MEDICAL POLICY

POLICY TITLE	PROCEDURES FOR THE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE (FORMERLY SURGICAL TREATMENTS FOR GASTROESOPHAGEAL REFLUX DISEASE)
POLICY NUMBER	MP 2.053

Effective Date:	5/1/2023

I. POLICY

Magnetic sphincter augmentation (LINX device) may be considered **medically necessary** for the treatment of gastroesophageal reflux disease (GERD) when **ALL** of the following are met:

- Presence of typical GERD symptoms (i.e. heartburn, regurgitation, difficulty swallowing, chest pain)
- Abnormal pH study
- Failed medical management with PPI for at least 8 – 12 weeks
- BMI < 35 kg/m^2
- Absence of large hiatal hernia (> 3 cm) or severe esophagitis

Transoral incisionless fundoplication (TIF) [e.g., EsophyX; MUSE] may be considered **medically necessary** for the treatment of GERD when **ALL** of the following are met:

- Age 18 or older
- Daily symptomatic GERD symptoms that have failed to resolve after 6 months of medical therapy
- Absence of erosive esophagitis, or low-grade erosive esophagitis (Grades A or B)
- Absence of, or small hiatal hernia (<2 cm)
    - A hiatal hernia greater than 2 cm must be repaired prior to or simultaneously with TIF procedure
- No history of Barrett's esophagus

Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (i.e., Stretta procedure) is considered **investigational** as a treatment of GERD. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., polymethylmethacrylate beads, zirconium oxide spheres) is considered **investigational** as a treatment of GERD. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

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Cross-references:

MP 1.118 Endoscopic Radiofrequency Ablation or Cryoablation for Barrett's Esophagus

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual. 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 a common disorder characterized by heartburn and other symptoms related to reflux of stomach acid into the esophagus. Nearly all individuals experience such symptoms at some point in their lives; a smaller number have chronic symptoms and are at risk for complications of GERD. The prevalence of GERD has been estimated to be 10% to 20% in the Western world, with a lower prevalence in Asia. GERD is objectively defined by the presence of characteristic mucosal injury seen at endoscopy and/or abnormal esophageal acid exposure demonstrated on a reflux monitoring study

Pathophysiology

The pathophysiology of GERD involves excessive exposure to stomach acid, which occurs for several reasons. There can be an incompetent barrier between the esophagus and stomach, either due to dysfunction of the lower esophageal sphincter or incompetence of the diaphragm. Another mechanism is abnormally slow clearance of stomach acid. In this situation, delayed clearance leads to an increased reservoir of stomach acid and a greater tendency to reflux.

In addition to troubling symptoms, some patients will have a more serious disease, which results in complications such as erosive esophagitis, dysphagia, Barrett's esophagus, and esophageal carcinoma. Pulmonary complications may result from aspiration of stomach acid into the lungs and can include asthma, pulmonary fibrosis, and bronchitis, or symptoms of chronic hoarseness, cough, and sore throat.

Treatment

Guidelines on the management of GERD emphasize initial medical management. Weight loss, smoking cessation, head of the bed elevation, and elimination of food triggers are all recommended in recent practice guidelines. Proton pump inhibitors have been shown to be the most effective medical treatment. In a Cochrane systematic review, van Pinxteren et al (2010)

reported that proton pump inhibitors demonstrated superiority to H_2-receptor agonists and prokinetics in both network meta-analyses and direct comparisons.

Surgical Treatment
The most common surgical procedure used for GERD is laparoscopic Nissen fundoplication; however, the utilization of this procedure steadily declined between 2009 and 2013 with the advancement of novel nonmedical (endoscopic and surgical) techniques. Fundoplication involves wrapping a portion of the gastric fundus around the distal esophagus to increase lower esophageal sphincter pressure. If a hiatal hernia is present, the procedure also restores the position of the lower esophageal sphincter to the correct location. Laparoscopic fundoplication was introduced in 1991 and has been rapidly adopted because it avoids complications associated with an open procedure.

Although fundoplication results in a high proportion of patients reporting symptom relief, complications can occur, and sometimes require conversion to an open procedure. Patients who have relief of symptoms of GERD after fundoplication may have dysphagia or gas-bloat syndrome (excessive gastrointestinal gas).

Other Treatment Options
Due in part to the high prevalence of GERD, there has been interest in creating a minimally invasive transesophageal therapeutic alternative to open or laparoscopic fundoplication or chronic medical therapy. This type of procedure may be considered natural orifice transluminal surgery. Three types of procedures have been investigated.

- Transesophageal endoscopic gastroplasty (gastroplication, transoral incisionless fundoplication) can be performed as an outpatient procedure. During this procedure, the fundus of the stomach is folded and then held in place with staples or fasteners that are deployed by the device. The endoscopic procedure is designed to recreate a valve and barrier to reflux.
- Radiofrequency energy has been used to produce submucosal thermal lesions at the gastroesophageal junction (this technique has also been referred to as the Stretta procedure.) Specifically, radiofrequency energy is applied through four electrodes inserted into the esophageal wall at multiple sites both above and below the squamocolumnar junction. The mechanism of action of the thermal lesions is not precisely known but may be related to ablation of the nerve pathways responsible for sphincter relaxation or may induce a tissue-tightening effect related to heat-induced collagen contraction and fibrosis.
- Submucosal injection or implantation of a prosthetic or bulking agent to enhance the volume of the lower esophageal sphincter has also been investigated. One bulking agent, pyrolytic carbon-coated zirconium oxide spheres (Durasphere), is being evaluated. The Gatekeeper™ Reflux Repair System (Medtronic) uses a soft, pliable, expandable prosthesis made of a polyacrylonitrile-based hydrogel. The prosthesis is implanted into the esophageal submucosa, and with time, the prosthesis absorbs water

and expands, creating bulk in the region of implantation. However, as the only identified RCT was terminated early due to lack of efficacy and it was voluntarily withdrawn by the manufacturer. Endoscopic submucosal implantation of polymethylmethacrylate beads into the lower esophageal folds has also been investigated

The Agency for Healthcare Research and Quality published a systematic review of management strategies for GERD in 2005, which was updated by Ip et al (2011). The 2005 comparative effectiveness review evaluated studies on the EndoCinch Suturing System, Stretta, Enteryx, and the NDO Plicator. The 2011 update excluded Enteryx and the NDO Plicator, because they were no longer available in the United States, and added the EsophyX procedure (endoscopic fundoplication), which was commercialized after the 2005 review. The 2011 report concluded that, for the 3 available endoscopic procedures (EndoCinch, Stretta, EsophyX), effectiveness remained substantially uncertain for the long-term management of GERD. All procedures have been associated with complications, including dysphagia, infection/fever, and bloating, although bloating and dsyphagia are also adverse events of laparoscopic fundoplication. A review of endoscopic treatment of GERD by Hummel and Richards (2015) noted that EndoCinch is no longer manufactured.

The LINX™ Reflux Management System 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.

The American College of Gastroenterology

The ACG put forth the following recommendations for surgical and endoscopic options for GERD:

- We recommend antireflux surgery performed by an experienced surgeon as an option for long-term treatment of patients with objective evidence of GERD, especially those who have severe reflux esophagitis (LA grades C or D), large hiatal hernias, and/or persistent, troublesome GERD symptoms. (Strong recommendation, moderate level of evidence)
- We recommend consideration of magnetic sphincter augmentation (MSA) as an alternative to laparoscopic fundoplication for patients with regurgitation who fail medical management. (Strong recommendation, moderate level of evidence)

- We suggest consideration of Roux-en-Y gastric bypass (RYGB) as an option to treat GERD in obese patients who are candidates for this procedure and who are willing to accept its risks and requirements for lifestyle alterations. (Conditional recommendation, low level of evidence)
- Since data on the efficacy of radiofrequency energy (Stretta) as an antireflux procedure is inconsistent and highly variable, we cannot recommend its use as an alternative to medical or surgical antireflux therapies. (Conditional recommendation, low level of evidence)
- We suggest consideration of transoral incisionless fundoplication (TIF) for patients with troublesome regurgitation or heartburn who do not wish to undergo antireflux surgery and who do not have severe reflux esophagitis (Los Angeles grades C or D) or hiatal hernias >2 cm. (Conditional recommendation, low level of evidence)

The Los Angeles Classification of Esophagitis

The endoscopic findings of erosive esophagitis (EE) and Barrett's esophagus are specific for the diagnosis of GERD. The Los Angeles (LA) classification of EE is the most widely used and validated scoring system. Refer to T1 for the LA classification.

T1. The Los Angeles Classification of Erosive Esophagitis

Grade	Description
Grade A	One (or more) mucosal break no longer than 5mm that does not extend between the tops of two mucosal folds
Grade B	One (or more) mucosal break more than 5mm long that does not extend between the tops of top mucosal folds
Grade C	One (or more) mucosal break that is continuous between the tops of two or more mucosal folds but which involve less than 75% of the circumference
Grade D	One (or more) mucosal break with involves at least 75% of the esophageal circumference

Regulatory Status

The EsophyX® (EndoGastric Solutions) is a transesophageal (or transoral) incisionless fundoplication (TIF) device that was originally cleared for marketing by FDA through the 510(k) process om 2007 and has subsequently undergone 2 evolutions: Generation 2=EsophyX2 iterations (E2-Plus, HD) and Generation 3=Z iterations (EZ/ZR, Z+).[8,] Some of the key Regulatory Status changes are summarized herein. In 2007, EsophyX® (EndoGastric Solutions) was cleared for marketing by the FDA through the 510(k) process for full-thickness plication. In 2016, EsophyX® Z Device with SerosaFuse Fasteners was cleared for marketing by FDA through the 510(k) process (K160960) for use in transoral tissue approximation, full-thickness plication, ligation in the gastrointestinal tract, narrowing the gastroesophageal junction, and

reduction of hiatal hernias of 2 cm or less in patients with symptomatic chronic GERD.[9] In June 2017, EsophyX2 HD and the third-generation EsophyX Z Devices with SerosaFuse fasteners and accessories were cleared for marketing by FDA through the 510(k) process (K171307) for expanded indications, including patients who require and respond to pharmacologic therapy and patients with hiatal hernias larger than 2 cm when a laparoscopic hiatal hernia repair reduces a hernia to 2 cm or less.[10] The most recent FDA 510(k) clearance (K172811) occurred in October 2017 for new product specification iterations of EsophyX2 HD and EsophyX Z Devices. This clearance allows for "a moderate increase in the upper limit of the temporary Tissue Mold clamping pressure occurring during each fastener deployment"[11]. FDA product code: ODE.

The Medigus SRS Endoscopic Stapling System (MUSE, Medigus) was cleared for marketing by FDA through the 510(k) process in 2012 (K120299) and 2014 (K132151). MUSE is intended for endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach to create anterior partial fundoplication for treatment of symptomatic chronic GERD in patients who require and respond to pharmacologic therapy. FDA product code: ODE.

In 2000, the CSM Stretta® System was cleared for marketing by FDA through the 510(k) process for general use in the electrosurgical coagulation of tissue and was specifically intended for use in the treatment of GERD. In 2010, Mederi Therapeutics began manufacturing the Stretta® device. Mederi was acquired by Respiratory Technology Corporation in 2018. FDA product code: GEI.

Durasphere® is a bulking agent approved for treatment of urinary and fecal incontinence (see evidence review MP 4.012). Use of this product for esophageal reflux would be considered off-label use. The website of Carbon Medical Technologies states that the Durasphere® GR product is “intended to treat problems associated with GERD” but is considered an investigational device in the United States.

In 2012, the LINX™ Reflux Management System (Torax Medical) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P100049) for patients diagnosed with 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. In 2018, the manufacturer initiated a device recall due to a possible separation of the bead component with the adjacent wire link causing a potential discontinuous or open LINX device. FDA product code: LEI.

In March 2018, the FDA approved an update of the LINX ® Reflux Management System precautions statement, stating that the use of the system "in patients with a hiatal hernia larger than 3 cm should include hiatal hernia repair to reduce the hernia to less than 3 cm and that the LINX Reflux Management System has not been evaluated in patients with an unrepaired hiatal hernia greater than 3 cm, add a hiatal hernia clinical data summary in the instructions for use, update he instructions for use section to highlight the recommendation to repair a hiatal hernia, if present, at the time of the LINX Reflux Management System implantation, and update the

patient information booklet to align with the instructions for use and include 5 year clinical study results."

IV. RATIONALE

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Summary of Evidence

Transesophageal Endoscopic Therapies

For individuals who have GERD and a hiatal hernia of 2 cm or less that is not controlled by PPIs who receive TIF (eg, EsophyX), the evidence includes 2 RCTs comparing TIF with PPI therapy, nonrandomized studies comparing TIF with fundoplication, and case series with longer term follow-up. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The highest quality RCT (RESPECT) was sham-controlled that compared TIF with PPI therapy while the other RCT (TEMPO) compared TIF with maximum PPI therapy. Both trials found a significant benefit of TIF on the primary outcome measure in about 65% of patients. The sham-controlled trial reported improvement in 45% of the sham-controlled group and no benefit on secondary subjective outcome measures. The nonblinded RCT found significant improvements in subjective measures but no difference in objective outcome measures compared with PPI therapy. Together, these trial results would suggest a strong placebo effect of the surgery and a modest benefit of TIF in patients whose symptoms were not controlled by PPIs. For these patients, the most appropriate comparator would be laparoscopic fundoplication. Studies comparing TIF with fundoplication have limitations that include earlier TIF procedures and unbalanced groups at baseline and are inadequate to determine relative efficacy.

For individuals who have GERD and a hiatal hernia of 2 cm or less that is controlled by PPIs who receive TIF (e.g., EsophyX), the evidence includes 2 RCTs and observational studies with longer term follow-up. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. A sham-controlled trial found that the time to resume PPI therapy was longer following TIF and the remission rate was higher, indicating that TIF is more effective than no therapy. The nonblinded RCT found a benefit of TIF compared with continued PPI therapy for subjective measures, but not for the objective measures of pH normalization and esophagitis. These results raise questions about a possible placebo effect for the procedure. Also, observational studies have indicated a loss of treatment effectiveness over time. Adverse events associated with the procedure (e.g., perforation) may be severe. At present, the available evidence does not support the use of this intervention in patients whose symptoms are adequately controlled by medical therapy.

For individuals who have GERD who receive endoscopic radiofrequency energy (e.g., Stretta), the evidence includes 2 meta-analyses, 6 small RCTs, 2 nonrandomized comparative studies, and observational studies with longer-term follow-up. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The RCTs reported some improvements in symptoms and quality of life following treatment with radiofrequency energy compared with sham controls. However, objective measures of GERD

and a meta-analysis of 4 RCTs found no significant improvements in outcomes, raising questions about the mechanism of the symptom relief. Symptom relief and clinical success is reported to be lower than after fundoplication, and reoperations and other severe adverse events greater. Larger RCTs with longer follow-up, preferably compared with fundoplication, are needed to define the risks and benefits of this procedure better. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have GERD who receive esophageal bulking agents, the evidence includes case series. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. High-quality data from large RCTs are needed to compare bulking procedures with both sham controls and with the currently accepted treatments for GERD (i.e., drug therapy, laparoscopic fundoplication). Well-designed trials should use standardized outcome measures to examine whether subjective improvement (e.g., discontinuation of medication therapy, GERD Health-Related Quality of Life scores) is supported by objective improvement (e.g., esophageal acid exposure). The evidence is insufficient to determine the effects of the technology on health outcomes.

Magnetic Esophageal Sphincter Augmentation (MSA)
For individuals who have GERD who receive MSA, the evidence includes one randomized controlled trial comparing MSA to proton pump inhibitor therapy, a single nonrandomized registry study comparing MSA to laparoscopic fundoplication, single-arm cohort studies, and systematic reviews of observational studies comparing MSA to laparoscopic Nissen fundoplication. The relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. A randomized controlled trial comparing MSA to omeprazole 20 mg twice daily found significantly more patients who received MSA reported improvements in symptoms and quality of life at six months. A major limitation of the trial was that the patients had not received optimal medical treatment prior to enrollment. A prospective, observational registry study comparing MSA to laparoscopic fundoplication found similar improvements in QOL, satisfaction, and medication use. Limitations of the study included lack of randomization and blinding, heterogeneity in fundoplication techniques, use of an outdated MSA protocol, and selection bias as patients with less severe symptoms received MSA. In the two single-arm, uncontrolled pivotal trials submitted to the U.S. Food and Drug Administration with materials for device approval, subjects showed improvements in GERD-health-related quality of life scores and reduced proton pump inhibitor use. Similarly, observational comparative studies included in systematic reviews, most often comparing MSA with laparoscopic Nissen fundoplication, generally have shown that GERD-health-related quality of life 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 and may be affected by selection bias. Randomized comparisons of MSA with laparoscopic Nissen fundoplication are needed to evaluate the relative risk-benefit of these two procedures.

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V. DEFINITIONS

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GASTROESOPHAGEAL REFLUX (GERD) is a backflow of contents of the stomach into the esophagus that is often the result of incompetence of the lower esophageal sphincter. Gastric juices are acid and therefore produce burning pain in the esophagus. Repeated episodes of reflux may cause esophagitis, peptic esophageal stricture, or esophageal ulcer.

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 health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross'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. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross 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 for Transesophageal Endoscopic Therapies for gastroesophageal reflux disease:

Procedure Codes								
43201	43212	43236	43257					

Covered when medically necessary for Magnetic Esophageal Sphincter Augmentation:

Procedure Codes								
43284	43285							

Covered when medically necessary for Transoral Incisionless Fundoplication (TIF):

Procedure Codes								
43210								

ICD-10-CM Diagnosis Codes	Description
K21.00	Gastro-esophageal reflux disease with esophagitis, without bleeding
K21.9	Gastro-esophageal reflux disease without esophagitis

IX. REFERENCES

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X. POLICY HISTORY

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MP 2.053	**3/20/19 Minor review**. Reverted policy information related to Transesophageal Endoscopic Therapies for GERD back to full BCBSA adoption. Stretta procedure is considered investigational. Information from MP 1.145 - Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease combined into this policy. Policy title changed to “Surgical Treatments for Gastroesophageal Reflux Disease.” Background and references updated. Coding updated and combined from both policies. Effective 9/1/2019.

POLICY TITLE	PROCEDURES FOR THE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE (FORMERLY SURGICAL TREATMENTS FOR GASTROESOPHAGEAL REFLUX DISEASE)
POLICY NUMBER	MP 2.053

	4/1/20 Consensus review. Policy statement unchanged. Description, Background, Rationale, and References updated.
	12/11/20 Minor review. Magnetic sphincter augmentation (LINX device) changed to medically necessary with criteria. References and coding updated.
	6/16/21 Minor review. Transoral incisionless fundoplication (TIF) changed to medically necessary with criteria. Background, Rationale, Coding, and References updated.
	2/3/22 Consensus. Policy statements unchanged; MUSE added for clarification (per BCBSA), intent unchanged. References updated.
	1/13/23 Consensus review. Title change, now "Procedures for the Treatment of Gastroesophageal Reflux Disease". Editorial changes for clarity, no change to policy stance. Updated background to include LA Grading system and ACG recommendations. Updated ref.

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