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Subject: Minimally Invasive Procedures for the Treatment of Gastroesophageal Reflux Disease (GERD) and Dysphagia

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DESCRIPTION:

Gastroesophageal reflux disease (GERD) is a common disorder characterized by heartburn and other symptoms related to reflux of stomach acid into the esophagus. The pathophysiology of GERD involves excessive exposure to stomach acid, which occurs for several reasons. There can be an incompetent barrier between the esophagus and stomach, either due to dysfunction of the lower esophageal sphincter or incompetence of the diaphragm. Another mechanism is an abnormally slow clearance of stomach acid. In this situation, delayed clearance leads to an increased reservoir of stomach acid and a greater tendency to reflux. Treatment options for GERD include weight loss, smoking cessation, head of the bed elevation, elimination of food triggers, and proton pump inhibitors.

Esophageal achalasia is characterized by reduced numbers of neurons in the esophageal myenteric plexuses and reduced peristaltic activity, making it difficult to swallow food and possibly leading to complications such as regurgitation, coughing, choking, aspiration pneumonia, esophagitis, ulceration, and weight loss. Treatment options for esophageal achalasia include pharmacotherapy (eg, injections with botulinum toxin), pneumatic dilation, and laparoscopic Heller myotomy.

Surgical options investigated for treating GERD and dysphagia caused by achalasia include transoral incisionless fundoplication (ITIF), transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction, endoscopic submucosal implantation of a biocompatible polymer, endoscopic submucosal implantation of a prosthesis or injection of a bulking agent, magnetic sphincter augmentation, and peroral endoscopic myotomy (POEM). Variations of peroral endoscopic myotomy

(POEM) include diverticular peroral endoscopic myotomy (D-POEM), gastric peroral endoscopic myotomy (G-POEM), and zenker peroral endoscopic myotomy (Z-POEM).

Summary and Analysis of Evidence: In an update of the clinical practice from the American Gastroenterological Association (AGA), Kahrilas et al (2017) described a place for per-oral endoscopic myotomy (POEM) among the currently available robust treatments for achalasia. The recommendations outlined were based on expert opinion and on relevant publications from PubMed and Embase. The Clinical Practice Updates Committee of the AGA included the following recommendation: "if the expertise is available, POEM should be considered as primary therapy for type III achalasia." UpToDate review "Overview of the treatment of achalasia" (Spechler, 2024) states that "POEM is an effective submucosal endoscopic technique for performing myotomy of the LES and more proximal esophageal muscle. In addition, good results for POEM have been reported in patients with achalasia conditions that often do not respond well to conventional therapies, such as type III (spastic) achalasia and "end-stage" achalasia (markedly dilated, sigmoid esophagus), and in patients who have failed prior endoscopic and surgical achalasia treatments. The role of POEM in the treatment of achalasia continues to evolve, although there is a consensus that POEM is the procedure of choice for the treatment of type III achalasia. It has been suggested that patients undergoing POEM should be counseled regarding the increased risk of post-procedure reflux compared with other treatments." Tan et al (2021) examined the safety and efficacy of POEM in achalasia patients with failed previous intervention. These investigators searched the Medline, Embase, Cochrane, and PubMed databases using the queries "achalasia", "peroral endoscopic myotomy" and related terms in March 2019. Data on technical and clinical success, AEs, Eckardt score and lower esophageal sphincter (LES) pressure were collected. A total of 15 studies with 2,276 achalasia patients were included. Overall, the pooled technical success, clinical success and AE rate of rescue POEM were 98.0 %, 90.8 %, and 10.3%, respectively; 7 studies compared the clinical outcomes of POEM between previous failed treatment and the treatment naïve patients. The RR for technical success, clinical success, and AEs were 1.00 (95 % CI: 0.98 to 1.01), 0.98 (95 % CI, 0.92 to 1.04), and 1.17 (95 % CI: 0.78 to 1.76), respectively. Overall, there was significant reduction in the pre- and post-Eckardt score and LES pressure for achalasia patients with failed previous intervention after POEM. The authors concluded that POEM appeared to be a safe, effective and feasible treatment for individuals who had undergone previous failed intervention. Zhong et al (2021) stated that peroral endoscopic myotomy (POEM) is a novel minimally invasive intervention, which has shown to be effective and safe for treating achalasia in adults. The authors conducted a study to explore the clinical outcomes of POEM for pediatric achalasia. A systematic literature search in PubMed, Embase, and Cochrane databases was performed, which covered the period from January 2009 to June 2020. A total of 11 studies with 389 children were identified in the final analysis. Pooled technical success of POEM treatment achalasia was achieved in 385 children (97.4%), and the pooled clinical success was achieved in 348 children (92.4%). After POEM, the Eckardt score was significantly decreased by 6.76 points, and the lower esophageal sphincter pressure was significantly reduced by 19.38 mmHg. The pooled major adverse events rate related to POEM was 12.8% and the gastroesophageal reflux rate was 17.8%. The authors stated "our study demonstrated that the POEM was an effective and safe technique for treating achalasia in children", however, "further randomized comparative studies of POEM and other therapeutic methods are warranted to determine the most effective treatment modality for achalasia in children."

Yang et al (2019) conducted a study to report on a multicenter experience with the diverticular peroral endoscopic myotomy (D-POEM) technique in the management of esophageal diverticula. It was an

international, retrospective study involving three centers. D-POEM was performed using the principles of submucosal endoscopy. A total of 11 patients with an esophageal diverticulum (Zenker's 7, mid-esophagus 1, epiphrenic 3) were included. The mean size of the esophageal diverticula was 34.5 mm. The overall technical success rate of D-POEM was 90.9 %, with a mean procedure time of 63.2 minutes. There were no adverse events. Clinical success was achieved in 100 % (10 /10), with a decrease in mean dysphagia score from 2.7 to 0.1 during a median follow-up of 145 days. The authors concluded that "endoscopic management of esophageal diverticula using the novel technique of D-POEM appears promising. This first case series on D-POEM suggests that the procedure is feasible, safe, and effective in the management of esophageal diverticula. D-POEM offers the distinct advantage of ensuring a complete septotomy. Larger studies are needed to confirm these intriguing results." Maydeo et al (2019) stated that "submucosal tunneling diverticular septotomy by diverticular peroral endoscopic myotomy (D-POEM) has emerged as an alternative to surgery for symptomatic esophageal diverticula, but its medium to long-term outcomes are currently unexplored." The authors prospectively studied D-POEM for patients with symptomatic esophageal diverticula to assess its safety and the 12-month outcomes. Twenty-five patients (72 % male; median age 61 years [range 48 - 88]) with a Zenker's diverticulum (n = 20) or epiphrenic diverticulum (n = 5) were included. Major indications were dysphagia, recurrent bronchoaspiration, and foreign body sensation in 20 patients (80 %), with a mean symptom duration of 2.5 years. Complete submucosal tunneling septotomy was achieved in a mean of 36 minutes, with 100 % technical success. The median hospitalization was 5 days. The mean (standard deviation) Eckardt Score improved significantly from 13.2 (1.0) at baseline to 3.2 (1.4) at 12 months with clinical success in 19/22 patients (86 %) and no long-term adverse events. The authors concluded "D-POEM appears safe and durable in patients with esophageal diverticula. Further multicenter studies with a larger patient cohort are warranted." Sato et al (2019) stated that "esophageal diverticula are rare conditions that cause esophageal symptoms, such as dysphagia, regurgitation, and chest pain. They are classified according to their location and characteristic pathophysiology into three types: epiphrenic diverticulum, Zenker's diverticulum (ZD), and Rokitansky diverticulum." The authors set out to review the pathophysiology of each type of diverticulum and the current state-of-the-art treatment based on their own experience. They concluded that the relative proportion of pulsion-type esophageal diverticula (epiphrenic and ZD) is increasing, while that of the traction-type (Rokitansky) is decreasing. Minimally invasive endoscopic treatment is indicated for pulsion-type diverticula and is being increasingly adopted owing to lower complication rates and equivalent efficacy to surgery. However, no randomized controlled trials comparing the difference between endoscopic treatment and surgery, or among the different endoscopic techniques have been performed. They stated "studies of long-term follow-up results, including esophageal motility outcomes, are required to decide the best intervention modality for esophageal diverticulum." Zeng et al (2020) reported on their experience with the use of diverticular POEM (D-POEM) technique in the management of esophageal diverticulum. This retrospective study included 10 consecutive patients with symptomatic esophageal diverticulum (Zenker's 2, mid-esophagus 5, and epiphrenic 3) who visited their endoscopy center between April 2014 and January 2019. D-POEM was performed based on the principles of submucosal endoscopy. A new symptomatic scoring system was introduced to evaluate the severity of diverticular symptoms. The overall technical success rate of D-POEM was 100%, with a mean procedure time of 38.9 ± 20.5 minutes. No serious complications occurred. Clinical improvement was achieved in 90% (9/10) of patients. The symptomatic score was significantly decreased from 2.5 to 1.0 during a median follow-up period of 11.0

months. The authors concluded their "preliminary data and experience put forwarded D-POEM as a safe and effective technique for esophageal diverticulum." The study limitations included small size.

Kahaleh et al (2018) stated that "gastroparesis is a difficult-to-treat motility disorder with a poor response to medical therapy. Gastric peroral endoscopic pyloromyotomy (G-POEM) has been offered as a novel therapy in the treatment of refractory gastroparesis." The authors conducted an international multicenter case series of patients who underwent G-POEM for the treatment of gastroparesis. The severity of gastroparesis was assessed by delayed gastric emptying scintigraphy (GES) and an elevated gastroparesis cardinal symptoms index (GCSI). Patients then underwent G-POEM using the submucosal tunneling technique. The primary endpoint was improvement in the GCSI score and improvement in gastric emptying on repeat scintigraphy. Secondary endpoints were technical success, complication rate, procedure duration, and length of hospital stay post-procedure. They stated "G-POEM was technically successful in all 33 patients. Symptomatic improvement was seen in 28/33 patients (85 %), with a decrease in symptom score by GCSI from 3.3 to 0.8 at follow-up. The mean procedure duration was 77.6 minutes (37 - 255 minutes). Mean GES improved significantly from 222.4 minutes to 143.16 minutes. Complications were minimal and included bleeding (n = 1) and an ulcer (n = 1) treated conservatively. The mean length of hospital stay post-procedure was 5.4 days (1 - 14 days). The mean follow-up duration was 11.5 months (2 - 31 months)." They concluded that G-POEM is a technically feasible, safe, and successful procedure for the treatment of refractory gastroparesis, noting "a further multicenter comparative study should be performed to compare this technique to laparoscopic pyloromyotomy." Myint et al (2018) stated "gastroparesis is a complex, debilitating dysmotility disorder with challenging symptom management." The authors noted that pharmacologic therapies are limited by significant side effects, including extrapyramidal effect and tachyphylaxis. Electrical stimulation and gastric pacing have been used, with small studies noting improved symptoms and gastric emptying. Botulinum toxin injection into the pylorus has shown some efficacy in small trials. Novel endoscopic treatment options such as G-POEM have shown some efficacy in small trials. They concluded "further investigation is warranted to identify new and effective treatment options … to address the substantial morbidity of gastroparesis." Tao et al (2019) noted that gastric peroral endoscopic pyloromyotomy (G-POEM or POP) is a feasible and effective procedure for the treatment of refractory gastroparesis. G-POEM is a technically demanding endoscopic procedure. As of yet, there is no consensus on the technique. A variety of techniques have been reported in published studies. The essential technical steps of the procedure are (1) establishment of submucosal tunnel in gastric antrum, (2) identification of the pyloric muscular ring, (3) selective circular myotomy, and (4) a 2.5-cm to 3.0-cm length of myotomy. There are still some technical questions unanswered, and more studies are needed to establish standardized techniques and possible improvement of outcomes. Zhang et al (2019) assessed the efficacy and safety of gastric peroral endoscopic myotomy for the treatment of gastroparesis. PubMed, Embase, Cochrane Library and Web of Science databases were searched from their earliest records to May 2018. The evaluation of clinical efficacy and safety was based on gastric emptying scintigraphy normalization, the improvement in clinical symptoms and adverse event rate. Fourteen studies with a total of 276 patients were included in this systematic review. The mean Gastroparesis Cardinal Symptom Index score improvement rate was about 90.2% at one month follow-up, 83.3% at three months, 70.3% at six months, 52.4% at twelve months and 57.1% at eighteen months. The authors stated that their systematic review "demonstrates that gastric peroral endoscopic myotomy is a safe and effective treatment for gastroparesis. Though the short-term outcomes are promising, prospective, randomized, controlled studies with large sample size and long-term follow-up are required to further confirm these

results." UpToDate review "Treatment of Gastroparesis" (Camilleri, 2024) states, "G-POEM may improve symptoms and gastric emptying in individuals with refractory gastroparesis. In a randomized trial of 41 patients with refractory gastroparesis, G-POEM resulted in a higher likelihood of treatment success (defined as a decrease in Gastroparesis Cardinal Symptom Index (GCSI) score of ≥50 percent) than a sham control (71 versus 22 percent). It appeared particularly effective in those with diabetic gastroparesis. A meta-analysis of 20 observational studies with 797 participants also found that G-POEM was associated with improved post-procedure GCSI scores and high rates of technical success." The review further stated, "endoscopy and laparoscopic interventions directed at the pylorus should be reserved for individuals with refractory gastroparesis. Interventions include laparoscopic (pyloroplasty) and endoscopic approaches (gastric peroral endoscopic myotomy [G-POEM], transpyloric stent). Although observational studies suggest that these procedures may improve symptoms in patients with refractory gastroparesis, these findings await confirmation by randomized, sham-controlled trials."

Zhang et al (2022) conducted a meta-analysis to estimate the safety and efficacy of Z-POEM for Zenker's diverticulum (ZD) and compare the feasibility and effectiveness of Z-POEM with that of flexible endoscopic septotomy (FES). The authors conducted a comprehensive literature search in PubMed, EMBASE, Web of Science, and Cochrane Library databases to query for studies that assessed the safety and efficacy of Z-POEM for ZD. All articles published from inception to July 31, 2021 were included. Eleven studies involving 357 patients undergone Z-POEM were included. The overall pooled technical success rate for Z-POEM was 96.3. The total pooled clinical success rate for Z-POEM was 93.0%. The pooled incidence of adverse events for Z-POEM was 12.4%. The pooled clinical recurrence rate for Z-POEM was 11.2%. The clinical success for Z-POEM was significantly better than that of FES, while there were no significant differences in technical success, adverse events, and clinical recurrence between Z-POEM and FES. They concluded "Z-POEM could be an effective and safe therapeutic modality for ZD, and even has a slightly higher clinical success rate than FES. However, comparative studies with long-term follow-up will be needed to further confirm our finding." Elkholy et al (2021) studied 24 patients diagnosed with Zenker's diverticulum (ZD) who underwent Z-POEM at seven independent endoscopy centers in five different countries. Mean patient age ± standard deviation (SD) was 74.3 ± 11 years. Most of the patients were males (n = 20, 83.3%); four (16.7%) were females. More than 50% of the patients (n = 14, 58.3%) had associated comorbidities. The mean size of the diverticula was 4 cm (range 2-7 cm). The Kothari-Haber Score was used to assess clinical symptoms; values ranged from 6 to 14 (median = 9). 100% technical success was achieved with a median procedure time of 61 min and no adverse events. Median hospital stay was 1 day (range 1-5 days). There is a significant reduction in the Kothari-Haber Score after Z-POEM. Technical success was achieved in 100% of the patients. Clinical success was achieved in 23/24 (95.8%) of the patients with a median follow-up of 10 months (range 6-24 months). UpToDate review "Zenker's diverticulum" (van Delft, 2024) states "Zenker-peroral endoscopic myotomy (Z-POEM) is a newer flexible endoscopic technique for the management of ZD which is considered the endoscopic equivalent of surgical myotomy. Z-POEM relies on submucosal tunneling to completely expose and dissect the septum. Submucosal tunneling may be particularly suitable for treating small (<2 cm) ZD because the small pocket may disappear after the myotomy is performed. For larger ZDs (>2 cm), however, division of some of the mucosa is also required to create a common channel between the diverticulum and the native esophageal lumen, which ensures proper drainage of the ZD. Data comparing the efficacy of POEM with other approaches are limited and conflicting, and expertise in Z-POEM is not widely available. UpToDate review "Peroral endoscopic myotomy (POEM) (Khashab, 2024) states "a variety of endoscopic techniques have been described for the treatment of Zenker's diverticula

(ZD) with clinical success rates between 56 and 100 percent and adverse events in an average of 15 percent of cases. Clinical recurrence occurs in 10.5 percent of patients, but recurrence rates up to 35 percent have been reported. It is not possible to accurately delineate the terminal end of the diverticulum during standard endoscopic Zenker's septotomy, and recurrence has been linked to incomplete septotomy. POEM could be a promising technique to allow complete transection of ZD septum (Z-POEM), as submucosal tunneling enables complete exposure and dissection of the septum. This may result in diminishing the risk of symptom recurrence.

Rausa et al (2023) published a network meta-analysis of RCTs comparing TIF (n=188) to anterior partial fundoplication (n=322), laparoscopic Toupet fundoplication (n=1120), laparoscopic Nissen fundoplication (n=1740), and PPI therapy (N=80) in patients with recalcitrant GERD. The outcomes of interest were differences in the rate of heartburn, regurgitation, dysphagia, bloating, and PPI discontinuation. TIF did not differ significantly from the other treatments in the pooled network analysis for any outcome. Treatment failure was not included in the quantitative analysis due to the considerable heterogeneity across studies. Testoni et al (2021) published a systematic review and meta-analysis focusing on long-term (≥3 years) outcomes of patients with GERD undergoing TIF (using either EsophyX or MUSE). Outcomes of interest included patient satisfaction, QOL, and PPI use. The mean follow-up time across studies was 5.3 years (range , 3 to 10 years). Daily PPI use was 100% in 5 studies, 97% in 1 study, and was not provided in the other 2 studies. Overall, the pooled proportion of patient-reported satisfaction before and after TIF was 12.3% and 70.6%, respectively. Additionally, the pooled rates of patients completely off, or on occasional, PPIs post-TIF was 53.8% and 75.8%. The analysis was limited by various factors including the nature of included studies, which involved only 1 open-label RCT among the 8 studies included, and the high heterogeneity across studies for patient reported overall satisfaction after the TIF procedure. Trad et al (2018) reported a 5-year follow-up for the TEMPO trial (Table 5). Data were available for 44 patients, of whom 37 (86%) showed elimination of troublesome regurgitation at 5 years. Twenty (43%) patients were completely off PPIs at the 5-year follow-up, and 31 (70%) patients expressed satisfaction with the procedure, as assessed by the GERD-HRQL scores. While data on pH normalization were available for 24 patients at the 3-year follow-up, at 5 years, 22% (n=5) of these patients could not be assessed for pH normalization.

Xie et al (2021) published a systematic review and network meta-analysis of 10 RCTs that evaluated the comparative effects of Stretta, TIF, and PPIs in patients with GERD. Of the included RCTs, 5 compared Stretta to control (PPI or sham + PPI) and 5 compared TIF to control (PPI or sham + PPI). Results of the network meta-analysis revealed that improvements in the health-related QOL score induced by Stretta were not significantly different than the improvements seen with TIF; however, both Stretta and TIF were significantly superior to PPIs. Additionally, both Stretta and TIF were significantly better than PPIs at improving heartburn scores. With regard to reduction in PPI use and esophagitis incidence, no significant differences between TIF and Stretta were observed. This network meta-analysis had several limitations including a lack of assessment of long-term efficacy, the inclusion of only 10 studies with even fewer studies evaluated for each individual outcome, and lack of RCTs directly comparing Stretta and TIF. Additionally, some of the comparisons were significantly affected by heterogeneity and the evidence quality of each outcome (as assessed by GRADE) ranged from moderate to very low. Zerbib et al (2020) published a double-blind RCT that compared Stretta plus PPI therapy (n=29) to sham plus PPI therapy (n=33) in individuals with PPI-refractory heartburn from 8 French centers. The primary endpoint was clinical success at week 24, defined as an intake of fewer than 7 PPI doses over the previous 2

weeks and adequate subjective patient-reported symptom control. Fewer patients achieved the primary endpoint in the Stretta group, but the difference was not statistically significant. Severe adverse events were more frequent in the Stretta group (7 vs. 2) and included epigastric pain (n=3), delayed gastric emptying, vomiting, headache, and 1 leiomyoma. Limitations of this RCT include that pH-impedance monitoring was not performed either at enrollment or during follow-up. Thus, baseline status of GERD diagnosis is unclear and the physiologic effects of Stretta are unknown. Ma et al (2020) reported on a retrospective comparison of laparoscopic Toupet fundoplication with the Stretta procedure. GERD relapse was the primary endpoint. The 2 groups were comparable at baseline in demographic characteristics, body mass index, GERD family history, and comorbid hypertension, coronary disease, and diabetes. Two patients in each group were lost to follow-up and excluded from the final analyses. At 12 months, there were no statistically significant differences between the laparoscopic Toupet fundoplication and Stretta groups in GERD relapse, reflux outcomes, dysphagia, bloating, diarrhea, or chronic stomach pain. However, compared to laparoscopic Toupet fundoplication, the Stretta group had a high DeMeester score and less lower esophageal sphincter pressure. Important limitations of this study are its single-center design and short follow-up time.

The available evidence for polymethylmethacrylate beads consists of a single case series. A case series by Feretis et al (2001) evaluated transesophageal submucosal implantation of polymethylmethacrylate beads in 10 patients with GERD who were either refractory to or dependent on PPIs. While a significant decrease in symptom scores was noted at posttreatment follow-up (time not specified), the small number of patients and lack of long-term follow-up precluded scientific analysis. No additional studies have been identified evaluating this treatment option.

In 2012, the LINX® Reflux Management System was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P100049) for patients diagnosed with GERD, as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximal therapy for the treatment of reflux. The FDA initially required a 5-year follow-up of 100 patients from the investigational device exemption pivotal study to evaluate the safety and efficacy of the device, which was completed in March 2016. In 2018, the manufacturer initiated a device recall due to a possible separation of the bead component with the adjacent wire link causing a potential discontinuous or open LINX device. This recall was terminated on November 4, 2020. In March 2018, the FDA approved an update of the LINX® Reflux Management System precautions statement, stating that the use of the system "in patients with a hiatal hernia larger than 3 cm should include hiatal hernia repair to reduce the hernia to less than 3 cm and that the LINX Reflux Management System has not been evaluated in patients with an unrepaired hiatal hernia greater than 3 cm, add a hiatal hernia clinical data summary in the instructions for use, update the instructions for use section to highlight the recommendation to repair a hiatal hernia, if present, at the time of the LINX Reflux Management System implantation, and update the patient information booklet to align with the instructions for use and include 5 year clinical study results." Asti et al (2023) published data from an observational, retrospective cohort study comparing MSA and laparoscopic Toupet fundoplication (LTF) in patients with refractory GERD at a single tertiary-care center in Italy. Patients underwent laparoscopic antireflux surgery for GERD and/or large hiatal hernias from January 2014 to December 2021 in 199 patients [130 MSA; 69 Toupet fundoplication). All patients included had persistent GERD symptoms despite PPI therapy for at least 6 months with abnormal acid exposure at the time of esophageal pH monitoring and initial hernia < 3cm. Patients with previous esophageal or gastric surgeries were excluded. Both groups had a median follow-

up time of 12 months. The morbidity rate in the MSA group was 0.8% and 2.9% after LTF, with no post-operative deaths in either group. A significant decrease in GERD-HRQL score was noted in both patient groups, but when adjusted for age, sex, and baseline GERD scores no significant differences in the change from baseline were observed between groups. Patients in the MSA group had a greater incidence of grade > 2 dysphagia (35.5%) compared to the LTF group (7.7%). No significant differences were observed in the rate of severe or persistent bloating between groups or continued PPI therapy. Limitations of the study include lack of randomization and blinding and imbalance of baseline patient characteristics including GERD-HREQL score, duration of PPI therapy, hernia size, gender, and age. It is unclear to what extent study results are generalizable to U.S. populations and broader care settings. Callahan et al (2023) published a retrospective review of a prospective database evaluating patients who underwent LNF, Toupet, MSA, or anti-reflux mucosectomy (ARMs). Patients were followed up at 3 weeks, 6 months, 1 year, 2 years, and 5 years post-operation. A total of 649 patients had reflux surgery during the study period from 2008 to 2021 including 356 LNF, 207 LTF, 46 MSA, and 40 ARMs procedures. These groups were imbalanced on several baseline characteristics including age, BMI, gender, hypertension medication usage, pre-operative dysphagia, esophageal motility, and hernia type. Procedure time was significantly shorter in patients treated with MSA or ARM compared to fundoplication. At 3 weeks follow-up patients in the MSA group had higher reflux symptoms index scores and GERD-HRQL scores than patients in the Toupet fundoplication group, but these differences had resolved by 6 months with all four treatment groups showing similar outcomes. One-year follow-up data on GERD-HRQL showed a significant difference between the MSA group and ARM groups with the MSA group having worse symptoms; this difference was not observed at 2-year follow-up, but at 5 years MSA patients had worse GERD-HRQL scores compared to the Toupet fundoplication group. All groups had similar scores at all time points follow-up for gas bloating and dysphagia symptoms. Limitations of the study include lack of randomization and blinding, imbalance of baseline patient characteristics, and changes in secular trends over the study period which resulted in predominantly younger patients with normal manometry receiving LNF. O'Neil et al (2023) published a retrospective cohort study of patients undergoing MSA (n=25) compared to LNF (n=45) for the management of symptomatic GERD from a single center from 2013 to 2015 with the intent of comparing long-term follow-up outcomes at 5 years. At baseline, patients were imbalanced on gender, with LNF having more females, BMI with LNF patients being more overweight, and baseline GERD-HRQL scores with LNF having worse symptoms. In the short term, both groups experienced improvements in GERD-HRQL and gastroesophageal reflux symptom scale (GERSS) scores and reductions in PPI usage from baseline levels, but no significant between-group differences were observed. The median long-term follow-up was 65 months for LNF (range, 51 to 85 months) and 68 months for MSA (range, 57 to 87 months); 5 patients in the MSA group and 4 patients in the LNF group did not have long-term outcomes reported. At the last available follow-up, between-group comparisons of outcomes were equivalent for all reported outcomes. Patients in the MSA group had a rate of PPI use of 40% compared to 33% in the LNF group. Median GERD-HRQL scores were 9 in the MSA group and 7.5 in the LNF group; median overall GERSS scores also did not vary significantly. Rates of revision were 20% in the MSA group and 7% in the LNF group. A within-group longitudinal comparison of pre-operative, to post-operative, and long-term follow-up values showed both groups had significant reductions in PPI usage, improvements in GERD-HRQL, and GERSS overall scores. Limitations of the study include lack of randomization and blinding as well as an imbalance of baseline patient characteristics. Ayazi et al (2020) published a retrospective review of 380 patients treated with MSA with a mean follow-up duration of 11.5 ± 8.7 months. Persistent dysphagia was reported in 59

(15.5%) patients with 31% requiring at least 1 dilation for dysphagia or chest pain. The overall response rate to dilation was 67%, with 7 (1.8%) patients requiring device removal for dysphagia. Independent predictors of persistent dysphagia included the absence of a large hiatal hernia, the presence of preoperative dysphagia, and having less than 80% peristaltic contractions on high-resolution impedance manometry. In January 2022, the American College of Gastroenterology (ACG) published a clinical guideline on the diagnosis and management of GERD. Relevant recommendations concerning surgical management of refractory GERD include: “We recommend consideration of MSA as an alternative to laparoscopic fundoplication for patients with regurgitation who fail medical management (strong recommendation; moderate level of evidence)." The guideline also notes that due to the paucity of long-term data on MSA outcomes and lack of randomized trials directly comparing MSA with fundoplication, "it is difficult to recommend one over the other at this time." The American Foregut Society (AFS) issued a statement on appropriate patient selection and use of MSA and noted that "patient selection criteria for MSA do not differ in principle from those of any other surgical procedure for reflux disease." Indications for MSA include: "Typical GERD symptoms (ie, heartburn, regurgitation) with break-through symptoms, intolerance to medical therapy, and/or unwillingness to take anti-reflux medications long term; regurgitation despite optimized medical therapy and lifestyle modification; extraesophageal symptoms with objective evidence of significant reflux disease (ie, endoscopic evidence of [Los Angeles] Class C or D esophagitis, Barrett's esophagus or positive pH study)." The statement additionally notes that "MSA candidacy largely mirrors that for laparoscopic fundoplication. Low dysphagia rates for MSA have been found when performed in patients with normal esophageal motility." The AFS also recommends that a full hiatal dissection and cruroplasty be performed prior to implantation of an MSA device. The AFS Bariatric Committee also issued a statement regarding the concurrent use of MSA at the time of primary bariatric surgery, noting that this practice "violates many basic surgical principles and is not considered judicious use by the American Foregut Society." The statement also notes that prospective trials demonstrating the safety and efficacy of concurrent MSA are needed. The American Gastroenterological Association (AGA) issued a statement on the personalized approach to evaluating and managing individuals with GERD in 2022. The authors provided a best practice recommendation: "In patients with proven GERD, laparoscopic fundoplication and magnetic sphincter augmentation are effective surgical options, and transoral incisionless fundoplication is an effective endoscopic option in carefully selected patients." In 2023, the National Institute for Health and Care Excellence (NICE) issued an interventional procedure guidance on laparoscopic insertion of a magnetic ring for GERD. The following recommendations were based on a comprehensive literature search and review: "Evidence on the safety and efficacy of laparoscopic insertion of a magnetic ring for GERD is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent, and audit”; and "Patient selection and the procedure should be done by clinicians who have specific training in the procedure and experience in upper gastrointestinal laparoscopic surgery and managing GERD." A multi-society consensus guideline on the treatment of GERD was issued by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), American Society for Gastrointestinal Endoscopy (ASGE), American Society for Metabolic and Bariatric Surgery (ASMBS), European Association for Endoscopic Surgery (EAES), Society for Surgery of the Alimentary Tract (SSAT), and the Society of Thoracic Surgeons (STS) in 2023. Based on a review of the available evidence the consensus panel determined the following recommendations: 1) “The panel suggests that adult patients with GERD may be treated with either MSA or Nissen fundoplication based on surgeon and patient shared decision-making” (Conditional recommendation based on very low certainty of evidence); and 2) “The panel

suggests that adult patients with GERD may benefit from MSA over continued PPI use" (Conditional recommendation based on moderate certainty of evidence). Latorre-Rodriguez et al (2023) stated that magnetic sphincter augmentation (MSA) is an alternative surgical treatment for gastroesophageal reflux disease; however, >1.5 T magnetic resonance imaging (MRI) is contraindicated for patients who have undergone MSA with the LINX Reflux Management System. This drawback can impose a barrier to access of MRI, and cases of surgical removal of the device to enable patients to undergo MRI have been reported. To evaluate access to MRI for patients with an MSA device, the authors conducted a structured telephone interview with all diagnostic imaging providers in Arizona in 2022. In 2022, only 54 of 110 (49.1%) locations that provide MRI services had at least one 1.5 T or lower MRI scanner. The rapid replacement of 1.5 T MRI scanners by more advanced technology may limit healthcare options and create an access barrier for patients with an MSA device. Fadel et al (2023) conducted a systematic review and meta-analysis to assess efficacy, quality of life and safety in patients that underwent MSA, with a comparison to fundoplication. A literature search of MEDLINE, Embase, Emcare, Scopus, Web of Science and Cochrane library databases was performed for studies that reported data on outcomes of MSA, with or without a comparison group undergoing fundoplication, for GERD from January 2000 to January 2023. Meta-analysis was performed using random-effect models and between-study heterogeneity was assessed. Thirty-nine studies with 8,075 patients were included: 6,983 patients underwent MSA and 1,092 patients had laparoscopic fundoplication procedure. Ten of these studies (7 retrospective, 3 prospective) directly compared MSA with fundoplication. A higher proportion of individuals successfully discontinued proton-pump inhibitors and had higher patient satisfaction following MSA when compared to fundoplication. Functional outcomes were better after MSA than after fundoplication including ability to belch and emesis, and bloating. MSA had higher rates of dysphagia when compared to fundoplication. The overall erosion and removal rate following MSA was 0.24% and 3.9% respectively, with no difference in surgical re- intervention rates between MSA and fundoplication. The authors concluded "MSA is a safe and effective procedure at reducing symptom burden of GERD and can potentially improve patient satisfaction and functional outcomes. However, randomized controlled trials directly comparing MSA with fundoplication are necessary to determine where MSA precisely fits in the management pathway of GERD." Jefferies et al (2024) conducted a comparative analysis of MSA and subtotal gastrectomy with Roux-en-Y reconstruction (SGRY) for post-sleeve gastrectomy (SG) GERD to evaluate postoperative outcomes. A retrospectively maintained prospectively gathered database from 2018 to 2023 was used to identify patients who underwent MSA or SGRY for the indication of GERD after SG. Differences among patient characteristics; GERD assessments, including the health-related quality of life (HRQL) questionnaire and the reflux symptom index (RSI); and procedure outcomes were collected and analyzed according to surgery type. A total of 92 patients (85 females and 7 males) met the inclusion criteria. The study included 17 patients in the MSA group, 71 patients in the SGRY group, and 4 patients who underwent both procedures. The average preoperative body mass index (BMI) of all patients was 33.3. Compared with patients who underwent MSA, those who underwent SGRY presented with higher BMI, preoperative GERD-HRQL, and RSI. Postoperatively, patients who underwent SGRY demonstrated a higher decrease in mean postoperative DeMeester score than those who underwent MSA, with 22 patients (50%) in the SGRY group vs 10 patients (20%) in the MSA group achieving normalization. The authors stated that although MSA remains a viable surgical alternative, "our study indicated that SGRY can produce better symptom control and decrease acid exposure compared with MSA in patients with post-SG GERD." UpToDate review "Surgical treatment of gastroesophageal reflux in adults" (Sachwaitzberg, 2024) states that

transoral incisionless fundoplication (TIF) with or without hiatal hernia repair, magnetic sphincter augmentation (MSA), laparoscopic Hill gastropexy, laparoscopic partial fundoplication and laparoscopic Nissen (complete) fundoplication "vary by efficacy and durability on one hand and adverse effect profiles on the other. At one end of the spectrum, laparoscopic Nissen fundoplication is highly effective in relieving GERD symptoms and is the most durable amongst all the procedures; however, it is also associated with the greatest potential for adverse effects, such as dysphagia, difficulty in vomiting, and gas bloating. At the other end of the spectrum, endoscopic procedures such as Stretta and TIF are least likely to be associated with adverse effects. However, their efficacy and durability are not as good as those of a complete fundoplication. Partial fundoplications, Hill procedure, and MSA generally fall in the middle of the spectrum balancing both efficacy/durability and adverse effect profile." The review further states, "Fundoplication remains the standard treatment for patients with GERD complicated by hiatal hernia >2 cm, severe (Los Angeles class C or D)erosive esophagitis, peptic stricture, and/or Barrett's esophagus. Newer procedures such as c-TIF or LINX have been attempted in patients with hiatal hernias >2 cm, but long-term results are not yet available."

POSITION STATEMENT:

Peroral endoscopic myotomy (POEM) **meets the definition of medical necessity** when **ALL** of the following are met:

- Age 18 or older
- Primary idiopathic achalasia confirmed by esophageal manometry
- Eckardt symptom score (ESS)* is greater than 3
- No previous history of open surgery of the stomach or esophagus

The following procedures are considered **experimental or investigational**:

- Diverticular peroral endoscopic myotomy (D-POEM)
- Gastric peroral endoscopic myotomy or pyloromyotomy (G-POEM)
- Zenker peroral endoscopic myotomy (Z-POEM)
- Transoral incisionless fundoplication (TIF) (e.g., Esophyx)
- Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (e.g., the Stretta procedure)
- Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., polymethylmethacrylate beads, zirconium oxide spheres)
- Magnetic sphincter augmentation (e.g., LINX™ Reflux Management System) for the treatment of GERD

There is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on safety and net health outcomes associated with the procedures listed above.

*Eckardt Symptom Score (ESS)

Each symptom is graded on a score of 0 to 3, with a maximum score of 12.

Score	Recent weight loss (kg)	Dysphagia	Chest pain	Regurgitation
0	None	None	None	None

1	< 5kg	Occasional	Occasional	Occasional
2	5-10kg	Daily	Daily	Daily
3	> 10kg	Each meal	Several times per day	Each meal

BILLING/CODING INFORMATION:

CPT Coding:

43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed **(Investigational)**
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 [Stretta] **(Investigational)**
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed **(Investigational)**
43285	Removal of esophageal sphincter augmentation device **(Investigational)**
43497	Lower esophageal myotomy, transoral (i.e., peroral endoscopic myotomy [POEM])

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

Achalasia: a disorder of the esophagus characterized by reduced numbers of neurons in the esophageal myenteric plexuses and reduced peristaltic activity, making it difficult to swallow food and possibly leading to complications such as regurgitation, coughing, choking, aspiration pneumonia, esophagitis, ulceration, and weight loss.

Dysphagia: Difficulty in swallowing.

Eckardt symptom score: a grading system most frequently used for the evaluation of symptoms, stages and efficacy of achalasia treatment. It attributes points (0 to 3 points) for four symptoms of the disease (dysphagia, regurgitation, chest pain and weight loss), ranging from 0 to 12.

Gastroesophageal junction: The lower part of the esophagus that connects to the stomach

Myotomy (i.e., Heller myotomy): a surgical procedure in which the muscles of the lower esophageal sphincter (LES) are cut, allowing food and liquids to pass to the stomach; used to treat achalasia.

Nissen fundoplication: A surgical procedure in which the upper portion of the stomach is wrapped around the lower end of the esophagus and sutured in place as a treatment for GERD.

Odynophagia: Pain produced by swallowing

Proton pump inhibitor (PPI): Any of a group of drugs (e.g., omeprazole) that inhibit the activity of proton pumps and are used to inhibit gastric acid secretion in the treatment of ulcers and gastroesophageal reflux disease.

RELATED GUIDELINES:

Endoscopic Radiofrequency Ablation or Cryosurgical Ablation for Barrett's Esophagus, 01-91000-10

OTHER:

NOTE: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available.

Other names used to report minimally invasive procedures for treating gastroesophageal reflux disease:

- Angelchik anti-reflux prosthesis
- ARD Plicator
- Bard Endoscopic Suturing System (BESS)
- Durasphere®
- EndoLuminal gastroplication
- Endoscopic Plicator™ System
- EsophyX™ System
- Gatekeeper™ Reflux Repair System
- Implantable magnetic esophageal ring
- LINX™ Reflux Management System
- Magnetic sphincter augmentation (MSA)
- Mechanical sphincter augmentation (MSA)
- MUSE™ System
- OverStitch Endoscopic Suturing System

- Plexiglas polymethylmethacrylate (PMMA) microspheres
- SRS™ Endoscopic Stapling System
- StomaphyX™ System
- Stretta® System

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/26/24.

GUIDELINE UPDATE INFORMATION:

06/15/01	New Medical Coverage Guideline.
03/15/02	Additions to Non-Covered section/Added CPT code 0008T.
04/15/03	Medical Coverage Guideline Reviewed.
01/01/04	Annual HCPCS coding update.
04/15/04	Review and revision of guideline consisting of updated references and added information regarding endoscopic submucosal biocompatible polymer (investigational).
10/01/04	4th quarter HCPCS coding update consisting of addition of S2215 (investigational).
01/01/05	Annual HCPCS update consisting of addition of 43257 and deletion of 0057T.
04/15/05	Review and revision of guideline consisting of updated references.
01/01/06	Annual HCPCS coding update consisting of the deletion of S2215 and the addition of 0133T.
04/15/06	Review and revision of guideline consisting of updated references.
01/01/07	HCPCS update consisting of the deletion of 0008T.
04/15/07	Review and revision of guideline consisting of updated references.
06/15/07	Reformatted guideline.
07/01/07	HCPCS update consisting of the deletion of 0133T.
03/15/08	Review and revision of guideline consisting of updated references.
03/15/09	Review and revision of guideline consisting of updated references.
05/15/09	Scheduled review; added informational statements relating to Stretta and Enteryx; no change in position statements; references updated.
06/15/10	Scheduled review; position statement unchanged, references updated.
03/15/11	Review Position Statement for Stretta procedure; Position Statement unchanged. References updated.
11/15/11	Revision consisting of the addition of clarification regarding TIF and Esophyx.
11/15/12	Annual review; position statement unchanged; references updated.
11/15/13	Annual review; position statement unchanged; Coding section revised; Program Exceptions section updated; references updated.
01/01/14	Annual HCPCS coding update: added 43212 and 43266; revised 43201, 43236, and 43257.
03/15/14	Revision to add Position Statement regarding magnetic sphincter augmentation procedures; coding and references updated.
10/15/14	Annual review; add position statement for POEM; other position statements are unchanged; update Description and Definition sections; update references.
07/01/15	Quarterly CPT/HCPCS update: added codes 0392T and 0393T.
06/15/16	Unscheduled review. Revised description section, maintained position statement. Revised CPT coding, Medicare Advantage program exception, and index terms. Updated references.
01/01/17	Annual CPT/HCPCS update. Added 43284, 43285. Deleted 0392T, 0393T.

02/15/17	Scheduled review. Maintained Position Statement section. Revised Description section and index terms. Updated references.
04/20/17	Deleted code 43499.
02/15/19	Revision. Updated description section. Maintained position statement. Updated references.
05/15/19	Deleted codes 43201, 43212, 43236, 43241, and 43266.
12/15/19	Unscheduled review. Maintained position statement and updated references.
04/15/20	Unscheduled review. Maintained position statement and updated references.
11/15/20	Scheduled review. Revised description and maintained position statement. Updated references.
07/15/21	Revision. Updated references and Program Exceptions section, and maintained position statement.
09/15/22	Scheduled review. Revised description and CPT coding. Added coverage criteria for peroral endoscopic myotomy (POEM). Designated D-POEM, G-POEM, and Z-POEM as experimental or investigational. Revised definitions and updated references.
05/22/23	Update to Program Exceptions section.
08/15/23	Revision. Added Eckardt Symptom Score grid.
01/01/24	Position statements maintained.
02/15/24	Revision. Updated references and maintained position statements.
10/15/24	Scheduled review. Revised description. Deleted reference to "transesophageal endoscopic gastroplasty". Updated references.