MEDICAL POLICY

Medical Policy Title	**Transendoscopic Therapies for Gastroesophageal Reflux Disease (GERD)**
Policy Number	**7.01.45**
Current Effective Date	**March 19, 2026**
Next Review Date	**March 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. The following transendoscopic procedures are considered **investigational** for the treatment of gastroesophageal reflux disease (GERD):

A. Thermal energy-based antireflux therapies applied to the gastroesophageal junction (e.g., Stretta procedure, anti-reflux mucosal ablation [ARMA]);

B. Endoscopic gastroplasty;

C. Endoscopic gastroplication (e.g., GERDx-System, Apollo OverStitch, EndoCinch, Syntheon ARD Plicator);

D. Transoral incisionless fundoplication (TIF) (e.g., EsophyX, MUSE);

E. Injection or implantation of biocompatible bulking agents (e.g., polymethylmethacrylate [PMMA] or plexiglas beads, Durasphere).

RELATED POLICIES

Corporate Medical Policy

7.01.89 Magnetic Sphincter Augmentation for the Treatment of Gastroesophageal Reflux Disease (GERD)

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Gastroesophageal reflux disease (GERD) is a prevalent condition characterized by classic symptoms such as heartburn and regurgitation, as well as other manifestations including chest discomfort, dysphagia, and chronic cough or throat clearing. While many individuals experience episodic reflux symptoms, a subset develops chronic GERD that increases the risk of complications such as erosive esophagitis, dysphagia, Barrett esophagus, and asthma.

The pathophysiology of GERD is multifactorial. Excessive acid exposure to esophageal mucosa may occur due to dysfunction of the lower esophageal sphincter, impaired diaphragmatic support of the gastroesophageal junction, or abnormalities in esophageal clearance mechanisms. Delayed acid clearance increases the duration of exposure and enhances the potential for mucosal injury.

Current guideline-based management emphasizes a stepwise approach beginning with lifestyle modification (e.g., weight loss, smoking cessation, head of bed elevation, elimination of food triggers) and pharmacologic therapy such as antacids and proton pump inhibitors (PPIs).

For patients who continue to experience symptoms despite optimized medical therapy, or for whom procedural intervention is clinically appropriate, antireflux surgical and transesophageal endoscopic therapies may be considered. Nissen fundoplication, the most commonly performed antireflux procedure, reinforces the lower esophageal sphincter by wrapping a portion of the gastric fundus around the distal esophagus and, when indicated, concurrently repairing an associated hiatal hernia to restore normal anatomy.

Transesophageal endoscopic therapies have emerged as minimally invasive alternatives to long-term pharmacologic management or laparoscopic. These procedures, considered forms of natural orifice transluminal endoscopic surgery (NOTES), generally fall into three categories:

- Energy-based therapies. The Stretta procedure delivers controlled RF energy to the lower-esophageal sphincter (LES)/gastroesophageal junction (GEJ) and appears to modulate neuromuscular function, reduce transient LES relaxations, and decrease GEJ compliance. The precise mechanism remains uncertain. Anti-reflux mucosal ablation (ARMA) uses thermal mucosal ablation (e.g., electrocautery in spray coagulation mode) of the gastric cardia to induce fibrosis and tighten the GEJ.
- Endoluminal/endoscopic GEJ-reshaping procedures (e.g., mechanical plication, mucosal resection/remodeling, hybrid techniques) are designed to recreate a functional valve and reinforce the antireflux by folding or fastening the fundus or by inducing mucosal fibrosis/scar remodeling. Devices examples include Medigus Ultrasonic Surgical Endostapler (MUSE), GERDx-System, StomaphyX, Apollo Overstitch, Captivator EMR Device).
- Transoral incisionless fundoplication (TIF), also referred to as endoluminal fundoplication (ELF), reconstructs the gastroesophageal valve and reinforce the antireflux barrier using a specialized device passed transorally under endoscopic visualization. Gastric fundus tissue is drawn into a shaping mold and secured with polypropylene fasteners to create a 3–5 cm partial fundoplication without external incisions.
- Injection or implantation of a prosthetic or bulking agent is used to increase tissue bulk at the LES and reduce reflux. These materials are intended to augment the antireflux barrier by improving closure of the sphincter.

SUPPORTIVE LITERATURE

The evidence is insufficient to determine that transesophageal endoscopic therapies for the treatment of GERD (e.g., application of radiofrequency energy, gastroplication, TIF, and injection/implantation of prosthetic devices or bulking agents) results in an improvement in the net health outcome. Large-

scale, long-term controlled studies of these transendoscopic techniques are needed to establish the safety and efficacy of these procedures.

Meta-Analyses Comparing Multiple Antireflux Procedures

Yao et al (2024) conducted a systematic review and network meta-analysis to assess the efficacy of various antireflux interventions when compared to a control group of either PPIs or sham. A total of 19 randomized controlled trials (RCTs) (n=1181 subjects) met inclusion criteria. Four RCTs compared endoscopic band ligation (EBL; n=306 cases); 6 RCTs compared Stretta (235 cases); 5 RCTs compared TIF (340 cases), 2 RCTs compared endoscopic full-thickness plication (EFTP) (214 cases), and 2 RCTs compared EndoCinch (86 cases). This network meta-analysis found that TIF was significantly inferior to PPIs, EFTP, and EndoCinch in decreasing acid exposure. EBL was not inferior to TIF in improving GERD symptoms. The effect of EBL in increasing the LES pressure and improving acid exposure could not be concluded given that no relevant data were provided in the 4 RCTs involved. EBL and TIF may achieve equivalent efficacy in improving the Health-Related Quality of Life (HRQL) score and decreasing the incidence of esophagitis and PPIs utility in patients with GERD, and both may be superior to control and other types of endoscopic interventions. TIF may significantly increase the LES pressure and was superior to Stretta and EndoCinch. The mechanism of Stretta in GERD therapy remains a mystery, has not yet been fully clarified, and more studies are required. The authors concluded that given the limited number of included RCTs on different types of endoscopic treatments, indirect comparison, and inherent heterogeneity, the analysis results should be interpreted with caution. More well-designed and prospective multicenter RCTs with long-term follow-up are required to evaluate the long-term efficacy and safety of different endoscopic minimally invasive interventions in the treatment of GERD.

Tade et al (2025) conducted a meta-analysis of randomized and cohort studies (1980–2024) including adults with GERD who underwent fundoplication (Nissen, Toupet), magnetic sphincter augmentation (MSA), or transoral incisionless fundoplication (TIF). The analysis pooled 9,516 patients with available pre- and post-operative acid exposure time (AET), DeMeester score, and/or symptom relief scores (e.g., GERD-HRQL); the median follow-up was 12 months. Across procedures, AET, DeMeester scores, and symptom relief improved significantly. In multilevel meta-regression, TIF showed significantly less improvement than Nissen in AET ($p = 0.045$) and DeMeester ($p = 0.023$), while MSA and Toupet demonstrated significantly better symptom relief than Nissen (MSA $p = 0.044$; Toupet $p = 0.034$). The authors noted study-level heterogeneity and limitations, including incomplete data on hiatal hernia characteristics/repair techniques and procedural variations, and they did not meta-analyze postoperative complications (e.g., dysphagia, bloating) as primary outcomes. Overall, Nissen fundoplication demonstrated significantly better improvement with acid exposure and DeMeester score compared to MSA and TIF. However, symptom relief scores are significantly improved with Toupet fundoplication and MSA compared to other surgical treatment options.

Endoscopic Energy-Based Therapies

Kalapala et al (2017) published interim results from a small RCT of 20 patients randomized to PPI plus Stretta or PPI alone, with 3 months of follow-up. While short-term outcomes such as GERD symptoms and cessation of PPIs appeared improved for the Stretta group, the study sample was small, and power calculations were not conducted.

Ma et al (2020) reported on a retrospective comparison of laparoscopic Toupet fundoplication with the Stretta procedure. The two 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. However, compared to laparoscopic Toupet fundoplication, the Stretta group had a high DeMeester score (8.8 vs. 7.3; $p<.05$) and less LES pressure. Important limitations of this study are its single-center design and short follow-up time.

Zerbib et al (2020) published a double-blind RCT that compared Stretta plus proton pump inhibitor (PPI) therapy (n=29) to sham plus PPI therapy (n=33) in individuals with PPI-refractory heartburn from eight 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.

Xie et al (2021) published a systematic review and network meta-analysis of ten RCTs (n=516 participants) that evaluated the comparative effects of Stretta, TIF, and PPIs in patients with GERD. Of the included RCTs, five compared Stretta to control (PPI or sham + PPI) and five compared TIF to control (PPI or sham + PPI). Results of the network meta-analysis revealed that improvements in the health-related quality of life 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 small number of studies, and lack of RCTs directly comparing Stretta and TIF, some comparisons were significantly affected by heterogeneity, and the evidence quality of each outcome ranged from moderate to very low.

Endoluminal/Endoscopic GEJ-Reshaping Procedures

Weitzendorfer et al (2018) conducted a prospective single-center one-arm trial on the clinical and functional outcomes of endoscopic full-thickness plication with GERDx-system. The study included 40 adult patients with at least one typical reflux symptom despite treatment with a PPI for at least 6 months, pathologic esophageal acid exposure, endoscopic Hill grade II–III, a hiatal hernia measuring < 2 cm and excluded individuals with Barrett's esophagus or esophageal motility disorders. Outcomes measured Evaluation of Gastrointestinal Quality of Life Index (GIQLI), symptom scores, esophageal manometry, and impedance-pH monitoring which were performed at baseline and at three months after surgery. Although 30 participants (75%) reported symptomatic improvement, the authors noted grade A esophagitis persisted or recurred in about one-third of patients. Only 19 patients (63.3%) were off medication after application, which the authors report is similar to other endoscopic

procedures like MUSE and Esophyx. The study was limited by the lack of randomization, small sample size, and the necessity of high operator expertise needed to achieve a good procedure outcome. Long-term outcomes are required to expand our knowledge of the effects of this procedure.

Kalapala et al (2022) published results of a randomized, sham-controlled, single-blinded clinical trial using a new endoscopic full-thickness fundoplication device, the GERD-X. A total of 70 individuals with PPI-dependent GERD were randomized to either GERD-X treatment or a sham procedure. The primary end point was ≥ 50% improvement in GERD-HRQL score at 3 months. This outcome was more frequently achieved in the GERD-X group vs. sham (65.7% vs 2.9%; p<0.001). In the GERD-X group, 62.8% of subjects were off-PPI at 12 months compared with 11.4% in the sham group (p<0.001). Overall, the procedure using the GERD-X device was found to be effective at reducing GERD symptoms and improving quality of life. However, in this small, short-term study, reflux was not assessed objectively at the end of 12-month follow-up in all subjects. The authors concluded that large, prospective trials with long-term follow-up are required to conclude the benefits of this procedure after 1 year.

Liu et al (2019) evaluated the short-term efficacy of clip band ligation anti-reflux therapy (C-BLART), a new alternative endoscopic treatment for controlling GERD symptoms, esophageal acid exposure, esophagitis, and quality of life. Patients with refractory GERD were recruited for a nonrandomized concurrent comparison, with 60 patients in the C-BLART with tailored PPI use group and 43 patients in the BID proton pump inhibitor (PPI) group. Crossover from the BID PPI group to the C-BLART with tailored PPI use group was allowed after 6 months. The LES pressure and GERD-Q score improved more in the C-BLART with tailored PPI use group (P < 0.001) after 6 months, with no significant difference in the decrease in esophagitis compared with the baseline endoscopic results (P = 0.268). Treatment with PPIs had been halted in 43% of the patients at 6 months after C-BLART. At 12 months after C-BLART, the DeMeester score showed a significant improvement compared with the baseline measurements (P = 0.025). The GERD-Q score and LES pressure did not significantly improve compared with the baseline values (P = 0.102, P = 0.184) in C-BLART with tailored PPI use group. At 6 to 12 months, n = 6 (10%) patients had undergone laparoscopic fundoplication to control their symptoms in all the patients after C-BLART. The authors concluded that C-BLART is a novel treatment for controlling refractory GERD symptoms, esophageal acid exposure, and LES pressure according to this short-term analysis, safely performed endoscopically to create an anti-reflux barrier with ligated bands. Despite improvements in DeMeester score, LES pressure, and GERD-Q scores in the C-BLART with tailored PPI use group, many patients continue to demonstrate objective evidence of GERD.

Antireflux Mucosal Interventions

Al-Obaidi (2025) conducted a systematic review and meta-analysis that evaluated the efficacy of antireflux mucosal ablation (ARMA) and antireflux mucosectomy (ARMS). The meta-analysis included studies reporting pre- and post-procedure esophageal 24-hour pH monitoring following ARMA and ARMS. Based on pooled data from three studies, ARMA demonstrated a significant post-procedure decrease in median acid exposure time (AET) with a standardized mean difference of -20.74 (p < 0.0001). Based on six studies, ARMS showed a significant reduction in DeMeester score (SMD: -2.79, p < 0.0001). The overall clinical success rate, defined as significant symptom improvement or

reduced reliance on proton pump inhibitors, was 87% for ARMA and 78% for ARMS. The authors concluded that both procedures displayed promising efficacy in improving GERD-related outcomes, though they noted high heterogeneity suggesting further research is needed to identify patient-specific factors influencing treatment response.

Transoral Incisionless Fundoplication (TIF)

Current evidence is insufficient to determine the effect of this intervention on the net health outcome in patients whose symptoms are adequately controlled by PPIs.

Trad et al (2015; 2017; 2018) conducted TEMPO, prospective, randomized, multicenter trial comparing TIF 2.0 (n=40) with maximal-dose PPI therapy (n=23), with the primary endpoint of symptom elimination. At 6 months (pre-crossover), TIF eliminated troublesome regurgitation significantly more often than PPIs (97% vs 50%, $p = 0.006$), whereas pH normalization rates were not significant between groups (54% off PPI after TIF vs 52% on PPI in the control arm; $p = 0.914$). By the 3-year follow-up, all patients in the control group had crossed over to TIF and were included in the follow-up. Among 63 TIF-treated patients, 83% had available data on PPI use, with 71% reporting cessation, and 77% had evaluable symptom and pH data, showing pH normalization in 40% and resolution of troublesome regurgitation in 90%. At 5 years, follow-up data were available for 44 patients, of whom 86% continued to show elimination of troublesome regurgitation, 34%–43% were completely off PPIs, and GERD-HRQL scores remained improved with high satisfaction. No serious adverse events were reported, and 3 reoperations occurred over 5 years. Overall, the long-term results suggest that TIF provides durable improvement in regurgitation symptoms with moderate rates of PPI discontinuation, supporting its use in selected GERD patients seeking a minimally invasive alternative to medical therapy.

Testoni PA et al (2015 and 2019) published sequential prospective single-center cohorts evaluating the long-term durability of TIF using the EsophyX device. The 2015 study reported outcomes in 50 patients (51 procedures) followed for up to 6 years, with technical success in 48/50 and severe complications in 2/51 procedures. Patients experienced significant early improvement in GERD-HRQL, regurgitation scores, and PPI dependence. The subsequent 2019 study extended follow-up and demonstrated that the improvements in GERD-HRQL observed at 2 years were maintained without substantial decline through the 10-year period; however, at 10 years, only 14 patients had evaluable follow-up, which limits generalizability of the apparent durability. The proportions of patients who discontinued or halved PPI therapy were 86.7%, 84.4%, 73.5%, 83.3%, and 91.7% at 2, 3, 5, 7, and 10 years, respectively. Non-responders (n=7) ultimately underwent surgical fundoplication, and some patient attrition occurred over time. These findings suggest that symptom control and reduced PPI use can be maintained long-term (6-10 years) after EsophyX-based TIF in selected patients; however, the single-arm observational design, modest sample size, and loss to follow-up limit generalizability.

Richter et al (2018) performed a systematic review and network meta-analysis of RCTs completed through May 2017 to compare the relative efficacies of TIF and laparoscopic Nissen fundoplication (LNF) in GERD. Across seven trials (n=1,128 patients), LNF demonstrated the highest probability of improving physiologic GERD parameters, including increased LES pressure and reduced esophageal acid exposure. TIF ranked below LNF and PPIs on most objective measures, and the authors

concluded that LNF is superior to TIF and PPIs for improving physiologic parameters of chronic GERD, including increased LES pressure and decreased percent time pH. TIF was not recommended as a long-term alternative to PPI or LNF treatment of GERD, as long-term efficacy has not been demonstrated.

Chimukangara et al (2019) performed a single-center, retrospective cohort study evaluating long-term outcomes in 57 patients who underwent TIF (EsophyX) between 2007 and 2014 at a large academic medical center. All patients had symptomatic GERD and were taking a PPI at least daily. Patients were excluded for hiatal hernia > 2 cm, LA grade C or D esophagitis, or biopsy-proven Barrett's esophagus. Reflux symptoms and GERD-HRQL were assessed at baseline, short-term (median 12 months, n=36), and long-term (median 97 months, n=23) follow-up. Twelve patients (21%) underwent subsequent laparoscopic antireflux surgery during follow-up, including five within the first year. GERD-HRQL improved from 24 at baseline to 7 at short-term and 10 at long-term ($p < 0.01$ for both). Dissatisfaction with symptom control decreased from 100% at baseline to 26% at long-term. While most patients were on twice-daily PPI therapy pre-TIF, 73% of those who resumed PPIs long-term were on daily PPI therapy (20 mg or 40 mg). The study is limited by its retrospective design, small sample size, single-institution setting, and lack of a matched LARS comparison group. The authors concluded that TIF can provide durable improvements in disease-specific quality of life for some patients with GERD, although many resume antisecretory medications long-term, and most report ongoing satisfaction with symptom management.

Testoni SGG et al (2021) published a systematic review and meta-analysis examining long-term outcomes (≥3 years) after TIF performed with the EsophyX device, with outcomes including patient satisfaction, QoL, and PPI use. Among the 8 included studies (n=418; only one open-label RCT) the mean follow-up was 5.3 years, and many patients reported symptom improvement and reduced PPI use, with pooled satisfaction increasing from 12.3% pre-procedure to 70.6% post-procedure, 53.8% completely off PPIs and 75.8% off or on only occasional PPIs at long-term follow-up, mean GERD-HRQL improving from 26.1 to 5.9 (off PPIs), and normalization rates of 73% for heartburn and 86% for regurgitation. The analysis was limited by marked heterogeneity and the predominance of non-controlled designs (only one open-label RCT). The authors conclude that TIF appears to be a safe long-term option for selected patients who decline or cannot tolerate prolonged PPI therapy or surgery.

Testoni SGG et al (2022) conducted a prospective, single-center observational study evaluating the clinical, functional, and endoscopic effects of TIF performed with the MUSE device in 46 adults with chronic (≥6 months) GERD symptoms, partial or complete response to PPI therapy, non-erosive reflux disease (NERD) or hypersensitive esophagus, Barrett's esophagus <3 cm, and BMI <40 kg/m². TIF was successfully completed in 45/46 cases, with two perforations requiring surgery (4.4%) and one additional patient undergoing Nissen fundoplication within 6 months for lack of efficacy, after which these patients were excluded from follow-up analyses. The study showed significant symptom improvement with PPI cessation in 64.3%, 62.9%, and 74.2% of patients at 1, 2, and 3 years (corresponding ITT rates 58.7%, 56.4%, 65.7%), and ≥50% reductions in GERD-HRQL and Reflux Symptom Index (RSI) scores were sustained through 3 years; however, esophagitis persisted in about one-third of patients at 1 year, and improvements in pH-impedance observed at 6 months were not maintained at 1 year, although high-resolution manometry (HRM) at 6 months showed

increases in LES length and peristaltic waves. The authors note limitations including small sample size, inclusion limited to mild (grade A) esophagitis, lack of a control group, and the need for larger randomized trials with longer-term follow-up.

Canto et al (2025) conducted a prospective, multicenter cohort registry study across nine academic and community centers enrolling adults with confirmed GERD, body mass index <35 kg/m², and hiatal hernia <2 cm who underwent TIF 2.0. Primary outcomes were safety and clinical success (defined as response in 1 subjective and at least 1 of 3 objective secondary endpoints), and secondary outcomes included symptom improvement, esophageal acid exposure time (AET), esophagitis healing, proton pump inhibitor (PPI) use, and satisfaction. Patients completed surveys and postprocedure adverse assessments at 1-, 6-, and 12-months. Of 85 patients treated, 81 were included in the analysis. Clinical success was achieved in 94%, GERD-Health-Related Quality of Life improved in 89%, Reflux Symptom Index normalized in 85% of those with elevated baseline, patient satisfaction increased from 8% to 79% (P<.0001), and daily PPI use decreased from 81% at baseline to 80% on no or occasional PPI after TIF 2.0 (P<.0001). AET normalized in 72% overall and was more likely when an optimized TIF 2.0 valve (>300° circumference and >3-centimeter length) was achieved (94% vs 57%; P=.007). No TIF 2.0-related serious adverse events were reported. The authors conclude that TIF 2.0 is a safe and effective outpatient endoscopic option for appropriately selected patients with GERD. Larger prospective studies of long-term outcomes, particularly for concomitant hiatal hernia repair with TIF (cTIF), are needed to compare safety, effectiveness, and durability with surgical antireflux approaches.

Prosthetic or Bulking Agents

High-quality data from large RCTs are needed to compare bulking procedures with both sham controls and with the currently accepted treatments for GERD (i.e., drug therapy, laparoscopic fundoplication) to determine the effects on health outcomes.

The available evidence for Durasphere consists of a single case series. One open-label pilot study by Ganz et al (2009) assessed ten patients diagnosed with GERD and injected with Durasphere (Carbon Medical Technologies). At 12 months, seven patients (70%) discontinued all antacid medication completely. No erosion, ulceration, or sloughing of the material was noted at any injection site.

The available evidence for polymethylmethacrylate beads consists of a single case series that evaluated transesophageal submucosal implantation of polymethylmethacrylate beads in ten patients with GERD who were either refractory to or dependent on PPIs (Feretis 2001). 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.

PROFESSIONAL GUIDELINE(S)

In 2025, the American Society for Gastrointestinal Endoscopy (ASGE; Desai) published updated guidelines on the diagnosis and management of gastroesophageal reflux disease (GERD). In patients with GERD symptoms, the ASGE made a strong recommendation for lifestyle modification (e.g., dietary changes, weight loss when indicated, head-of-bed elevation), and medical management with PPIs at the lowest dose for the shortest duration. Recommendations for endoscopic therapies include:

- Conditional recommendation: Transoral incisionless fundoplication (TIF) may be considered as an alternative to chronic medical management for patients with confirmed GERD, small hiatal hernia (≤2 cm), Hill grade I or II, and any of the listed criteria (including GERD ≥6 months, chronic PPI use ≥6 months, refractory GERD, regurgitation-predominant GERD patient preference for avoidance of long-term PPI use).
    - Overall, the certainty in the evidence was moderate to very low. TIF 2.0 showed short-term improvement with durable symptom remission up to 5 years with relatively low serious adverse event rates.
- Conditional recommendation: Combined hiatal hernia repair with TIF (cTIF) may be considered for patients with large hiatal hernia (>2 cm) and Hill grade III or IV, in a multidisciplinary review.
    - Overall, the certainty of the evidence was very low. The panel considered the evidence as important but inadequate. Evidence for surgical therapies has been established and whether cTIF is comparable is not yet established with high-quality data.
- Best practice advice: Radiofrequency energy to the lower esophageal sphincter (e.g., Stretta) may be considered when other alternatives (e.g., endoscopic, or surgical fundoplication) are not available or feasible.
    - Overall, the certainty in the evidence was low to very low. The panel acknowledged that evidence on Stretta has been affected by differing results from RCTs and cohort studies. Existing challenges include lack of durable benefit, no effect on PPIs, no effect on acid exposure, higher adverse events, better available treatments. Stretta is only applicable for GERD patients with small hiatal hernias (≤2 cm) and Hill grade I or I.
- No recommendation for or against the following novel endoscopic antireflux therapies due to insufficient controlled long-term data: endoscopic full-thickness fundoplication (EFTP) using device GERDxTM, MUSE, antireflux mucosectomy (ARMS), antireflux mucosal ablation (ARMA).

Slater et al (2023) published a multi-society consensus guideline with recommendations on the treatment of GERD. The panel suggests that adult patients with GERD may benefit from:

- Either MSA or Nissen fundoplication based on surgeon and patient shared decision making. (Conditional recommendation, very low certainty of evidence).
    - The panel judged that the desirable and undesirable effects were balanced and thus favored neither MSA nor Nissen fundoplication.
- Fundoplication over TIF 2.0 (Expert Opinion recommendation; Grade recommendation was unable to be determined due to lack of evidence).
    - The low level of worldwide adoption of endoscopic treatment with TIF 2.0 is correlated with lack of sufficient comparative trials.
- TIF 2.0 over continued PPI (Conditional recommendation, moderate certainty of evidence).
    - TIF 2.0 is an intervention for those who want to avoid both traditional surgery and lifelong medication. Additional long-term prospective comparative studies of TIF (and especially

combined laparoscopic hiatal hernia repair and endoscopic TIF) versus fundoplication (partial fundoplication in particular) are needed.

- Fundoplication over Stretta (Conditional recommendation, very low certainty of evidence).
- Stretta over PPI (Conditional recommendation, low certainty of evidence).
- Partial fundoplication compared to complete fundoplication. (Conditional recommendation, moderate certainty of evidence).

In 2022, the American Gastroenterological Association (AGA) issued a clinical practice update on the personalized approach to the evaluation and management of GERD (Yadlapati 2022). The guideline states "transoral incisionless fundoplication is an effective endoscopic option in carefully selected patients" with proven GERD. The guideline further stated that TIF has "demonstrable value in patients with regurgitation-predominant GERD" and that "further research into risks/benefits, durability, effectiveness, and treatment outcomes will enhance optimal utilization" as part of a personalized approach to treatment.

In 2022, the American College of Gastroenterology (ACG) issued guidelines on the diagnosis and management of GERD include the following recommendations for surgical and endoscopic options for GERD (Katz 2022):

- Recommend consideration of magnetic sphincter augmentation (MSA) as an alternative to laparoscopic fundoplication for patients with regurgitation who fail medical management. (Strong, moderate level of evidence)
- Suggest consideration of Roux-en-Y gastric bypass (RYGB) as an option to treat GERD in obese patients who are candidates for this procedure and who are willing to accept its risks and requirements for lifestyle alterations. (Conditional, low level of evidence)
- No recommendation for radiofrequency energy (Stretta) as an alternative to medical or surgical antireflux therapies since data on the efficacy is inconsistent and highly variable. (Conditional, low level of evidence)
- Suggest 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 >2 cm. (Conditional, low level of evidence)

Gawron et al (2020) published recommendations from an expert U.S. panel, facilitated by the American Foregut Society, for adults with objectively confirmed GERD. The panel concluded that optimization of medical therapy with continued PPI and tapering to the lowest effective dose is appropriate for complete responders without a significant hernia. For PPI non-responders, invasive therapy should be pursued only when objective evidence of abnormal reflux is present (e.g., positive impedance-pH on PPI), recommending:

- Laparoscopic fundoplication (LF) and magnetic sphincter augmentation (MSA) are appropriate options for complete or partial PPI responders regardless of whether a clinically significant hiatal hernia is present.
- Transoral incisionless fundoplication (TIF) is considered appropriate for complete or partial

responders without a clinically significant hiatal hernia.

- Radiofrequency energy delivery is not appropriate for complete or partial responders.

National Institute for Health and Care Excellence (NICE) issued the following interventional practice guidelines (IPG) for the treatment of GERD:

- In 2023 (IPG753), NICE concluded that the evidence on the safety of endoluminal gastroplication for gastroesophageal reflux disease is adequate; however, evidence on its efficacy is inadequate in quality, particularly in terms of patient selection and long-term outcomes. Therefore, this procedure should be used only in research.
- In 2013 (IPG461), NICE concluded that the evidence on the safety of endoscopic radiofrequency ablation for gastro-esophageal reflux disease is adequate in the short and medium term, but there is uncertainty about longer-term outcomes. There is evidence of symptomatic relief, but objective evidence on reduction of reflux is inconclusive.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates devices for transendoscopic procedures as medical devices. All devices require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Jan 27]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls-and-early-alerts [accessed 2026 Jan 27]

Radiofrequency Thermal Energy

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

Endoluminal Endoscopic GEJ-Reshaping

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

The EsophyX (EndoGastric Solutions) is a transesophageal (or transoral) incisionless fundoplication (TIF) device that was originally cleared for marketing by the FDA through the 510(k) process in 2007 and has subsequently undergone 2 evolutions: Generation 2=EsophyX2 iterations (E2-Plus, HD) and Generation 3=Z iterations (EZ/ZR, Z+). In 2007, EsophyX (EndoGastric Solutions) was cleared for marketing by the FDA through the 510(k) process for full-thickness plication. In 2016, EsophyX Z

Device with SerosaFuse Fasteners was cleared for marketing by the FDA through the 510(k) process (K160960) for use in transoral tissue approximation, full-thickness plication, ligation in the gastrointestinal tract, narrowing the gastroesophageal junction, and reduction of hiatal hernias of 2 cm or less in patients with symptomatic chronic GERD. In June 2017, EsophyX2 HD and the third-generation EsophyX Z Devices with SerosaFuse fasteners and accessories were cleared for marketing by the FDA through the 510(k) process (K171307) for expanded indications, including patients who require and respond to pharmacologic therapy and patients with hiatal hernias larger than 2 cm when a laparoscopic hiatal hernia repair reduces a hernia to 2 cm or less. An additional FDA 510(k) clearance (K172811) occurred in October 2017 for new product specification iterations of EsophyX2 HD and EsophyX Z Devices. This clearance allows for "a moderate increase in the upper limit of the temporary Tissue Mold clamping pressure occurring during each fastener deployment." A 2024 FDA 510(k) clearance (K240879) updated instructions for use and other device labeling.

The GERDx-System was cleared through the 510(k) process in 2024 (K233240) for endoscopic full-thickness plication in individuals with chronic GERD who require and respond to pharmacological therapy. The device was found substantially equivalent to the NDO Surgical Endoscopic Plication System (K071553), which was cleared in 2007 for the treatment of chronic GERD but was later removed from the market due to durability concerns and limited long-term clinical effectiveness. The GERDx-System incorporates technological refinements intended to improve safety and performance compared with its predicate device.

The Bard EndoCinch Suturing System received FDA 510(k) clearance on January 5, 2001 (K003956), and the NDO Surgical Endoscopic Plication System (Plicator) received FDA 510(k) clearance on April 17, 2003 (K023234) for the treatment of chronic GERD. Although both devices were cleared for marketing for the treatment of GERD, they are no longer available for clinical use in the United States. They were discontinued or withdrawn from the market due to limited efficacy, durability concerns, and lack of sustained commercial adoption.

Esophageal Bulking Agents

Durasphere and plexiglas (PMMA) do not currently have FDA approval for use in an anti-reflux application. The Gatekeeper System was withdrawn in late 2005, before FDA approval. Enteryx received FDA clearance 2003 and was recalled from market October 2005 based on a joint decision by the FDA and Boston Scientific. The recall was initiated by Boston Scientific, based upon growing data evidence of serious adverse effects.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
43192 (E/I*)	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance Excludes: Injection of sclerosis esophageal varices: Flexible, transoral (43204); Rigid, transoral (43192, 43499) (*E/I when used to report injection of a bulking agent or any other submucosal injection to treat GERD)
43201 (E/I*)	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance Excludes: Injection of sclerosis esophageal varices: Flexible, transoral (43204); Rigid, transoral (43192, 43499) (*E/I when used to report injection of a bulking agent or any other submucosal injection to treat GERD)
43210 (E/I*)	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed (*E/I when used to report any endoscopic treatment for GERD)
43236 (E/I*)	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance Excludes: Flexible, transoral; with control bleeding, any method (43255); Flexible, transoral; with injection sclerosis esophageal/gastric varices (43243); Injection sclerosis varices, esophageal/gastric (43243) (*E/I when used to report injection of a bulking agent or any other submucosal injection to treat GERD)
43257 (E/I)	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 (e.g., Stretta procedure)

HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
K21.0 - K21.9	Gastro-esophageal reflux disease (code range)
K44.0 - K44.9	Diaphragmatic hernia (code range)

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Select Minimally Invasive GERD Procedures (LCD L35080) [accessed 2026 Feb 24]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
10/18/01, 02/21/02, 01/16/03, 11/20/03, 10/20/04, 08/18/05, 06/15/06, 05/17/07, 05/14/08, 05/28/09, 05/27/10, 05/19/11, 05/24/12, 05/23/13, 05/22/14, 05/28/15, 05/25/16, 05/18/17, 05/17/18, 05/16/19, 03/19/20, 03/18/21, 03/24/22, 03/23/23, 03/21/24, 03/20/25, 03/19/26	
Date	**Summary of Changes**
03/19/26	• Annual review, policy intent unchanged.
03/20/25	• Annual review, policy intent unchanged
01/01/25	• Summary of changes tracking implemented.
10/18/01	• Original effective date