Minimally Invasive Procedures for the Treatment of Upper Gastrointestinal Diseases

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Instructions for Use

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Related Policy

- Bariatric Surgery

Coverage Rationale

Gastric electrical stimulation therapy is proven and medically necessary for treating refractory Gastroparesis that has failed other therapies or chronic, intractable (drug-refractory) nausea and vomiting secondary to Gastroparesis of diabetic or idiopathic etiology.

Refer to the U.S. Food and Drug Administration (FDA) section for information regarding FDA labeling and Humanitarian Device Exemption for gastric electrical stimulation.

Surgical pyloroplasty (open or laparoscopic) is proven and medically necessary for treating refractory Gastroparesis that has failed other therapies or chronic, intractable (drug-refractory) nausea and vomiting secondary to Gastroparesis of diabetic or idiopathic etiology.

The following are unproven and not medically necessary for treating Gastroesophageal Reflux Disease due to insufficient evidence of efficacy:

- Endoscopic therapies
- LINX™ Reflux Management System

Refer to the Medical Policy titled Bariatric Surgery for information regarding endoscopic therapies for the treatment of obesity.

Definitions

Gastroesophageal Reflux Disease: A condition in which the lower esophageal sphincter relaxes too often or weakens, which allows stomach acid to flow backward (or reflux) into the esophagus. (American College of Gastroenterology)

Gastroparesis: A digestive disorder in which the motility of the stomach is either abnormal or absent; it is also known as delayed gastric emptying. (Camilleri et al., 2022)

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered

health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

CPT Code	Description
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed
43257	Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43659	Unlisted laparoscopy procedure, stomach
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array

Description of Services

Gastroesophageal Reflux Disease (GERD) is a condition that is characterized by either a weak or dysfunctional lower esophageal sphincter (LES) that results in partially digested food from the stomach to flow back into the esophagus, a process known as reflux. Persistent GERD may lead to esophageal damage or other serious conditions, such as severe esophagitis, strictures, Barrett metaplasia, and adenocarcinoma of the esophagus.

Individuals with Gastroparesis may experience symptoms of frequent nausea and vomiting, early satiety, bloating, postprandial fullness, and epigastric pain and burning. Although Gastroparesis can occur with no obvious cause, individuals with diabetes frequently develop this condition. If Gastroparesis causes nausea and persistent vomiting, it can lead to frequent hospitalization for hypoglycemia, hyperglycemia, acidosis, dehydration, pseudo-obstruction, electrolyte dyscrasias, or other complications. The diagnosis of Gastroparesis requires objective evidence of clearly delayed gastric emptying in symptomatic individuals. Scintigraphy is the reference standard for measurement of gastric emptying. (Keller et al., 2018)

Gastric electrical stimulation involves implanting a device that sends electrical pulses to the stomach muscles to enhance gastric motility, which accelerates stomach emptying and alleviates the frequency and intensity of related symptoms. (Hayes, 2018)

Pyloroplasty is a surgical procedure used to address conditions that obstruct the stomach's outlet. It involves enlarging the pylorus, which is the muscular opening at the lower end of the stomach, to allow food to pass more easily into the small intestine (duodenum). This procedure can be performed either through traditional open surgery or minimally invasively using a laparoscope.

Minimally invasive procedures, including endoscopic or endoluminal therapies and laparoscopic approaches, have been proposed as treatment methods to improve the function of the LES, with the objective of eliminating symptoms, healing esophagitis, preventing recurrence of symptoms or progression of disease, and reducing the need for lifelong pharmacological therapy.

Minimally invasive approaches proposed in the treatment of GERD include the following:

- Radiofrequency energy: The Stretta® procedure administers radiofrequency energy via endoscopic needles placed in the tissues surrounding the LES. The radiofrequency energy heats this neighboring tissue, creating thermal lesions. Submucosal scarring forms as the lesions heal, causing shrinkage and tightening around the LES.

- Endoscopic plication or suturing:
  - The NDO Endoscopic Plication System, also known as the NDO Plicator System, places a full-thickness transmural plication near the gastroesophageal junction under direct endoscopic visualization.
  - The Medigus Ultrasonic Surgical Endostapler (MUSE™ system, Medigus) is an endoscopic stapling device for transoral partial fundoplication. According to the manufacturer's website, as the MUSE system contains the surgical stapler and microvisual and ultrasonic capabilities, it allows a single physician to complete the procedure.
  - EsophyX™ is an endoluminal therapeutic option that uses a transoral and fastener deploying device. It is inserted orally within a thin, flexible tube and deployed inside the stomach to create a full-thickness plication of the stomach fundus at the gastroesophageal junction, thereby resembling an endoscopic fundoplication. The current TIF 2.0 technique (the initial TIF 1.0 technique is no longer recommended) generates a physiological valve via fasteners placed on the far posterior and anterior sides of the lesser curvature, with additional fasteners placed 1 to 3 cm proximal to the gastroesophageal junction. (Hayes, 2023)
  - The LINX Reflux Management System is an implant that consists of a ring that fits around the esophagus and is intended to prevent reflux of bile and acid from the stomach into the esophagus. According to the company website, the LINX system is a small, flexible band of interlinked titanium beads with magnetic cores. The magnetic attraction is intended to help the LES resist opening to gastric pressures, preventing reflux from the stomach into the esophagus. A surgeon uses a laparoscopic incision to implant the device around the individual's esophagus, just above the stomach, while the individual is under general anesthesia.

Clinical Evidence

Gastric Electrical Stimulation Therapy

Cassidy et al. (2024) conducted a retrospective single-center case series in patients who were treated for medically refractory gastroparesis (MRG) with gastric electrical stimulation (GES) to evaluate the safety and efficacy of GES. The study included 157 patients (median age, 45.3 years; 61.8% female) who underwent placement of GES and completed Gastroparesis Cardinal Symptom Index (GCSI) surveys prior to the operation and at subsequent follow-up visits, with data extracted from a prospective internal review board–approved database. The patients included 57 (36.3%) with diabetic gastroparesis, 93 (59.2%) with idiopathic gastroparesis, and seven (4.5%) with postsurgical gastroparesis. At the 1-year follow-up, 141 patients (89.8%) completed the GCSI survey, while 110 patients (70.1%) completed the GCSI survey at the 5-year follow-up. The authors reported that symptom severity in all nine gastroparesis symptoms evaluated by the GCSI as well as the total GCSI score were reduced significantly at 1 year post implantation and that the improvements were sustained through the 5-year follow-up. Patient satisfaction with improvement in their gastroparesis symptoms was reported by the authors to be high, with 87.1% satisfied or very satisfied at 1 year and 79.7% at 5 years. When the authors evaluated the efficacy of GES in patients based on the cause of gastroparesis, they reported that they observed no difference between patients with idiopathic gastroparesis and those with diabetic gastroparesis. The authors also reported that the use of prokinetic and antiemetic medications was reduced during the follow-up period, with reduction in prokinetic medications from 1.9 agents prior to the operation to 0.3 at 1 year and 0.4 at 5 years and in antiemetics from 2.1 agents prior to the operation to 0.6 at 1 year and 0.7 at 5 years. Hospitalizations due to gastroparesis symptoms were also reported to be reduced, with 91 hospitalizations reported prior to the operation to 18 in the first year and 16 in the fifth year. GES devices were reported to be explanted in five patients (one for infection and four for lack of sufficient improvement), while 12 patients required generator exchanges; seven patients required reoperation for mechanical issues (four for lead erosion and fracture and three for displaced device leads) during the 5-year study period. The authors concluded that GES was associated with sustained symptomatic relief, reduced reliance on medications, and reduced gastroparesis-related hospitalizations. Limitations of the study include the retrospective design, lack of a comparison group, inability to capture potential hospitalizations at other facilities, and single-center design.

Samaan et al. (2022) conducted a single-center retrospective study in 181 consecutive patients who underwent GES or primary gastrectomy (PG) for MRG between January 2003 and December 2017 to compare the therapeutic efficacy of GES vs that of PG for MRG. The authors collected data through chart review and a follow-up telephone survey. There were 130 patients (68.5% female; median age, 42 years) who underwent GES and 51 (74.5% female; median age, 44 years) who underwent PG as their primary intervention. Of the 130 patients who underwent GES placement, 44 (33.8%) underwent GES removal and subsequent secondary gastrectomy for clinically significant persistence of gastroparesis symptoms. The authors reported that patients who underwent GES were more likely to have diabetic and idiopathic gastroparesis (GES, 95% vs PG, 39%), while the patients who underwent PG were more likely to have postsurgical gastroparesis (GES, 5% vs PG, 43%); post operation, primary PG patients had a higher rate of major inpatient morbidity events (GES, 5% vs PG, 18%) and longer lengths of stay (GES, 3 days vs PG, 9 days). Prior foregut surgery was more prevalent in patients with PG (66.7% vs GES, 43.1%). The authors noted that over an average of a 37.3-month (range, 0.3-176.8 months) follow-up period, there were no differences between the GES patient population and the PG patient population in the rates of major morbidity, readmissions, or mortality and that multivariable regression analysis showed

that patients who underwent GES as their primary intervention were less likely to report improvement in symptoms at follow-up than patients with PG. The authors also reported that patients who converted to PG from GES were more likely to have postsurgical gastroparesis as the primary etiology. Limitations of the study include the retrospective, observational, single-center design; potential for recall bias related to the use of the postoperative telephone survey; heterogeneity of the types of gastropareses and with the various gastrectomy types that were performed; and potential for selection bias, as the cohort consisted of patients who were willing to adhere to the survey and follow-up requirement of the study. The authors concluded that patients who underwent GES as a first-line surgical treatment for MRG had worse outcomes than those who underwent PG. They also concluded that postsurgical etiology was associated with an increased likelihood of GES failure and that in patients who experienced GES failure, up-front gastrectomy may be a superior alternative to GES. The authors recommended further studies to determine individuals' selection criteria for the operative treatment of MRG.

In a systematic review of the therapeutic role of gastric pacemakers in adults with gastroparesis, Rajamanuri et al. (2021) reviewed 12 studies that included data on adults with MRG that required GES therapy and found that the studies showed varying effects of GES on gastroparesis symptoms like nausea, vomiting, and abdominal bloating. They also concluded that there was significant weight gain noted, based on the evidence in the studies that they reviewed, and that while most of the studies suggested a significant improvement in quality of life and GCSI scores, the evidence supporting no difference in quality of life seemed stronger, as shown by the meta-analysis and randomized controlled trials (RCTs) vs open-label trials that showed positive results for quality of life with gastric pacing. The authors also found other beneficial effects of GES, including reductions in inflammatory indicators, improved metabolic hormone levels, and improved mucosal electrogram frequencies over baseline that were sustained for over 6 months. The authors noted that their review is limited due to the inclusion of open-label studies. They recommended additional RCTs to analyze the impact of gastric pacemakers in the improvement of symptoms in individuals with gastroparesis; studies that evaluate the efficacy for the different causes of gastroparesis, such as diabetes, both idiopathic and postsurgical; and future studies that include the pediatric population. (Ducrotte et al., 2020, Chu et al., 2012, and Shada et al., 2018, previously cited in this policy, are included in this systematic review.)

Hayes (2018; updated 2022) published a Health Technology Assessment on the safety and efficacy of GES for gastroparesis following their review of 12 studies, including three RCTs, six pretreatment/posttreatment studies, one nonrandomized comparative study, one comparative cohort study, and one compilation of case series. The Hayes Health Technology Assessment stated that the effectiveness of GES for treating chronic gastroparesis remains uncertain, as findings have not provided consistent evidence. They noted that the available randomized studies provide little confirmation of the apparent benefit that was seen in unblinded studies. The report noted that GES appears safe in most individuals but that serious complications can occur, including the movement of the stimulator and/or the electrical leads following implantation. They noted that the device removal rates in the studies that they reviewed were between 7% and 12%. The overall quality of the evidence for GES for the treatment of gastroparesis was low due to the individual study limitations and inconsistency in the findings. The Health Technology Assessment concluded that additional randomized and placebo-controlled studies are needed to determine whether GES is a reliable therapy for gastroparesis and whether the benefits of GES treatment outweigh the potential risks.

Levinthal and Bielefeldt (2017) conducted a systematic review and meta-analysis to determine if GES is effective in reducing symptoms in individuals with gastroparesis. Five studies randomly allocated individuals to periods with or without GES. Total Symptom Severity (TSS) scores did not differ between these periods (0.17; 95% CI, -0.06 to 0.4; $p = 0.15$). However, 16 open-label studies of GES showed a significant TSS decrease (2.68; 2.04-3.32; $q = 39.0$; $p < 0.001$). Other treatment modalities similarly improved TSS by 1.97 (1.5-2.44) for medical therapy, by 1.52 (0.9-2.15) for placebo arms, and by 2.32 (1.56-3.06) for botulinum toxin. There were significant differences in baseline TSS ratings among these studies [GES: 6.28 (6.28-7.42); medical therapy: 4.76 (4.09-5.42); placebo arms: 4.59 (3.77-5.42); botulinum toxin: 6.02 (5.3-6.74); $q = 35.1$; $p < 0.001$]. A meta-regression analysis showed these baseline differences to significantly impact TSS ratings during treatment ($q = 71.8$; $p < 0.001$). Independent of the treatment modality, baseline symptom severity impacts treatment results in gastroparesis. With consideration of the skewed population with refractory symptoms, regression to the mean likely contributes to the substantial discrepancies between the reported results of controlled and open-label GES studies. (Chu et al., 2012, previously cited in this policy, is included in this systematic review.)

Heckert et al. (2016) assessed the effectiveness of GES with Enterra® for the treatment of refractory symptoms of gastroparesis, the improvement in specific symptoms of gastroparesis, and the clinical factors impacting outcomes in a cohort of 151 individuals with refractory gastroparesis at a single center. Individuals with gastroparesis (n = 151; 120 female individuals) with refractory gastroparesis (72 diabetic, 73 idiopathic, and six other) underwent GES with Enterra (Medtronic). Individuals filled out a symptom severity questionnaire [PAGI-SYM (Patient Assessment of Upper Gastrointestinal Disorders-Symptom Severity Index)] prior to insertion. At each follow-up visit, the individual filled out the PAGI-SYM and assessed their therapeutic response using the Clinical Patient Grading Assessment Scale. The

investigators concluded that GES improved symptoms in 75% of individuals, with 43% being at least moderately improved. Response in individuals with diabetes was better than that in individuals without diabetes. Nausea, loss of appetite, and early satiety responded the best. The unknown length of study follow-up did not allow for assessment of intermediate- and long-term outcomes. Furthermore, the lack of a comparison group limits the conclusions that can be derived from this case series.

Clinical Practice Guidelines

American College of Gastroenterology (ACG)

The ACG published a clinical guideline for the management of gastroparesis that states that GES may be considered for control of gastroparesis symptoms as a Humanitarian Use Device, as defined by the U.S. Food and Drug Administration, for medically refractory diabetic gastroparesis or idiopathic gastroparesis. This conditional recommendation is based on a low-quality body of evidence. (Camilleri et al., 2022)

American Gastroenterological Association (AGA)

The AGA published a clinical practice update on the management of MRG, based on a review of existing literature combined with expert opinion, to provide practical advice. Based on this review, the AGA states that clinicians can consider GES for patients with gastroparesis and refractory/intractable nausea and vomiting who have experienced failure of standard therapy and are not on opioids. This guidance is based on their review of six published studies that they state show that GES improved refractory nausea and vomiting in some patients with gastroparesis; may improve glycemic control, nutritional status, and quality of life; and may reduce hospitalizations and medication use. They noted that this document is not based on a systematic review, so no formal rating of the quality of evidence or strength of recommendation was made. (Lacy et al., 2022)

In a white paper on current approaches for the treatment of gastroparesis, the AGA (Pasricha et al., 2017) includes GES therapy (recommendation: conditional; level of evidence: moderate).

National Institute for Health and Care Excellence (NICE)

The NICE (2014) interventional procedure guidance on GES for gastroparesis notes that GES is an option for treating chronic, intractable nausea and vomiting secondary to gastroparesis, observing that further publications providing data on the effects of the procedure on symptoms in the long term and on device durability would be useful.

Surgical Pyloroplasty

Fonseca et al. (2021) conducted a systematic literature review examining current therapeutic approaches for gastroparesis, including dietary, medical, and surgical management strategies. The review encompassed 68 full-text articles published between 1980 and 2018, involving a total of 4,878 individuals. Among them, 435 individuals underwent surgical pyloroplasty, either as a stand-alone procedure (n = 81), in combination with fundoplication (n = 227), or alongside GES (n = 127). Included in the population were 142 individuals with idiopathic gastroparesis, 89 with diabetic gastroparesis, and 28 with postsurgical gastroparesis. The authors reported that success rates varied by intervention; pyloroplasty alone achieved a 61% success rate, pyloroplasty with fundoplication reached 86%, and pyloroplasty combined with GES showed a 74.8% success rate. Improvements in gastric emptying time were observed in 75% of individuals who underwent pyloroplasty alone, 85% of those who had pyloroplasty with fundoplication, and 75% of individuals treated with GES. The authors concluded that pyloroplasty can effectively normalize gastric emptying and alleviate symptoms in individuals with idiopathic or diabetic gastroparesis. Furthermore, when pyloroplasty is combined with gastric neurostimulation, additional reductions in nausea, vomiting, bloating, and abdominal pain may be achieved.

Zoll et al. (2018) conducted a systematic literature review to evaluate the outcomes of three surgical treatments for refractory gastroparesis: GES, pyloric interventions (PIs), and gastrectomy. The review included 38 studies, with a total of 441 individuals undergoing GES, 141 receiving PIs, and 263 treated with gastrectomy. The authors found that all three interventions demonstrated improvements in symptoms such as nausea, vomiting, and abdominal pain. Specifically, GES led to a 46.9% improvement in nausea, 55.9% improvement in vomiting, and 39.3% improvement in epigastric pain. PIs showed the most consistent symptom relief, with a 64.5% improvement in nausea, 65.5% improvement in vomiting, and 63.0% improvement in epigastric pain. Gastrectomy, although supported by fewer studies and data from individuals, resulted in a 55.3% improvement in nausea, 65.0% improvement in vomiting, and 37.3% improvement in epigastric pain. They concluded that pyloroplasty provided significantly better symptom relief than GES in both weighted and unweighted analyses. Based on these findings, they reported that this systematic review suggests PIs as a first-line therapy for individuals with refractory gastroparesis.

Clinical Practice Guidelines

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

Shada et al. (2016) reported that laparoscopic pyloroplasty (LP) is a highly effective first-line surgical option for patients with refractory gastroparesis. They determined that LP leads to improvement or normalization of gastric emptying in approximately 90% of cases, with minimal associated morbidity. LP has been shown to significantly alleviate key symptoms such as nausea, vomiting, bloating, and abdominal pain. They added that while some patients may eventually require additional surgical interventions, LP holds a well-defined and valuable place in the treatment algorithm for gastroparesis in patients who do not respond to medical therapy.

Endoscopic Therapies

The below referenced endoscopic therapies for GERD are unproven due to insufficient and low-quality evidence of efficacy. While multiple techniques have been evaluated, existing studies are generally limited by small sample sizes, heterogeneous populations of individuals, short follow-up periods, and inconsistent outcome measures. Many trials lack rigorous methodology, including randomization, blinding, and appropriate controls, raising concerns of bias. Furthermore, durability of benefit and long-term safety have not been adequately established.

Radiofrequency Energy (Stretta System)

Currently, there is insufficient evidence regarding the safety and effectiveness of radiofrequency energy for gastroesophageal conditions. Studies are limited by small sample sizes, single-center locations, and short-term follow-up. Meta-analyses were limited by the lack of control groups in a large portion of the included studies. Its role must be better defined in robust, well-designed clinical trials that have long-term results.

A Hayes Health Technology Assessment (2023) evaluated the effectiveness and safety of Stretta radiofrequency to treat GERD. Overall, 14 articles found an overall low-quality body of evidence that suggests that Stretta radiofrequency therapy may be safe and may improve GERD symptoms in individuals and quality of life for up to 5 years; however, the evidence also reflects substantial uncertainty regarding its effectiveness compared with that of laparoscopic fundoplication, which is considered the surgical standard of care. The overall conclusion of the report is that there is potential but unproven benefit for this technology.

In a 2020 randomized, double-blinded, sham-controlled, multicenter study, Zerbib et al. assessed the efficacy of esophageal radiofrequency (Stretta system, Mederi Therapeutics) in 62 participants with moderate to severe GERD at least three times a week that was refractory to PPIs. Completed questionnaires consisting of the Gastrointestinal Symptom Rating Scale and the Quality of Life in Reflux and Dyspepsia were collected. Participants were then randomized to receive either esophageal radiofrequency or a sham procedure performed by a physician who would not be involved in follow-up to maintain double blinding. All participants were instructed to take a double dose of PPIs after the procedure, and follow-up visits were planned at weeks 4, 8, 12, 18, and 24 and at the end of study at 48 weeks post procedure to assess symptom relief, PPI use, and any side effects. The intake of antacids as well as the presence of other digestive symptoms were also assessed. At each visit, if symptoms were adequately controlled, participants were instructed to decrease the PPI from a double to a single dose and to on-demand use as improvement continued. In participants who were having success, at week 24, an upper gastrointestinal endoscopy was performed (for therapeutic failures, the participants were offered an open esophageal radiofrequency procedure with the same follow-up). Five participants were lost to follow-up, and one withdrew their consent to participate, resulting in 26 participants being treated and 30 participants being treated with the sham procedure. The results showed that there was no significant difference between the treatment and sham groups at weeks 24 and 48 regarding days without heartburn, days without any other digestive symptoms, PPI and antacid intake, and the number of participants not taking PPIs. There were no procedure-related safety issues. The authors concluded that esophageal radiofrequency is a relatively invasive procedure for a benign disorder, and it did not demonstrate efficacy for the treatment of GERD refractory to PPIs.

Viswanath et al. (2019) reported a prospective case series in 50 participants who underwent endoscopic antireflux radiofrequency treatment (Stretta) for refractory GERD. Assessment involved the use of the GERD-HRQL questionnaire, which evaluated symptoms and PPI dependency, before and after treatment. Median follow-up post treatment was 771 days. The average GERD-HRQL score improved from 46.2/75 (±14.2) before Stretta treatment to 15.2/75 (±17.3) after Stretta treatment. The authors concluded that in select individuals with GERD, Stretta improves quality of life and decreases PPI dependency and is a viable option for individuals who are unwilling or unable to undergo surgery. They also concluded that RCTs that have larger participant populations are needed to further assess Stretta. Limitations of this study include the lack of a concurrent comparison group and its small numbers. Additionally, the pre-Stretta assessments were carried out by a variety of teams; therefore, there is a potential for inconsistencies.

In another case series, Noar et al. (2017) prospectively assessed and compared participant-reported outcomes in 18 participants with disease refractory to laparoscopic Nissen fundoplication (LNF) and 81 participants with GERD refractory to medical management, all of whom underwent Stretta during the 10-year follow-up. The participant-reported outcomes measured were GERD-HRQL (health-related quality of life), participant satisfaction scores, and daily medication requirements. The refractory LNF subset had median improvements in GERD-HRQL, satisfaction, and medication use at all follow-up time points ≥ 6 months to 10 years, which was significant from a baseline of both on and off medications ($p < 0.05$). Specifically, at 10 years, the median GERD-HRQL decreased from 36 to 7 ($p < 0.001$), satisfaction increased from 1 to 4 ($p < 0.001$), and medication score decreased from 7 to 6 ($p = 0.040$). Nine participants decreased medication use by half at 10 years. No significant differences existed between refractory LNF and standard refractory GERD subsets at any follow-up time point ≥ 6 months to 10 years ($p > 0.05$) after Stretta. At 10 years, no significant differences were noted between refractory LNF and standard Stretta subsets regarding medication use ($p = 0.088$), participant satisfaction ($p = 0.573$), and GERD-HRQL ($p = 0.075$). Stretta procedures were completed without difficulty or significant intraoperative or long-term adverse events. The authors concluded that in a small series of participants with refractory LNF, Stretta resulted in sustained improvement over 10 years, with equivalent outcomes to non-LNF standard Stretta participants. Study limitations include the lack of a concurrent comparison group, nonrandomization, and small participant population.

An ECRI Evidence Analysis examining Stretta for the treatment of refractory GERD indicates that evidence from three systematic reviews, including RCTs comparing Stretta with conservative management and pre-post treatment studies, suggests that Stretta is a safe, minimally invasive option that may improve GERD symptoms, reduce PPI use, and enhance health-related quality of life. Additionally, two indirect network meta-analyses and five nonrandomized comparative studies indicated that Stretta may be as effective as antireflux mucosectomy or endoscopic plication procedures but potentially less effective than laparoscopic Toupet or Nissen fundoplication. However, these studies are subject to a high risk of bias and provide very low-quality evidence, limiting the ability to draw firm conclusions regarding comparative safety and effectiveness. Large, multicenter RCTs that directly compare Stretta with other devices or procedures and report long-term, individual-centered outcomes to better inform clinical decision-making are needed. (ECRI, 2014; updated 2024)

Arts et al. (2012) conducted a small, double-blinded, randomized crossover study of Stretta and sham treatment (included in the Fass et al., 2017, systematic review above). Participants underwent two upper gastrointestinal endoscopies, with a 3-month interval, during which active or sham Stretta treatment was performed in a randomized, double-blinded manner. In all, 22 participants with GERD (17 female; mean age, 47 ±12 years) participated in the study, with 11 in each group. Initial sham treatment did not affect any of the parameters studied. Three months after the initial Stretta procedure, no changes were observed in esophageal acid exposure and LES pressure. In contrast, symptom score was significantly improved, and gastroesophageal junction (GEJ) compliance was significantly decreased. Administration of sildenafil, an esophageal smooth muscle relaxant, normalized GEJ compliance to a pre-Stretta level, providing evidence against GEJ fibrosis as the underlying mechanism. The authors concluded that Stretta improved GERD symptoms and decreased GEJ compliance. According to the authors, the limitation of this study is reflux evaluation that did not include impedance monitoring. The study is also limited by a small participant population, short follow-up, and lack of comparison to other surgical alternatives.

Endoscopic Plication or Suturing

There is a lack of quality evidence to support the use of endoscopic plication or suturing for GERD. Studies are limited by the definition of proper PPI use and evaluation prior to determining candidacy for procedures. Studies are limited by small sample sizes, a lack of randomization, a lack of control groups, and short durations of follow-up. Post hoc analysis introduces bias to outcomes. Additional studies are needed to support the safety and efficacy of these techniques, with long-term effectiveness.

EndoCinch

Schwartz et al. (2013) evaluated the long-term effects of EndoCinch as a treatment option for GERD. Overall, 60 participants were randomized into three different groups: EndoCinch treatment, sham treatment, and observation. The inclusion criteria consisted of participants with persistent heartburn and/or regurgitation, unwillingness to take lifelong medications, and esophageal pH results compatible with a GERD diagnosis. A baseline questionnaire using a 6-point numeric scale, which measured heartburn and regurgitation frequency, and a 4-point numeric scale, which measured severity, was completed prior to the study and again at 3 months; additional reassessment took place at 6 and 12 months and then yearly thereafter. Quality-of-life assessments were done using the 20-Item Short Form Survey. Endoscopic suturing was carried out with the EndoCinch suturing device (Bard Endoscopic Technologies), which created three plications. During the first year, any participants with failure were offered one or two additional plications; three participants were lost to follow-up in the first year. Between 12 and 48 months, eight participants underwent antireflux surgery, and one participant received an alternative endoscopic treatment. Four questionnaires were either incomplete or

missing and therefore not used. In the end, 43 participants were completely analyzed. At the end of follow-up, while the EndoCinch procedure looked to improve GERD symptoms, decrease use of medications, and increase the quality of life in approximately half of the participants, 80% of them still required PPI management. The authors concluded that EndoCinch in the long term was not beneficial. Limitations include the small sample size and large loss to follow-up.

Endoscopic Plicator or Suturing

Niu et al. (2024) conducted a comprehensive systematic review and meta-analysis to assess the efficacy, safety, and long-term results of endoscopic fundoplication in treating GERD. Their analysis encompassed 13 studies, comprising four RCTs and nine prospective cohort studies, with a total of 429 individuals undergoing endoscopic full-thickness plication (EFTP) and 146 individuals undergoing sham surgery for GERD treatment. The key studies included in this review were Kalapala et al. (2022), Antoniou et al. (2012), and Rothstein et al. (2006), cited below. The primary outcomes focused on improvements in GERD-HRQL scores (> 50% improvement), cessation of PPI use, and the need for laparoscopic fundoplication post EFTP. The secondary outcomes included changes in GERD-HRQL scores, DeMeester scores, esophageal acid exposure time, total reflux events, Gastrointestinal Quality of Life Index (GIQLI), procedure duration, and adverse events associated with the procedure. The authors' review of prospective studies indicated significant improvement in symptoms following EFTP, with 63% of individuals achieving > 50% improvement in GERD-HRQL scores. Moreover, there was a substantial reduction in PPI dependency, with a cessation rate of 65%. EFTP also led to improvements in esophageal pH levels and DeMeester scores, demonstrating an average weighted MD of -16.44. Additionally, there was a decrease in total reflux events and a low incidence of severe adverse events reported. Based on these findings, the authors suggested that EFTP could be a promising alternative for individuals who do not respond adequately to conventional therapies. They recommended further research comparing EFTP with other minimally invasive GERD treatments, such as transoral incisionless fundoplication (TIF). They also emphasized the importance of long-term follow-up to assess the durability of treatment effects and to identify potential late-onset complications or symptom recurrence. Standardized follow-up protocols across studies are recommended to enhance comparability. The study has several limitations, including the need for long-term data on the durability of EFTP as a GERD treatment. Previous research on surgical GERD treatments has indicated significant rates of symptom recurrence after 5 years. Furthermore, while the majority of the individuals were indeed resistant to long-term PPI treatment, not all studies reviewed included individuals who were on long-term PPI therapy or were unresponsive to it before undergoing EFTP, which could affect generalizability.

Gong et al. (2022) conducted a systematic review and network meta-analysis that included 25 RCTs and 2,854 individuals to evaluate the effectiveness of various endoscopic and surgical interventions for GERD. The analysis focused on several outcomes, including the continued need for PPI therapy and GERD-HRQL. The findings indicated that surgical fundoplication, LES reinforcement, and endoscopic plication were more effective than PPI therapy in reducing the need for ongoing PPI use. These interventions also demonstrated superior outcomes in improving GERD-HRQL. However, the authors reported that comparative ranking of these treatments should be interpreted cautiously, as no statistically significant differences were observed among them. In contrast, radiofrequency energy delivery, endoscopic plication, and LES reinforcement did not show improved efficacy over PPI therapy in terms of objective measures such as abnormal acid exposure and LES resting pressure. They reported that these results suggest that aside from surgical fundoplication, other interventions may be less effective in preventing pathological reflux. Importantly, the authors emphasized that while endoscopic and surgical treatments showed certain benefits, PPI therapy remains a valid and effective option for many individuals. The study also acknowledged several limitations. Many comparisons were based on indirect estimates using PPI therapy as a common comparator; the outcome measures varied across studies; the number of studies included in each comparison was relatively small; long-term follow-up data for endoscopic treatments were limited; and lastly, some procedures reviewed are no longer commercially available due to adverse events and insufficient long-term data. Several studies that were previously cited in this policy were included in this systematic review: Coron et al. (2008), Aziz et al. (2010), Arts et al. (2012), Kalapala et al. (2017), Rothstein et al. (2006), Hunter et al. (2015), Rinsma et al. (2015), Witterman et al. (2015), Bell et al. (2019), and Antoniou et al. (2012).

Kalapala et al. (2022) conducted a randomized, double-blinded, sham-controlled trial to assess the safety and efficacy of EFTP in participants with GERD who were dependent on PPI therapy. Overall, 70 participants were assigned to one of two groups: one received EFTP, and the other received the sham therapy. The sham procedure positioned the device 1 cm below the GEJ, but the sutures were not deployed like in the EFTP procedure. Participant follow-up was completed at 3, 6, and 12 months, along with telephone calls made every 2 to 4 weeks. In the EFTP group, 65.7% of participants obtained a 50% or more reduction in GERD-HRQL score compared with only 2.9% in the sham group. The PPI dependence at 12 months in the sham group was significantly higher than that in the EFTP group. The authors concluded that EFTP appears to be a new promising alternative to surgery for individuals who may not want to continue with long-term PPI therapy; however, larger trials that have longer follow-up periods are required to confirm the benefits.

De Moura et al. (2018) evaluated long-term results in 47 participants who were nonresponsive to PPIs and underwent endoluminal plication (n = 26) or polymer injection (n = 21) for the treatment of GERD as part of a case series. The number of participants with no response to endoscopic treatment with reintroduction of PPIs increased in time for both techniques. There was symptomatic improvement up to 12 months, with progressive loss of this trending up to 60 months for both procedures. GERD-HRQL demonstrated total response in both procedures at 1, 3, 6, and 12 months. The 60-month analysis showed an increased number of participants with no response in both groups. The quality-of-life assessment (36-Item Short Form Survey) showed benefit in polymer injection up to 3 months and showed a higher rate of complications. There were no deaths. There was healing of esophagitis at 3 months in 45% of participants with polymer injection and 40% with endoluminal plication. There was no improvement in manometric or pH findings. The authors concluded that endoscopic therapies were ineffective in controlling GERD in the long term. Limitations include the lack of randomization and lack of uniform objective data analysis.

In an RCT, Antoniou et al. (2012) evaluated the effectiveness of endoscopic plication and laparoscopic fundoplication in terms of quality of life and symptom control. Overall, 60 participants with documented GERD were randomly assigned to undergo either endoscopic plication or laparoscopic fundoplication. Quality-of-life scores and symptom grading were recorded before treatment and at 3 and 12 months of follow-up. In total, 29 participants from the endoscopic group and 27 participants from the operative group were available at follow-up. Quality-of-life scores showed a substantial and similar increase for both groups after treatment. Symptoms of heartburn, regurgitation, and asthma were significantly improved in the endoscopic group, whereas laparoscopic fundoplication was more effective in controlling symptoms of heartburn and regurgitation than the endoscopic procedure. The authors concluded that endoscopic plication and laparoscopic fundoplication resulted in significant symptom improvement, with similar quality-of-life scores in a selected participant population with GERD; operative treatment was more effective in the relief of heartburn and regurgitation at the expense of higher short-term dysphagia rates. A small sample size and lack of long-term follow-up limit the validity of these conclusions.

In a randomized, single-blinded, prospective, multicenter trial by Rothstein et al. (2006), 159 participants were selected to either undergo endoscopic full-thickness restructuring of the gastric cardia with transmural suture (n = 78) or a sham procedure (n = 81) to determine the effectiveness of EFTP for the treatment of GERD. Group assignments were revealed following the 3-month evaluation. By intention-to-treat analysis, at 3 months, the proportion of participants achieving a ≥ 50% improvement in GERD-HRQL score was significantly greater in the active group than the sham group. Complete cessation of PPI therapy was higher in participants in the active group than in the sham group. However, the median percentage of time that pH was < 4 was not differently improved between the active and sham groups. Between-group analysis revealed that the active therapy was superior to sham treatment in improving the median percentage of time that the pH value was < 4. The authors concluded that EFTP was effective in reducing GERD symptoms and PPI use compared with a sham procedure. Additional studies are needed to evaluate the durability of EFTP for the treatment of GERD, as this study is limited by a relatively short follow-up.

MUSE

Testoni et al. (2022) assessed the effects of TIF by MUSE in 46 individuals. The inclusion criteria consisted of individuals who were > 18 and < 70 years of age, had chronic GERD-related symptoms, had endoscopic findings of GERD or Barrett esophagus, had a body mass index of < 40 kg/m^2, were seeking alternative treatment, and were available for long-term follow-up. Symptoms and daily PPI consumption were assessed prior to the TIF-MUSE procedure, at 6 and 12 months, and then yearly thereafter for at least 3 years. All individuals completed the GERD-HRQL and Reflux Symptom Index (RSI) questionnaires as tools to assess the symptom severity of GERD. The authors found that the GERD-HRQL and RSI scores were reduced by almost 50% in approximately 75% of the individuals at the 6-month follow-up and that this decreased to 67.7% of individuals at 3 years. Two severe adverse events occurred “as a consequence of delayed esophageal and intra-procedural gastric perforation at the stapler site.” The authors concluded that the MUSE device proved to be effective in approximately two-thirds of individuals but that severe complications requiring surgery occurred in two cases. Limitations include the small sample size, lack of control group, and inability to draw conclusions in individuals with more severe degrees of esophagitis or individuals with hypersensitive esophagus.

Kim et al. (2016) reported, in a case series, the long-term outcome from the Zacherl et al. (2015) Medigus Ultrasonic Surgical Endostapler MUSE study. Efficacy and safety data for 37 participants were analyzed at baseline, 6 months, and 4 years post procedure. In one center, efficacy and safety data were evaluated at baseline, 6 months post procedure, and then annually up to 4 years. No new complications were reported in their long-term analysis. The proportion of participants who remained off daily PPIs was 83.8% (31 of 37) at 6 months and 69.4% (25 of 36) at 4 years post procedure. GERD-HRQL scores (off PPI) were significantly decreased from baseline to 6 months and 4 years post procedure. The daily dosage of GERD medications, measured as omeprazole equivalents (mean ±SD, mg), decreased from 66.1 ±33.2 at baseline to 10.8 ±15.9 at 6 months and 12.8 ±19.4 at 4 years post procedure ($p < 0.01$). The authors concluded that the MUSE stapling device appears to be safe and effective in improving symptom scores as well as reducing PPI use in

individuals with GERD and that the results appeared to be equal to or better than those of the other devices for endoluminal GERD therapy. Future studies, with larger series of individuals, a sham control group, and a greater number of staples, are awaited to further evaluate MUSE. Findings are limited by the lack of a comparison group.

Zacherl et al. (2015) reported 6-month outcomes from a multicenter, prospective case series using MUSE for the treatment of GERD (n = 69; three lost to follow-up). Six months after the procedure, the GERD-HRQL score improved by > 50% off PPI in 73% of participants (48 of 66; 95% CI, 60%-83%). Overall, 42 participants (64.6%) were no longer using daily PPI medication. Of the 23 participants who continued to take PPIs following the procedure, 13 (56.5%) reported a ≥ 50% reduction in dose. The mean percentage of total time with an esophageal pH of < 4.0 decreased from baseline to 6 months ($p < 0.001$). Common adverse events were perioperative chest discomfort and sore throat. Two severe adverse events requiring intervention occurred in the first 24 participants, and no further esophageal injury or leaks were reported in the remaining 48 enrolled participants. Early experience with the device necessitated procedure and device changes to improve safety, with improved results in the later portion of the study. Continued assessment of durability and safety is ongoing in a 3-year follow-up study in this participant group. Findings are limited by the lack of a comparison group.

Other clinical trials regarding endoscopic plicator or suturing are limited to observational case series that do not allow for conclusions about durability and long-term effectiveness. (Birk et al., 2009; von Renteln et al., 2009)

EsophyX System (Transoral Incisionless Fundoplication)

A Hayes (2023) report evaluated the effectiveness and safety of TIF when performed concurrently with laparoscopic hiatal hernia repair for the treatment of chronic GERD in adults. The literature search returned six relevant studies, but overall, the very low-quality body of evidence was insufficient to draw any conclusions regarding the procedure's safety and efficacy. Future studies that include long-term follow-up are warranted.

A Clinical Evidence Assessment from ECRI (updated 2023) focused on the safety and efficacy of EsophyX and how they compared with those of LNF or other GERD treatments. Based on evidence from five systematic reviews, it was concluded that EsophyX was safe for most individuals, improved individuals' GERD symptoms, and improved quality of life; however, limitations include the lack of individuals in the comparisons performed. Additional RCTs that compare EsophyX with other devices and procedures for treating GERD are warranted, along with long-term outcomes; ongoing trials may partially address this gap.

A systematic review conducted by Haseeb et al. (2023) assessed the efficacy of TIF for atypical GERD symptoms in 564 individuals. The inclusion criteria consisted of adult individuals who were > 18 years of age with chronic or refractory GERD and at least 6 months of follow-up. A literature search using PubMed, Embase, Web of Science Core Collection, and the Cochrane Central Register returned an RCT, four prospective studies, and five retrospective observational studies, for a total of 10 studies for analysis. The primary outcome was the efficacy of TIF, which was measured by the RSI, a nine-item questionnaire. Overall, nine serious adverse events were documented, but no mortality was observed. Following the TIF procedure, the authors found a reduction in the mean RSI score of approximately 15 points at 6 months and 14.73 points at 12 months. In addition, many individuals had a reduction in daily PPI usage, with only 19% on PPIs at 6 months and 26% at 12 months. The authors concluded that TIF was effective in controlling atypical GERD symptoms at 6 and 12 months. Limitations include the lack of a comparison group, lack of subjective outcomes after the TIF procedure, lack of long-term outcomes, and high heterogeneity.

Testoni et al. (2021) conducted a systematic review and meta-analysis on the long-term outcomes of TIF in individuals with GERD. A search of publications through May of 2020 returned eight articles with long-term outcomes of greater than 3 years for analysis. The outcomes evaluated in the analysis included individuals' satisfaction overall, daily PPI consumption, GERD-HRQL scores, and normalization of heartburn and regurgitation scores before and after the TIF procedure. The authors found that TIF resulted in long-term satisfaction in individuals, with reduction in PPI use in approximately 75% of the individuals during a 5-year period. At the 10-year mark, approximately two-thirds of the individuals were satisfied. However, the findings are limited by the lack of a comparison group for most of the included studies.

Janu et al. (2019; included in the Haseeb et al., 2023, systematic analysis above) examined the safety and efficacy of the EsophyX TIF device in a case series of individuals with hiatal hernias of between 2 and 5 cm. Data were collected from 99 individuals who were aged 18 to 75 years and had moderate to severe GERD symptoms for greater than 1 year, more than 6 months of daily PPI, and a hiatal hernia. Three validated questionnaires [GERD-HRQL, RSI, and GERSS (Gastroesophageal Reflux Symptom Score)] were administered before the procedure and again at 6 and 12 months post procedure. Scores of ≤ 2 for each question were indicative of successfully treated symptoms. Symptoms were considered significantly improved if the total GERD-HRQL, GERSS, and RSI scores were reduced by ≥ 50% at the follow-up assessments. The questionnaire response rate was 73% at 6 months, 67% at 12 months, and 48% for both. The authors

found that the results at 12 months indicated that all scores moved in a positive direction; they concluded that the hiatal hernia repair and TIF provided significant control of heartburn, with no long-term dysphagia or bloating. Limitations of the study include the lack of a comparison group, relatively short-term follow-up, lack of objective outcomes data such as pH testing, and incomplete data.

Testoni et al. (2019; included in the Testoni et al., 2021, meta-analysis above) examined the long-term results in 50 participants who underwent TIF with the EsophyX 2.0 device for symptomatic GERD. Prior to surgery, all participants completed the GERD-HRQL and GERD Quality of Life questionnaires; these were again filled out at 6, 12, and 24 months following the TIF. All participants underwent a gastrointestinal endoscopy to determine the grade and length of the gastroesophageal valve, presence and size of the hiatal hernia, and presence and severity of esophagitis. TIF 2.0 was successful in 49 of the 50 participants; one participant experienced a pneumothorax. The GERD-HRQL, heartburn and regurgitation scores, and daily PPI consumption were documented by telephone interview or office consultation at 2, 3, 5, 7, and 10 years post TIF. During the 10-year follow-up, daily PPI dependence was eliminated in 86.7% of the participants at 2 years and 91.7% of the participants at 10 years. Limitations include the lack of a comparison group, the small number of participants evaluated in this study, and the low number clinically evaluated at 7 and 10 years. However, the authors believe that the symptomatic curve over the 7- to 10-year period suggests that the results would not have differed, even with a larger number of cases, and that their results confirm that TIF is a safe and effective option for individuals with GERD that is as effective as Nissen fundoplication.

McCarty et al. (2018) performed a systematic review and meta-analysis on TIF for the treatment of GERD. Overall, 32 articles were reviewed, which included 1,390 individuals who received the EsophyX device and 85 who received MUSE. The review included five RCTs, 21 prospective studies, and six retrospective studies; many of these studies are summarized individually below. The primary outcomes were feasibility, efficacy, and tolerability of the TIF. Symptom improvement was measured by cessation of the use of PPIs, in addition to pre- and post-questionnaires, which included assessment of GERD-HRQL, GERSS, and RSI. Objective measurement of GERD improvement was determined by reduction in hiatal hernia size and pH monitoring. Of the 21 studies that addressed surgical intervention due to poorly controlled GERD symptoms, 88 individuals required further surgical intervention after the TIF. The vast majority of these were completed within 6 months of the original TIF procedure, and only three studies assessed for symptomatic improvement, which demonstrated that 77.8% of individuals had improvement in their symptoms. The GERD-HRQL, GERSS, and RSI all showed significant improvement in their before-and-after scores. Limitations to this analysis include inherent variation in study outcomes between the studies, inclusion of EsophyX 1.0 and 2.0 devices, and lack of data comparing the EsophyX device with MUSE. In addition, few studies included comparison of the TIF with LNF, which is considered the gold standard. Despite this, the authors concluded that overall, the TIF procedure had a very high success rate of 99%, was well tolerated, and had few adverse effects. The authors concluded that TIF appeared to be safe and effective as an alternative to the standard treatment for GERD; however, future controlled trials are warranted to compare TIF devices with more invasive surgical approaches. (Barnes et al., 2011, Bell and Freeman, 2011, Trad et al., 2012, Testoni et al., 2015, Hunter et al., 2015, and Witterman et al., 2015, previously cited in this policy, are included in this meta-analysis.)

Trad et al. (2018; included in the Testoni et al., 2021, meta-analysis above) reported 5-year outcomes from the previously described TEMPO clinical trial (TIF 2.0). Overall, 63 participants with chronic GERD refractory to PPI therapy, absent or ≤ 2-cm hiatal hernia, and abnormal esophageal acid exposure were randomized to the TIF group or PPI group. Following the 6-month evaluation, all participants in the PPI group elected for crossover to TIF. Of 63 participants, 60 were available at 1 year, 52 were available at 3 years, and 44 were available at 5 years for evaluation. Troublesome regurgitation was eliminated in 88% of participants at 1 year, 90% at 3 years, and 86% at 5 years. Resolution of troublesome atypical symptoms was achieved in 82% of participants at 1 year, 88% at 3 years, and 80% at 5 years. No serious adverse events occurred. There were three reoperations by the end of the 5-year follow-up. At the 5-year follow-up, 34% of participants were on daily PPI therapy compared with 100% of participants at screening. The total GERD-HRQL score improved by decreasing from 22.2 to 6.8 at 5 years ($p < 0.001$). The authors concluded that in this participant population, the TIF 2.0 procedure provided safe and sustained long-term elimination of troublesome GERD symptoms. Study limitations include a small participant population, loss to follow-up, and lack of a comparison group after the 6-month crossover.

Richter et al. (2018) conducted a systematic review and meta-analysis of RCTs to indirectly compare TIF and LNF using a network meta-analysis technique. Included were seven trials, comprising 1,128 individuals, none of which included a direct comparison between the two methods. The authors found LNF to have the greatest ability to improve physiological parameters of GERD, including increased LES pressure and decreased percentage of time with a pH of < 4. Although TIF produced the largest increase in health-related quality of life, this could be due to the shorter follow-up time in individuals treated with TIF vs LNF or PPIs. TIF is a minimally invasive endoscopic procedure, yet based on evaluation of benefits vs risks, the authors do not recommend it as a long-term alternative to PPI or LNF treatment of GERD. Limitations identified were a lack of individual patient data, differences in follow-up time, and the number of individuals across LNF and TIF

studies; additionally, studies were moderate to very low in quality. This analysis is also limited by the inherent indirectness of network meta-analyses.

Ebright et al. (2017) reported follow-up data on endoscopic fundoplication performed in 80 individuals using a case series design. Although symptoms and satisfaction improved significantly over a mean follow-up period of 24 months, approximately 30% of individuals continued to take PPIs. Future studies are needed to focus on longer-term durability and comparisons to laparoscopic techniques.

Stefanidis et al. (2017a) evaluated the long-term benefit of TIF using the EsophyX device (n = 45) for the management of GERD responsive to medical therapy in a case series. After a median follow-up period of 59 months (36-75 months), the median GERD-HRQL scores improved significantly from 27 (2-45) at baseline to 4 (0-26) ($p < 0.001$) in the 44 individuals completing the study. Heartburn was eliminated in 12 of the 21 individuals included (57.1%); regurgitation was eliminated in 15 of the 17 individuals included (88.2%); and finally, chest pain was eliminated in five of the six individuals included (83.3%). Overall, 32 of the 44 individuals (72.7%) who completed the study follow-up reported elimination of their main symptom, without the need for PPI administration. Furthermore, six more individuals (13.6%), five with heartburn and one with regurgitation, reported half the PPI dose taken for < 50% of the preceding follow-up period (occasional PPI usage), while six more individuals (four with heartburn, one with regurgitation, and one with chest pain) reported a full or half PPI dose taken for more than 50% of the preceding follow-up period (daily PPI usage). Randomized clinical trials are needed to validate these results compared with those of other treatments for GERD.

Huang et al. (2017) performed a systematic review with meta-analysis of studies evaluating the role of TIF in GERD. Only RCTs evaluating the efficacy of TIF and prospective observational studies reporting outcomes after TIF were included. The authors identified that the total number of refluxes was reduced after TIF compared with the PPI/sham group. The esophageal acid exposure time and acid reflux episodes after TIF were not significantly improved. PPI usage increased with time, and most of the individuals resumed PPI treatment at a reduced dosage during the long-term follow-up. The total satisfaction rate after TIF was approximately 69.15% in 6 months. The incidence of severe adverse events consisting of gastrointestinal perforation and bleeding was 2.4%. The authors concluded that TIF results in comparable short-term satisfaction among individuals as an alternative intervention to GERD-related symptoms. Long-term results showed decreased efficacy with time, and individuals often resumed PPIs at reduced doses.

In a double-blinded sham-controlled study in participants with moderate to severe GERD who were chronic PPI users, Håkansson et al. (2015; included in the McCarty et al., 2018, meta-analysis above) evaluated the TIF2 procedure (using the EsophyX device) vs sham (upper gastrointestinal endoscopy). Participants (n = 44) were randomized into the two groups. The primary effectiveness end point was the proportion of participants in clinical remission after the 6-month follow-up. The secondary outcomes were PPI consumption, esophageal acid exposure, reduction in the Quality of Life in Reflux and Dyspepsia and Gastrointestinal Symptom Rating Scale scores, and healing of reflux esophagitis. The time (average days) in remission offered by the TIF2 procedure (197 days) was significantly longer than that in participants receiving the sham intervention (107 days) ($p < 0.001$). After 6 months, 13 of 22 (59%) of the participants with chronic GERD remained in clinical remission after the active intervention. Likewise, the secondary outcome measures were all in favor of the TIF2 procedure. No safety issues were raised. Although the authors concluded that the TIF2 procedure is effective in PPI-dependent individuals with chronic GERD, the study is limited by a small participant population and short follow-up period.

Rinsma et al. (2015) conducted an RCT to evaluate the effect of endoscopic fundoplication and PPI therapy on baseline impedance and heartburn severity in participants with GERD. Overall, 47 participants with GERD were randomized to endoscopic fundoplication (n = 32) or PPI therapy (n = 15), and 29 healthy controls were included. Before randomization and 6 months after treatment, baseline impedance was obtained during 24-hour pH-impedance monitoring. Heartburn severity was evaluated using the GERD-HRQL questionnaire. Before treatment, baseline impedance in participants with GERD was lower than that in healthy controls ($p < 0.001$). Antireflux therapy increased baseline impedance [from 1,498 (IQR, 951-2,472) to 2,393 (IQR, 1,353-3,027) Ω, $p = 0.001$]; however, it only led to a partial recovery compared with healthy controls [2,393 (IQR, 1,353-3,027) vs 2,983 (2,335-3,810) Ω, $p < 0.01$]. The effect of both treatment options was not significantly different ($p = 0.13$) despite the increased number of non–acid reflux events in the PPI group. No correlation was found between baseline impedance and GERD symptoms before or after treatment.

LINX Reflux Management System

There is insufficient evidence to conclude that LINX is effective and safe in the long-term for GERD treatment. While short-term results are promising, there are limited data on the long-term effectiveness and safety of the LINX device. The follow-up periods in most studies may be insufficient to fully capture long-term complications or device durability. Additional research involving larger RCTs, with long-term outcomes, is needed to establish its safety and efficacy in the

context of other mechanical approaches to GERD treatment that have shown benefits in the short term but not in the long term.

Fadel et al. (2024) conducted a systematic review and meta-analysis to evaluate the efficacy, safety, and impact on quality of life of magnetic sphincter augmentation (MSA) through the placement of the LINX device compared with laparoscopic fundoplication for the treatment of GERD. The analysis included 39 studies, encompassing a total of 8,075 individuals; 6,983 underwent MSA, and 1,092 received fundoplication. The authors reported that their findings suggest that MSA may offer enhanced outcomes and improved well-being in individuals, with a safety profile comparable to that of fundoplication. They added that MSA was notably associated with high rates of PPI discontinuation and increased satisfaction among individuals. As such, MSA is emerging as a promising option in the contemporary surgical management of GERD and may also serve as a viable revisional procedure following fundoplication, although this application warrants further investigation. The authors emphasized the current lack of robust comparative data regarding adverse events and long-term surgical reinterventions, particularly device explantation. Additionally, outcomes related to device erosion were not thoroughly addressed in the included studies, highlighting a need for further research. Limitations of the review include the predominance of retrospective studies, many of which focused solely on MSA, without direct comparison to fundoplication. Only two RCTs were included, and not all studies assessed every outcome considered in the meta-analysis. Given that MSA is a relatively novel procedure, there is potential for publication bias, with some surgeons possibly reporting more favorable outcomes while underreporting complications. Therefore, high-quality RCTs are needed to directly compare MSA and fundoplication and to evaluate long-term outcomes and adverse events associated with MSA.

Valinoti et al. (2024) conducted a systematic review and meta-analysis in accordance with PRISMA guidelines to evaluate the effectiveness and safety of MSA in individuals with GERD. The review included 22 studies, with a total of 4,663 MSA individuals. The authors' findings indicated that the MSA device is highly effective and provides symptom relief and improved quality of life in most individuals. However, postoperative dysphagia and the need for endoscopic dilation are relatively common, and while the risk of esophageal erosion is low, it significantly increases over time. The authors recommended further studies that have objective assessments and longer follow-up periods. They also emphasized the importance of standardized diagnostic methods for more objective and comparable outcome assessments. They noted that the study has several limitations. Firstly, there were methodological design discrepancies among the included studies. Secondly, the majority of the studies had a short follow-up period. Thirdly, there was significant statistical heterogeneity in many of the outcomes assessed. Lastly, few studies evaluated individuals using postoperative pH monitoring. (Ganz et al., 2016 and Louie et al., 2019, previously cited in this policy, is included in this review. Ferrari et al., 2020, is included below.)

An ECRI Clinical Assessment on the LINX Reflux Management System for treating GERD identified a review of evidence from 2017 through 2023 that included three systematic reviews, one RCT, one patient registry study, and two economic studies. The evidence appears to indicate that LINX may be safe and as effective as LNF; however, the studies had a high risk of bias, and not enough individuals were included to confirm the conclusions. It was concluded that larger, multicenter RCTs and longer follow-up, with comparisons of LINX with other GERD devices, would be useful to determine long-term safety and efficacy. (ECRI, 2023)

A Hayes Health Technology Assessment (2022) evaluated the effectiveness and safety of MSA with the LINX Reflux Management System for the treatment of GERD. One RCT compared MSA with twice-daily PPI treatment, and the other five nonrandomized cohort studies compared MSA with laparoscopic fundoplication. While the low-quality body of evidence suggests that MSA may improve the individual's quality of life and their GERD symptoms, along with a reduction in PPI use, there remains uncertainty about the long-term safety and efficacy of this device. The reported overall conclusion is that there is potential but unproven benefit with the LINX system.

Zhuang et al. (2021; included in the Hayes report above) performed a systematic review and meta-analysis to determine the efficacy and safety of MSA in the management of refractory GERD as well as compare the efficacy of MSA to that of PPI or LNF. Ten single-arm studies, one RCT, and three cohort studies, involving 1,138 individuals, were included. Post MSA PPI withdrawal, significant GERD-HRQL improvement and acid exposure time normalization were achieved in 87.0%, 88.0%, and 75.0% of the individuals, individually. The incidence of postoperative dysphagia was 29%, and endoscopic dilation was required in 7.4% of individuals undergoing MSA. MSA showed better efficacy in symptom control than PPI (PPI cessation: 91% vs 0%; GERD-HRQL improvement: 81% vs 8%) and similar effectiveness but a lower risk of gas-bloat syndrome (risk ratio, 0.69; 95% CI, 0.51-0.93; p = 0.01) and better reserved ability to belch (risk ratio, 1.48; 95% CI, 0.76-2.86; p = 0.25) than LNF. Study limitations include the limited number of clinical studies; inclusion of only three studies in the comparative results between MSA and LNF; and potential for selection bias that could have led to an overestimation of efficacy in MSA, since the individuals selected had less severe GERD. The authors concluded that MSA was an effective and safe therapy for GERD in individuals with PPI-refractory symptoms and pathological reflux. There

was only one randomized comparative trial that presented an advantage over a double dose of PPI. Therefore, there is a need for additional randomized trials that compare the efficacy of MSA with that of other therapies. (Bonavina et al., 2010, Lipham et al., 2012, Ganz et al., 2013, Riegler et al., 2015, Saino et al., 2015, Ganz et al., 2016, and Warren et al., 2016, previously cited in this policy, are included in this meta-analysis.)

Chandan et al. (2021) conducted a systematic review and meta-analysis in individuals undergoing treatment for refractory GERD and compared the efficacy of MSA with that of TIF2. Overall, 24 articles were included in the analysis, which consisted of 1,074 individuals who underwent MSA and 868 individuals who underwent TIF2. In the MSA cohort, six studies were prospective and three studies were retrospective; in the TIF cohort, 11 studies were prospective and four were retrospective. The authors found that the clinical success rate, demonstrated by improvement of scores in GERD-HRQL, was 80% for MSA and 77% for TIF. It was concluded that both procedures have a similar efficacy, but MSA seems to outperform TIF2. Overall, 91.3% of the MSA individuals were able to discontinue PPI therapy compared with 63.8% of the TIF2 individuals. Limitations include the lack of long-term data.

Bell et al. (2020; included in the Hayes report above) compared the effects of MSA vs those of PPI in a randomized trial. Overall, 152 participants with moderate to severe regurgitation symptoms across 21 U.S. clinical sites were randomized into two groups. Additional inclusion criteria for the participants were once-daily PPIs for at least 8 weeks, a body mass index of < 35 kg/m^2, abnormal pH testing (DeMeester score of < 4), hiatal hernia of < 3 cm by endoscopy, and absence of Barrett esophagus or Los Angeles Classification grade C or D esophagitis. Participants were assessed at 6 and 12 months with the Reflux Disease Questionnaire and GERD-HRQL standard assessments, along with specific questions concerning bloating, diarrhea, flatulence, and medication use. One group (n = 102) received PPI (20 mg of omeprazole twice daily), and the other group (n = 50) received laparoscopic MSA. The authors found that MSA controlled regurgitation in 96% of participants, whereas only 19% of participants receiving PPIs reported control of regurgitation. The regurgitation had been sustained over 12 months. The second portion of the study allowed eligible participants (39%) from the PPI group to cross over and receive the laparoscopic MSA if they had not experienced improvement with the twice-daily medication. The authors concluded that MSA is an effective surgical treatment option for individuals with medically refractory, regurgitative GERD. The study is limited by the limited follow-up.

Ferrari et al. (2020) followed up a cohort of 124 participants who underwent laparoscopic implantation of an MSA device. The goal was to assess the long-term safety and efficacy of the LINX Reflux Management System for 6 to 12 years. Prior to surgery, all participants completed a diagnostic assessment that included the GERD-HRQL questionnaire, upper gastrointestinal endoscopy, barium swallow study, ambulatory esophageal pH monitoring, and esophageal manometry. Success was defined as a ≥ 50% improvement in the GERD-HRQL total score and discontinuation of PPI medication. During follow-up, over a 5-year period, eight participants (2.4%) required a single endoscopic PD due to persistent dysphagia. Overall, 31 participants (9.2%) required removal of the device for various reasons; erosion and regurgitation were the top two reasons, with six participants each. The average total GERD-HRQL score decreased from 19.9 (baseline) to 4.01. The authors found that 81% of the participants had a successful clinical outcome and were able to discontinue their PPI use. Long-term results in 32 participants past 10 years found zero dysphagia, seven participants with occasional PPI use, and only three with daily PPI use. The total overall participant satisfaction rate was 92.5%. The authors concluded that MSA allows control of GERD symptoms and improvement in individuals' quality of life, without significant safety issues. However, it was also concluded that additional RCTs could provide more definitive conclusions. Limitations include the absence of a comparison group and possible selection bias, with a large loss to follow-up over time.

Schizas et al. (2020) conducted a systematic review to investigate the safety and efficacy of the LINX Reflux Management System. After screening 614 articles, a total of 35 studies fit the criteria and were analyzed. According to the authors, although laparoscopic fundoplication and MSA both appear to be safe and effective procedures, MSA appears to have a few distinct advantages; MSA is a less technical procedure, results in less bloating, has superiority in the ability to vomit/belch, and is easily reversible. If MSA fails, laparoscopic fundoplication is still a viable option after device removal. The authors' findings suggest that MSA with the LINX device is a safe procedure and has the potential to bridge the treatment gap between maxed-out medical treatment and laparoscopic fundoplication. The authors also concluded that further studies that include longer follow-up are needed. (Asti et al., 2016, Ganz et al., 2016, Desart et al., 2015, Reynolds et al., 2015, Bonavina et al., 2008, Bonavina et al., 2010, Louie et al, 2019, and Warren et al., 2018, previously cited in this policy, are included in this systematic review.)

A prospective multicenter RCT was conducted by Bell et al. (2019; included in the ECRI report above) comparing MSA (n = 50) with double-dose PPI therapy (omeprazole, 20 mg, twice a day; n = 102). The goal of the study was to compare the effect of the two treatments for elimination of moderate to severe regurgitation. As reported on a foregut symptom questionnaire, at 6 months, 89% of participants treated with MSA reported relief of regurgitation, with 81% reporting ≥ 50% improvement in GERD-HRQL scores. Overall, 10% of the PPI group reported relief of regurgitation, with 8% of the

PPI group reporting ≥ 50% improvement in GERD-HRQL scores. However, 28% of MSA participants reported transient dysphagia, with 4% reporting ongoing dysphagia. The authors concluded that individuals who continue to experience moderate to severe regurgitation despite PPI treatment should be considered for MSA. RCTs that include larger populations of individuals and long-term follow-up are needed to further assess the long-term safety and efficacy of MSA.

In a systematic review and meta-analysis of the LINX magnetic esophageal sphincter augmentation vs Nissen fundoplication for GERD, Skubleny et al. (2017) included RCTs, a nonrandomized comparison study, and case series with more than five individuals. Overall, 547 titles were identified through a primary search, and 197 titles or abstracts were screened after removing duplicates. A meta-analysis was performed on postoperative quality-of-life outcomes, procedural efficacy, and individuals' procedural satisfaction. Three primary studies identified a total of 688 individuals, of whom 273 and 415 underwent Nissen fundoplication and MSA, respectively. MSA was statistically superior to LNF in preserving individuals' ability to belch (95.2% vs 65.9%; $p < 0.00001$) and the ability to experience emesis (93.5% vs 49.5%; $p < 0.0001$). There was no statistically significant difference between MSA and LNF in gas/bloating (26.7% vs 53.4%; $p = 0.06$), postoperative dysphagia (33.9% vs 47.1%; $p = 0.43$), and PPI elimination (81.4% vs 81.5%; $p = 0.68$). The authors' conclusion is that MSA appears to be an effective treatment for GERD, with short-term outcomes comparable to those of the more technically challenging and time-consuming Nissen fundoplication. The authors also concluded that long-term comparative outcome data past 1 year are needed in order to further understand the efficacy of MSA.

Smith et al. (2017) reported that of a total of 3,283 procedures reviewed for an MSA device, device removal occurred in 2.7% of cases. The most common causes of removal were dysphagia, continued reflux, and device erosion into the esophagus. Salvador et al. (2017), Parmar et al. (2017), and Lipham et al. (2015) reported similar findings.

Clinical Practice Guidelines

American College of Gastroenterology (ACG)

In an ACG clinical guideline (Camilleri et al., 2022) for gastroparesis, the ACG suggests pyloromyotomy over no treatment for patients with gastroparesis who have not responded to medical therapy and who continue to experience symptoms (conditional recommendation; low quality of evidence). The preferred myotomy method (laparoscopic or endoscopic) is, however, not specified.

In a 2021 ACG published clinical guideline (Katz et al., 2021) for the diagnosis and management of GERD, the following recommendations are cited:

- Recommend antireflux surgery as an option for long-term treatment of patients with objective evidence of GERD (strong recommendation; moderate level of evidence).
- Recommend consideration of MSA as an alternative to laparoscopic fundoplication for patients with regurgitation who experience failure of medical management (strong recommendation; moderate level of evidence).
- Consideration of TIF for patients with troublesome regurgitation or heartburn who do not wish to undergo antireflux surgery and who do not have severe reflux esophagitis or hiatal hernias (conditional recommendation; low level of evidence).
- Do not recommend radiofrequency energy (Stretta) as an antireflux procedure due to inconsistent data on the efficacy of the device (conditional recommendation; low level of evidence).

American Gastroenterological Association (AGA)

An AGA clinical practice update offers guidance on best practices for personalized diagnosis and treatment of GERD. The AGA recommends a stepwise approach for patients presenting with GERD symptoms, aimed at identifying underlying mechanisms. When symptoms persist despite lifestyle changes and optimal medication use, management strategies should be tailored based on factors such as the integrity of the antireflux barrier, presence of visceral hypersensitivity and hypervigilance, confirmation of PPI-refractory GERD, symptom patterns, body mass index, and esophageal (and gastric) motor function. (Yadlapati et al., 2022)

American Society for Gastrointestinal Endoscopy (ASGE)

In a 2015 clinical guideline on the role of endoscopy in the management of GERD, the ASGE suggests that endoscopic antireflux therapy be considered for selected patients with uncomplicated GERD after careful discussion with the patient regarding potential adverse effects, benefits, and other available therapeutic options.

American Society of General Surgeons (ASGS)

In 2014, the ASGS published a position statement regarding its support for the LINX procedure. The ASGS states that the total management of GERD will likely rely on a combination of medical and surgical care in the current and near future. The ASGS recommends that when considering a surgical procedure, the procedure will need to provide safe control of

GERD, with minimal side effects. The ASGS states, “Based on currently available information and the experience of our members with the procedure, we do support the LINX procedure as a mechanism for controlling GERD when it is placed by properly trained laparoscopic surgeons with experience in foregut surgery and the management of GERD patients.”

In April 2011, the ASGS published a position statement regarding the use of TIF, stating that it supports the use of TIF in patients with symptomatic, chronic GERD who are not responsive to a standard dose of PPI therapy (ASGS, 2011). The ASGS also supports the use of TIF for patients who wish to avoid lifetime drug therapy for this condition. The ASGS also supports the adoption of the procedure by trained general surgeons as a less invasive alternative to more conventional surgical techniques, stating that the preferred surgical technique should be based on the discretion and judgment of the surgeon and the patient’s clinical circumstances.

In a statement regarding coverage for TIF, the ASGS states that there is a sufficient body of peer-reviewed literature that establishes transoral fundoplication as reasonable and medically necessary for a subset of patients who are candidates for surgical fundoplication, specifically patients who either cannot obtain satisfactory relief from standard PPI therapy or who wish to avoid a lifetime of dependence on such medications and present with a 2-cm or smaller hiatal hernia. (ASGS, 2011)

National Institute for Health and Care Excellence (NICE)

NICE (NICE, 2023) conducted a rapid review of the published literature on the efficacy and safety of laparoscopic insertion of a magnetic ring for GERD. They evaluated evidence from three systematic reviews and meta-analyses, one RCT, three nonrandomized comparative studies, and two case series. The committee notes that the magnetic ring use has evolved over time and is considered adequate. In addition, it is stated that the use of the device should be performed by clinicians who have specific training in the procedure.

The NICE guideline on endoscopic radiofrequency ablation for GERD considers the evidence on this procedure to be adequate in the short and medium term, but there is uncertainty about longer-term outcomes. Regarding efficacy, there is evidence of symptomatic relief, but objective evidence on the reduction of reflux is inconclusive. (NICE, 2013)

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

The following recommendations are made by SAGES (Auyang et al., 2013) on endoluminal treatments for GERD:

- Results for EsophyX appear to be mixed and lack long-term data. Further studies are required to define optimal techniques and to further evaluate the device and its safety [quality of evidence: (++)]. GRADE recommendation: weak.
- The evidence for the Stretta device demonstrates that Stretta is considered appropriate therapy for patients older than 18 years with GERD who have symptoms of heartburn, regurgitation, or both for 6 months or more; have been partially or completely responsive to antisecretory pharmacological therapy; and have declined laparoscopic fundoplication [quality of evidence: (++++)]. GRADE recommendation: strong.

The SAGES Technology and Value Assessment Committee updated its safety and effectiveness analysis of the LINX Reflux Management System.

- Review of published studies suggests that MSA is safe, with no reported deaths and a 0.1% rate of intra-/perioperative complications.
- Long-term efficacy of LINX appears good for typical GERD symptoms, with reduced acid exposure, improved GERD symptoms, and freedom from PPI in 85% to 88% at 3 to 5 years.
- Dysphagia resolves in most patients, and the incidence is roughly 10% at 1 year and 4% at 3 years. The need for endoscopic dilation ranges from 6% to 12%, and the primary reason for explantation appears to be persistent dysphagia, with a rate in larger series from 3% to 6%.
- Erosion appears to be rare, with one case reported in the first 1,000 patients, one additional published case report, a large series reporting two erosions, and several additional reports in the U.S. Food and Drug Administration MAUDE (Manufacturer and User Facility Device Experience) dataset (true number unknown, as multiple entries in this dataset may be made for each patient). Based on very limited literature, erosion can be successfully treated with explantation. (Telem et al., 2017)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The only gastric electrical stimulation device for gastroparesis treatment approved for marketing in the United States is the Enterra Therapy system, manufactured by Medtronic, Inc. On March 31, 2000, the FDA approved a Humanitarian Device

Exemption for the marketing of the Enterra gastric electrical stimulation system for the treatment of chronic, intractable (drug-refractory) nausea and vomiting secondary to paresis of diabetic or idiopathic etiology. Enterra is indicated for the treatment of chronic, intractable (drug-refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years. Based on the FDA label, the Enterra device should not be used for patients with gastric obstruction or pseudo-obstruction, prior gastric resection, fundoplication, eating disorders, history of seizures, primary swallowing disorders, chemical dependency, or psychogenic vomiting. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id = 376493. (Accessed February 10, 2026)

Several endoscopic antireflux (endoluminal) devices have received approval by the FDA for the treatment of gastroesophageal reflux disease (GERD).

The Stretta system (Mederi Therapeutics) was approved in April 2000 for radiofrequency thermal ablation treatment of GERD. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf10/k103017.pdf. (Accessed February 10, 2026)

The Bard EndoCinch Endoscopic Suturing System (Bard Endoscopic Technologies, Billerica, MA, a subsidiary of C.R. Bard Inc) was approved in January 2001 for endoscopic suturing in the treatment of GERD. Subsequent FDA approval was received in September 2007 for an updated version. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf7/k071651.pdf. (Accessed February 10, 2026)

The NDO Surgical Endoscopic Plication System was approved in September 2007 for endoscopic suturing in the treatment of GERD in patients who require and respond to pharmacological therapy. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf7/K071553.pdf. (Accessed February 10, 2026)

The current generation of EsophyX, EsophyX2, was cleared for marketing as substantially equivalent to the original EsophyX system, with minor changes in November 2009 under the FDA 510(k) process. The original system was cleared for marketing in September 2007 as substantially equivalent to the predicate devices NDO Surgical Endoscopic Plication System, Bard EndoCinch, and EGS StomaphyX endoluminal fasteners and delivery system. According to the approval summary letter, EsophyX2 is indicated for:

- Use in transoral tissue approximation.
- Full-thickness plication and ligation in the gastrointestinal tract.
- The treatment of symptomatic, chronic GERD in patients who require and respond to pharmacological therapy.
- Narrowing of the gastroesophageal junction.
- Reduction of hiatal hernia of < 2 cm in patients with symptomatic, chronic GERD.

Refer to the following websites for more information:

- http://www.accessdata.fda.gov/cdrh_docs/pdf7/K071651.pdf
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?db = PMN&id = k092400

(Accessed February 10, 2026)

The Medigus Ultrasonic Surgical Endostapler (MUSE™ System) received 510(k) approval on January 15, 2015, for the endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach in order to create anterior partial fundoplication for treatment of symptomatic, chronic GERD in patients who require and respond to pharmacological therapy. Refer to the following website for additional information: https://www.accessdata.fda.gov/cdrh_docs/pdf14/k143634.pdf. (Accessed February 10, 2026)

These products are Class II devices (moderate risk) deemed substantially equivalent to other endoscopic devices using other procedures.

Torax Medical obtained FDA premarket approval (PMA) in March 2012 for the LINX Reflux Management System. Additional approvals for PMA supplements can be found on the FDA website. Refer to the following website for more information, using PMA number P100049: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed February 10, 2026)

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Policy History/Revision Information

Date	Summary of Changes

08/01/2026	**Coverage Rationale**
	• Removed content/language pertaining to:
	  ○ Endoluminal therapy with GERDx™
	  ○ Injection or implantation techniques
	  ○ Per oral endoscopic myotomy (POEM)
	Definitions
	• Removed definition of:
	  ○ Achalasia
	  ○ Diffuse Esophageal Spasm
	Applicable Codes
	• Removed CPT codes 43289, 43497, 43499, and 43999
	Supporting Information
	• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
	• Removed *Medical Records Documentation Used for Reviews* section
	• Archived previous policy version 2026T0322LL

Instructions for Use

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