MEDICAL POLICY

POLICY TITLE	MAGNETIC ESOPHAGEAL SPHINCTER AUGMENTATION TO TREAT GASTROESOPHAGEAL REFLUX DISEASE
POLICY NUMBER	MP-1.145

Original Issue Date (Created):	**2/1/2016**
Most Recent Review Date (Revised):	**12/4/2018**
Effective Date:	**2/1/2019**

I. POLICY

Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:
MP 2.053 – Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.137 Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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GASTROESOPHAGEAL REFLUX DISEASE

Gastroesophageal reflux disease (GERD) is defined as reflux of stomach acid into the esophagus that causes symptoms and/or mucosal injury. GERD is a common medical disorder, with

estimates of 10% to 20% prevalence in developed countries. The severity of GERD varies widely. Many patients have mild, intermittent symptoms that do not require treatment or only require episodic use of medications. Other patients have chronic, severe GERD that can lead to complications such as Barrett esophagus and esophageal cancer.

Treatment

For patients with severe disease, chronic treatment with acid blockers is an option. For some patients, medications are not adequate to control symptoms; other patients prefer to avoid the use of indefinite, possibly lifelong medications. Surgical treatments are available for these patients, primarily a Nissen fundoplication performed either laparoscopically or by open surgery. A number of less invasive procedures are also being evaluated as an intermediate option between medical therapy and surgery.

The LINX™ Reflux Management System (Torax Medical) is composed of a small flexible band of 10 to 18 interlinked titanium beads with magnetic cores. Using standard laparoscopic techniques, the band is placed around the esophagus at the level of the gastroesophageal junction. The magnetic attraction between the beads is intended to augment the lower esophageal sphincter to prevent gastric reflux into the esophagus, without compressing the esophageal wall. It is proposed that swallowing food or liquids creates sufficient pressure to overcome the magnetic bond between the beads, allowing the beads to separate and temporarily increase the size of the ring. The target population is patients who have GERD symptoms despite maximum medical therapy (e.g., proton pump inhibitors) but who do not want to risk the adverse effects of a surgical procedure like Nissen fundoplication. Adverse events of the LINX™ Reflux Management System may include dysphagia or odynophagia. The device can be removed by a laparoscopic procedure if severe adverse events occur or if magnetic resonance imaging is needed for another condition.

Regulatory Status

In 2012, the LINX™ Reflux Management System (Torax Medical, Shoreview, MN) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for patients diagnosed with gastroesophageal reflux disease (GERD), as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximum therapy for the treatment of reflux. FDA initially required 5-year follow-up of 100 patients from the investigational device exemption pivotal study to evaluate safety and efficacy of the device, which was completed in March 2016. FDA product code: LEI.

IV. RATIONALE

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SUMMARY OF EVIDENCE

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For individuals who have GERD who receive MSA, the evidence includes prospective and retrospective observational comparative studies, 2 single-arm interventional trials, and a number of single-arm observational studies. Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. In the 2 single-arm, uncontrolled manufacturer-sponsored studies submitted to the U.S. Food and Drug Administration with materials for device approval, subjects showed improvements in GERD-HRQL scores and reduced proton pump inhibitor use. Similarly, observational comparative studies, most often comparing MSA with laparoscopic Nissen fundoplication, generally have shown that GERD-HRQL scores do not differ significantly between fundoplication and MSA, and patients can reduce proton pump inhibitor use after MSA. However, the comparative studies are retrospective and nonrandomized, may be affected by selection bias, and the subjective outcome measures used in these studies (e.g., the GERD-HRQL scores) may be biased. A randomized trial is in progress (NCT02505945); it will compare treatment with the MSA and treatment with double-dose proton pump inhibitors. Randomized comparisons of MSA with laparoscopic Nissen fundoplication are also needed to evaluate the relative risk-benefit of these 2 procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered:

CPT Codes®								
43284	43285							

IX. REFERENCES

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1. *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. Aug 2016; 30(8):3289-3296. PMID 26541740*
2. *Asti E, Bonitta G, Lovece A, et al. 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). Jul 2016;95(30):e4366. PMID 27472725*
3. *Reynolds JL, Zehetner J, Wu P, et al. Laparoscopic magnetic sphincter augmentation vs laparoscopic nissen fundoplication: a matched-pair analysis of 100 patients. J Am Coll Surg. Jul 2015;221(1):123-128. PMID 26095560*
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6. *Riegler M, Schoppman SF, Bonavina L, et al. Magnetic sphincter augmentation and fundoplication for GERD in clinical practice: one-year results of a multicenter, prospective observational study. Surg Endosc. May 2015;29(5):1123-1129. PMID 25171881*
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10. *Ganz RA, Peters JH, Horgan S, et al. Esophageal sphincter device for gastroesophageal reflux disease. N Engl J Med. Feb 21 2013;368(8):719-727. PMID 23425164*
11. *Saino G, Bonavina L, Lipham JC, et al. 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. Oct 2015;25(10):787-792. PMID 26437027*
12. *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. May 2016;14(5):671-677. PMID 26044316*
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14. *Lipham JC, Taiganides PA, Louie BE, et al. Safety analysis of first 1000 patients treated with magnetic sphincter augmentation for gastroesophageal reflux disease. Dis Esophagus. Mar 11 2015;28(4):305-311. PMID 24612509*
15. *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. Apr 2014;218(4):776-781. PMID 24529809*
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21. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.137, Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease. November 2018*

X. POLICY HISTORY

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MP-1.145	**CAC 9/29/15** New policy. BCBSA adopted. An implantable magnetic esophageal ring to treat gastroesophageal reflux disease is considered investigational. FEP variation added. No Medicare variation. Coding added.
	Admin update 12/5/16: Product variation section reformatted. **Admin update 1/1/17:** New codes 43284, 43285 added and end dated codes 0392T, 0393T removed; effective 1/1/17.
	CAC 1/31/17 Minor review Name change from "Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease" to " Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease." No change to policy statements. References and rationale updated. Coding reviewed.
	12/19/17 Consensus review. No change to the policy statement. Rationale updated and references reviewed. FEP variation revised to refer to the FEP medical policy manual.
	12/4/18 Consensus. No change to policy statements. Background and references reviewed. Rationale condensed.

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