel Surgical Treatments for Gastroesophageal Reflux Disease: Systematic Review of Magnetic Sphincter Augmentation and Electric Stimulation Therapy. *Gastroenterology Res.* 2018;11(3):161-173.
12. Riva CG, Asti E, Lazzari V, Aquilino K, Siboni S, Bonavina L. Magnetic Sphincter Augmentation After Gastric Surgery. *JSLS.* 2019;23(4).
13. Kirkham EN, Main BG, Jones KJB, Blazeby JM, Blencowe NS. Systematic review of the introduction and evaluation of magnetic augmentation of the lower oesophageal sphincter for gastro-oesophageal reflux disease. *Br J Surg.* 2020;107(1):44-55.
14. Schizas D, Mastoraki A, Papoutsi E, et al. LINX®((R)) reflux management system to bridge the "treatment gap" in gastroesophageal reflux disease: A systematic review of 35 studies. *World J Clin Cases.* 2020;8(2):294-305.
15. Ayazi S, Chowdhury N, Zaidi AH, et al. Magnetic sphincter augmentation (MSA) in patients with hiatal hernia: clinical outcome and patterns of recurrence. *Surg Endosc.* 2019.
16. Rona KA, Tatum JM, Zehetner J, et al. Hiatal hernia recurrence following magnetic sphincter augmentation and posterior cruroplasty: intermediate-term outcomes. *Surg Endosc.* 2018;32(7):3374-3379.
17. 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.
18. Louie BE, Smith CD, Smith CC, et al. Objective Evidence of Reflux Control After Magnetic Sphincter Augmentation: One Year Results From a Post Approval Study. *Ann Surg.* 2019;270(2):302-308.
19. 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. f*2013;217(4):577-585.
20. Bonavina L, Saino GI, Bona D, et al. Magnetic augmentation of the lower esophageal sphincter: results of a feasibility clinical trial. *J Gastrointest Surg.* 2008;12(12):2133-2140.
21. Smith CD, DeVault KR, Buchanan M. Introduction of mechanical sphincter augmentation for gastroesophageal reflux disease into practice: early clinical outcomes and keys to successful adoption. *J Am Coll Surg.* 2014;218(4):776-781.
22. Reynolds JL, Zehetner J, Bildzukewicz N, Katkhouda N, Dandekar G, Lipham JC. Magnetic sphincter augmentation with the LINX® device for gastroesophageal reflux disease after U.S. Food and Drug Administration approval. *Am Surg.* 2014;80(10):1034-1038.
23. Warren HF, Brown LM, Mihura M, Farivar AS, Aye RW, Louie BE. Factors influencing the outcome of magnetic sphincter augmentation for chronic gastroesophageal reflux disease. *Surg Endosc.* 2018;32(1):405-412.
24. Prakash D, Campbell B, Wajed S. Introduction into the NHS of magnetic sphincter augmentation: an innovative surgical therapy for reflux - results and challenges. *Ann R Coll Surg Engl.* 2018;100(4):251-256.
25. Schwameis K, Nikolic M, Morales Castellano DG, et al. Results of Magnetic Sphincter Augmentation for Gastroesophageal Reflux Disease. *World J Surg.* 2018;42(10):3263-3269.
26. Schwameis K, Nikolic M, Castellano DGM, et al. Crural Closure improves Outcomes of Magnetic Sphincter Augmentation in GERD patients with Hiatal Hernia. *Sci Rep.* 2018;8(1):7319.
27. Kuckelman JP, Phillips CJ, Derickson MJ, Faler BJ, Martin MJ. Esophageal Magnetic Sphincter Augmentation as a Novel Approach to Post-bariatric Surgery Gastroesophageal Reflux Disease. *Obes Surg.* 2018;28(10):3080-3086.
28. Antiporda M, Jackson C, Smith CD, Bowers SP. Short-Term Outcomes Predict Long-Term Satisfaction in Patients Undergoing Laparoscopic Magnetic Sphincter Augmentation. *J Laparoendosc Adv Surg Tech A.* 2019;29(2):198-202.
29. Irribarra MM, Blitz S, Wilshire CL, et al. Does Treatment of the Hiatus Influence the Outcomes of Magnetic Sphincter Augmentation for Chronic GERD? *J Gastrointest Surg.* 2019;23(6):1104-1112.
30. Tatum JM, Alicuben E, Bildzukewicz N, Samakar K, Houghton CC, Lipham JC. Minimal versus obligatory dissection of the diaphragmatic hiatus during magnetic sphincter augmentation surgery. *Surg Endosc.* 2019;33(3):782-788.

31. Ganz RA, Peters JH, Horgan S. Esophageal sphincter device for gastroesophageal reflux disease. *N Engl J Med.* 2013;368(21):2039-2040.
32. Schwameis K, Schwameis M, Zorner B, et al. Modern GERD treatment: feasibility of minimally invasive esophageal sphincter augmentation. *Anticancer Res.* 2014;34(5):2341-2348.
33. Ward MA, Ebrahim A, Kopita J, et al. Magnetic sphincter augmentation is an effective treatment for atypical symptoms caused by gastroesophageal reflux disease. *Surg Endosc.* 2019.
34. Czosnyka NM, Buckley FP, Doggett SL, et al. Outcomes of magnetic sphincter augmentation - A community hospital perspective. *The American Journal of Surgery.* 2017;213(6):1019-1023.
35. Lipham JC, DeMeester TR, Ganz RA, et al. The LINX® reflux management system: confirmed safety and efficacy now at 4 years. *Surgical Endoscopy.* 2012;26(10):2944-2949.
36. Desart K, Rossidis G, Michel M, Lux T, Ben-David K. Gastroesophageal Reflux Management with the LINX®(R) System for Gastroesophageal Reflux Disease Following Laparoscopic Sleeve Gastrectomy. *J Gastrointest Surg.* 2015;19(10):1782-1786.
37. Riva CG, Siboni S, Sozzi M, Barbieri LA, Ogliari C, Bonavina L. High-Resolution Manometric Findings after Magnetic Sphincter Augmentation. *Neurogastroenterology & Motility.* 2019;31(S1):e13750.
38. Hawasli A, Sadoun M, Meguid A, Dean M, Sahly M, Hawasli B. Laparoscopic placement of the LINX®((R)) system in management of severe reflux after sleeve gastrectomy. *Am J Surg.* 2019;217(3):496-499.
39. Broderick RC, Smith CD, Cheverie JN, et al. Magnetic sphincter augmentation: a viable rescue therapy for symptomatic reflux following bariatric surgery. *Surg Endosc.* 2019.
40. Lipham JC, Taiganides PA, Louie BE, Ganz RA, DeMeester TR. Safety analysis of first 1000 patients treated with magnetic sphincter augmentation for gastroesophageal reflux disease. *Dis Esophagus.* 2015;28(4):305-311.
41. 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.* 2015;221(1):123-128.
42. Reynolds JL, Zehetner J, Nieh A, et al. Charges, outcomes, and complications: a comparison of magnetic sphincter augmentation versus laparoscopic Nissen fundoplication for the treatment of GERD. *Surg Endosc.* 2016;30(8):3225-3230.
43. 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.
44. Sheu EG, Nau P, Nath B, Kuo B, Rattner DW. A comparative trial of laparoscopic magnetic sphincter augmentation and Nissen fundoplication. *Surg Endosc.* 2015;29(3):505-509.
45. Asti E, Bonitta G, Lovece A, Lazzari V, Bonavina L. Longitudinal comparison of quality of life in patients undergoing laparoscopic Toupet fundoplication versus magnetic sphincter augmentation: Observational cohort study with propensity score analysis. *Medicine (Baltimore).* 2016;95(30):e4366.
46. Richards WO, McRae C. Comparative Analysis of Laparoscopic Fundoplication and Magnetic Sphincter Augmentation for the Treatment of Medically Refractory GERD. *Am Surg.* 2018;84(11):1762-1767.
47. Bonavina L, Horbach T, Schoppmann SF, DeMarchi J. Three-year clinical experience with magnetic sphincter augmentation and laparoscopic fundoplication. *Surg Endosc.* 2020.
48. Ayazi S, Zaidi AH, Zheng P, et al. Comparison of surgical payer costs and implication on the healthcare expenses between laparoscopic magnetic sphincter augmentation (MSA) and laparoscopic Nissen fundoplication (LNF) in a large healthcare system. *Surg Endosc.* 2019.
49. Nikolic M, Schwameis K, Paireder M, et al. Tailored modern GERD therapy - steps towards the development of an aid to guide personalized anti-reflux surgery. *Sci Rep.* 2019;9(1):19174.
50. Pandolfino J, Lipham J, Chawla A, Ferko N, Hogan A, Qadeer RA. A budget impact analysis of a magnetic sphincter augmentation device for the treatment of medication-refractory mechanical gastroesophageal reflux disease: A United States payer perspective. *Surg Endosc.* 2019.
51. Alicuben ET, Bell RCW, Jobe BA, et al. Worldwide Experience with Erosion of the Magnetic Sphincter Augmentation Device. *J Gastrointest Surg.* 2018;22(8):1442-1447.68.
52. Smith CD, Ganz RA, Lipham JC, Bell RC, Rattner DW. Lower Esophageal Sphincter Augmentation for Gastroesophageal Reflux Disease: The Safety of a Modern Implant. *J Laparoendosc Adv Surg Tech A.* 2017;27(6):586-591.
53. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). SAGES Technology and Value Assessment Committee (TAVAC) Safety and Effectiveness Analysis: LINX® Reflux Management System (Torax Medical, Inc.). In: SAGES LINX® Safety and Effectiveness Analysis Committee, ed2017.
54. Ganz RA, Edmundowicz SA, Taganides PA, et al. Long-term outcomes of patients receiving a magnetic sphincter augmentation device for gastroesophageal reflux. Clin Gastroenterol Hepatol 2016;14:671-677.