MEDICAL POLICY

Medical Policy Title	**Transendoscopic Therapies for Gastroesophageal Reflux Disease (GERD)**
Policy Number	**7.01.45**
Current Effective Date	March 20, 2025
Next Review Date	March 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

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

   A. Radiofrequency energy applications to the gastroesophageal junction (e.g., Stretta procedure);

   B. Endoluminal gastroplasty/gastroplication (e.g., EndoCinch, Medigus Ultrasonic Surgical Endostapler [MUSE], Syntheon ARD Plicator, GERDx-System);

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

   D. Injection/implantation of biocompatible bulking agents (e.g., plexiglas or polymethylmethacrylate [PMMA] 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 common disorder characterized by classic symptoms of heartburn and regurgitation, as well as other symptoms such as pain, dysphagia, and dry cough/throat clearing). Most individuals experience symptoms of gastroesophageal reflux at some point in their lives, with a smaller number having chronic symptoms that put them at risk for complications of GERD (e.g., erosive esophagitis, dysphagia, Barrett 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.

Guidelines on the medical management of GERD emphasize initial lifestyle modification (e.g., weight loss, smoking cessation, head of the bed elevation, elimination of food triggers) and medication therapy (e.g., antacids, proton pump inhibitors). Surgical and endoscopic procedures are options for patients who have persistent symptoms or develop complications despite optimal medical therapy.

Due in part to the high prevalence of GERD, minimally invasive transesophageal therapeutic alternatives have been developed as an alternative to long-term medication therapy or anti-reflux surgery. These procedures aim to reduce reflux by altering gastroesophageal structures, including:

- Radiofrequency thermal energy (e.g., Stretta procedure) has been used to produce submucosal thermal lesions at the gastroesophageal junction. The mechanism of action of the thermal lesions is not precisely known but may be related to the ablation of the nerve pathways responsible for sphincter relaxation or may induce a tissue-tightening effect related to heat-induced collagen contraction and fibrosis.
- Endoluminal gastroplasty/gastroplication (e.g., EndoCinch, Syntheon ARD Plicator, GERDx) procedure is designed to recreate a valve and restore an antireflux barrier at the GEJ. During this procedure, the fundus of the stomach is folded and then held in place with sutures, staples or fasteners that are deployed by the device.
- Transoral incisionless fundoplication (TIF), also referred to as endoluminal fundoplication (ELF), is designed to restore the antireflux barrier by recreating the valve at the gastroesophageal junction. The fundoplication device is passed transorally under direct visualization by an endoscope. Gastric tissue from the fundus is then drawn between the body of the device and the tissue mold used to shape each portion of the gastroesophageal valve. Finally, polypropylene fasteners are delivered across the mold tissue, to create a three-to-five cm, serosa-to-serosa flap.
- Injection or implantation of a prosthetic or bulking agent to enhance the volume of the lower esophageal sphincter has also been investigated to reduce reflux.

SUPPORTIVE LITERATURE

The evidence is insufficient to determine that transesophageal endoscopic therapies for the treatment of GERD (e.g., application of radiofrequency energy, gastroplication, transoral incisionless fundoplication [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.

Yao and colleagues (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 proton pump inhibitors (PPIs) or sham. A total of 19 randomized controlled trials (n=1181 subjects) were met inclusion criteria. Four RCTs compared endoscopic band ligation (EBL) (306 cases); 6 RCT compared Stretta (235 cases); 5 RCTs compared transoral incisionless fundoplication (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 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.

Transesophageal Radiofrequency

Kalapala and colleagues (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 and colleagues (2020) reported on a retrospective comparison of laparoscopic Toupet fundoplication with the Stretta procedure. GERD relapse was the primary endpoint. 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 lower-esophageal sphincter pressure. Important limitations of this study are its single-center design and short follow-up time.

Zerbib and colleagues (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 and colleagues (2021) published a systematic review and network meta-analysis of ten RCTs (n=516 participants) that evaluated the comparative effects of Stretta, TIF, and proton pump inhibitors (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 (mean difference [MD], 2.45; 95% CI, -2.37 to 7.26); 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, lack of RCTs directly comparing Stretta and TIF, some comparisons were significantly affected by heterogeneity, and the evidence quality of each outcome (as assessed by GRADE) ranged from moderate to very low.

The American Society for Gastrointestinal Endoscopy (ASGE 2025) performed a systematic review and updated meta-analysis. The panel identified a low number of eligible RCTs and cohort studies that provided nonsignificant results with low study power. All studies were noted to be published several years ago The overall certainty in the evidence was low to very low based on differing results from RCTs and cohort studies, lack of durable benefit, and availability of better treatments.

Endoluminal Gastroplication

Kalapala and colleagues (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 Health-Related Quality of Life (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 stated that "large, prospective trials with long-term follow-up are required to conclude the benefits of this procedure after 1 year."

Weitzendorfer and colleagues (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 plication, 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 on the effects of this procedure.

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.

Richter and colleagues (2018) performed a systematic review and network meta-analysis of randomized, controlled trials completed as of May 2017, to compare the relative efficacies of transoral incisionless fundoplication (TIF) versus laparoscopic nissen fundoplication (LNF) in patients with GERD. The meta-analysis reviewed seven trials comprising 1,128 patients. The comparative results from direct and network meta-analysis included the following results: LNF had the highest probability of increasing percent time at pH<4 (0.99), followed by PPIs (0.64), TIF (0.32), and the sham procedure (0.05). LNF also had the highest probability of increasing LES pressure (0.78), followed by TIF (0.72) and PPIs (0.01). Patients who underwent the sham procedure had the highest probability for persistent esophagitis (0.74), followed by those receiving TIF (0.69), LNF (0.38), and PPIs (0.19). The meta-analysis did not review adverse effects/harm, as it was not reported consistently across all of the studies. 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 recommend as a long-term alternative to PPI or LNF treatment of GERD, as long-term efficacy has not been demonstrated.

Testoni and colleagues (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 studies. 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.

Testoni and colleagues (2022) conducted a prospective, single-center, observation study to evaluate the effect of TIF performed by a MUSE device on clinical, functional, and upper gastrointestinal endoscopic findings. The study included 46 patients aged 18 to 70 years; experiencing chronic (at least six months) GERD-related symptoms, both esophageal and extra-esophageal, with complete or partial response to PPI therapy; with endoscopic findings of GERD or Barrett's esophagus < 3 cm; and evidence of non-erosive reflux disease (NERD) or hypersensitive esophagus, and a body mass index < 40 kg/m2. The TIF was successfully performed in 45/46 patients. There were two severe complications (4.4%) requiring surgical repair. One patient was unresponsive to the procedure and underwent a Nissen fundoplication within 6-months. These patients were excluded from the follow-up. The study concluded that TIF by MUSE achieved significant improvement of GERD-related symptoms and allowed to stop or halve PPI consumption in about 65% and 77% of patients up to 3 years in a selected subset of symptomatic GERD patients. However, the procedure did not appear to be as effective in controlling esophagitis and improving functional parameters. The authors noted limitations of small sample size, inclusion of only grade A esophagitis, and lack of control group. Larger, randomized controlled trials with long-term results are needed.

Rausa and colleagues (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.

The American Society for Gastrointestinal Endoscopy (ASGE 2025) performed a systematic review and updated meta-analysis of studies assessing the efficacy and safety of TIF 2.0 for GERD compared with PPI and/sham interventions. The included studies (4 RCTs, 18 cohort studies, 4 existing meta-analyses), published through December 2022, consisted of varying patient population and vary definition of outcomes. Although studies showed short-term improvement of GERD symptoms and remission of symptoms maintained for up to five years, the panel voiced concerns on the appropriate selection of patients and made only conditional recommendations.

Esophageal 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 and colleagues (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. A case series by Feretis and colleagues (2001) evaluated transesophageal submucosal implantation of polymethylmethacrylate beads in ten 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.

PROFESSIONAL GUIDELINE(S)

In 2025, the American Society for Gastrointestinal Endoscopy (ASGE) published updated recommendations on the diagnosis and management of GERD. In patients with GERD symptoms the ASGE made a strong recommendation for lifestyle modification. Medical management, with PPIs at the lowest dose for the shortest duration, is strongly recommended for patients with symptomatic and confirmed GERD.

- Conditional recommendation (low quality of evidence) that suggests an evaluation for TIF as an alternative to long-term medical management in patients with confirmed GERD with small hiatal hernia (less than or equal to 2cm), Hill grade I or II, and additional criteria.
- Conditional recommendation (very low quality of evidence) that suggests an evaluation for hiatal hernia repair combined with TIF (cTIF) in patients with large hiatal hernia (>2cm) and Hill grade III or IV.

- Best practice advice (low to very low quality of evidence) to consider radiofrequency energy (e.g., Stretta) to the lower esophageal sphincter (LES) when other alternatives (endoscopic or surgical fundoplication) are not available or feasible.

In 2023, multi-society consensus guidance recommendations were published on the diagnosis and treatment of GERD (Slater 2023). The panel suggests that adult patients with GERD may benefit from:

- fundoplication over TIF 2.0 (Expert Opinion recommendation; Grade recommendation was unable to be determined due to lack of evidence).
- TIF 2.0 over continued PPI (conditional recommendation, moderate certainty of evidence).
- 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) guidelines on the diagnosis and management of GERD include the following recommendations for surgical and endoscopic options for GERD (Katz 2022):

- We recommend antireflux surgery performed by an experienced surgeon as an option for long-term treatment of patients with objective evidence of GERD, especially those who have severe reflux esophagitis (LA grades C or D), large hiatal hernias, and/or persistent, troublesome GERD symptoms. (Strong recommendation, moderate level of evidence)
- We recommend consideration of magnetic sphincter augmentation (MSA) as an alternative to laparoscopic fundoplication for patients with regurgitation who fail medical management. (strong recommendation, moderate level of evidence)
- We suggest consideration of Roux-en-Y gastric bypass (RYGB) as an option to treat GERD in obese patients who are candidates for this procedure and who are willing to accept its risks and requirements for lifestyle alterations. (Conditional recommendation, low level of evidence)
- Since data on the efficacy of radiofrequency energy (Stretta) as an antireflux procedure is inconsistent and highly variable, we cannot recommend its use as an alternative to medical or surgical antireflux therapies. (conditional recommendation, low level of evidence)

- We suggest consideration of 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 recommendation, low level of evidence)

REGULATORY STATUS

Transesophageal Radiofrequency

The Stretta System received Section 510(k) premarket clearance from the U.S. Food and Drug Administration (FDA) on April 18, 2000, for general use in the electrosurgical coagulation of tissue and was specifically intended for use in the treatment of GERD.

Endoluminal Gastroplication

The EndoCinch or Bard Suturing System received Section 510(k) premarket clearance from the FDA on March 20, 2000. The NDO Surgical Endoscopic Plication System received clearance from the FDA in 2003 for the treatment of GERD. Sew-Right Device, and the Syntheon ARD Plicator have not received FDA approval.

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, Inc.) was originally cleared for marketing by the FDA through the 510(k) process in 2007 and has subsequently undergone 2 evolutions. In 2016, the EsophyX Z Device with SerosaFuse Fasteners was cleared for marketing by the FDA through the Section 510(k) process for use in transoral tissue approximation, full-thickness plication, ligation in the gastrointestinal tract, narrowing of the gastroesophageal junction, and reduction of hiatal hernias of two 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 Section 510(k) process for expanded indications, including patients who require and respond to pharmacologic therapy and patients with hiatal hernias larger than two cm when a laparoscopic hiatal hernia repair reduces a hernia to two cm or less.

GERDX-System received was cleared through the FDA 510(k) process in 2024 (K233240). The device is intended for endoscopic full-thickness plication for chronic GERD in individuals who require and respond to pharmacological therapy

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
None	

ICD10 Codes

Code	Description
K21	Gastro-esophageal reflux disease
K21.0	Gastro-esophageal reflux disease with esophagitis
K21.00	Gastro-esophageal reflux disease with esophagitis, without bleeding
K21.01	Gastro-esophageal reflux disease with esophagitis, with bleeding
K21.9	Gastro-esophageal reflux disease without esophagitis

REFERENCES

Arts J, et al. A one-year follow-up study of endoluminal gastroplication (Endocinch) in GERD patients refractory to proton pump inhibitor therapy. Dig Dis Sci. 2005 Feb;50(2):351-6.

ASGE Standards of Practice Committee; Desai M, et al. American Society for Gastrointestinal Endoscopy guideline on the diagnosis and management of GERD: summary and recommendations. Gastrointest Endosc. 2025 Feb;101(2):267-284.

Chimukangara M, et al. Long-term reported outcomes of transoral incisionless fundoplication: an 8-year cohort study. Surg Endosc. 2019 Apr;33(4):1304–1309.

Cohen LB, et al. Enteryx implantation for GERD: expanded multicenter trial results and interim post approval follow-up to 24 months. Gastrointest Endosc. 2005 May;61(6):650-8.

Fass R, et al. Systematic review, and meta-analysis of controlled and prospective cohort efficacy studies of endoscopic radiofrequency for treatment of gastroesophageal reflux disease. Surg Endosc. 2017 Dec;31(12):4865-4882.

Feretis C, et al. Endoscopic implantation of Plexiglas (PMMA) microspheres for the treatment of GERD. Gastrointest Endosc. 2001;53(4):423-426.

Ganz RA, et al. A new injectable agent for the treatment of GERD: results of the Durasphere pilot trial. Gastrointest Endosc. 2009;69(2):318-323.

Janu P, et al. Laparoscopic hiatal hernia repair followed by transoral incisionless fundoplication with EsophyX device (HH + TIF): efficacy and safety in two community hospitals. Surg Innov. 2019 Dec; 26(6):675–686.

Kalapala R, et al. Treatment of gastroesophageal reflux disease using radiofrequency ablation (Stretta procedure): an interim analysis of a randomized trial. Indian J Gastroenterol. 2017 Sep;36(5): 337-342.

Kalapala R, et al. Endoscopic full-thickness plication for the treatment of PPI-dependent GERD: results from a randomised, sham controlled trial. Gut. 2022;71:686-694.

Katz PO, et al. ACG clinical guideline for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol 2022 Jan 01;117(1):27-56.

Liu S, et al. New treatment method for refractory gastroesophageal reflux disease (GERD): C-BLART (clip band ligation anti-reflux therapy)-a short-term study. Surg Endosc. 2020 Oct;34(10):4516-4524.

Ma L, et al. Stretta radiofrequency treatment vs Toupet fundoplication for gastroesophageal reflux disease: a comparative study. BMC Gastroenterol. 2020 May 27;20(1): 162.

Maydeo A, et al. Endoscopic full-thickness plication for the treatment of gastroesophageal reflux after peroral endoscopic myotomy: a randomized sham-controlled study. Endoscopy. 2023;55(08):699-700.

McCarty TR, et al. Efficacy of transoral incisionless fundoplication for refractory gastroesophageal reflux disease: a systematic review and meta-analysis. Endoscopy. 2018 Jul;50(7):708-725.

National Institute for Health and Clinical Excellence (NICE) [Internet]. Endoluminal gastroplication for gastro-oesophageal reflux disease. Interventional procedures guidance [IPG753]. 2023 Mar 01 [accessed 2025 Jan 30]. Available from: https://www.nice.org.uk/guidance/ipg753

National Institute for Health and Clinical Excellence (NICE) [Internet]. Endoscopic radiofrequency ablation for gastro-oesophageal reflux disease. Interventional procedures guidance [IPG461]. 2013 Aug 28 [accessed 2025 Jan 30]. Available from: https://www.nice.org.uk/guidance/ipg461

Richter JE, et al. Efficacy of laparoscopic nissen fundoplication vs transoral incisionless fundoplication or proton pump inhibitors in patients with gastroesophageal reflux disease: a systematic review and network meta-analysis. Gastroenterology. 2018 Apr;154(5):1298-1308.

Schiefke I, et al. Long-term failure of endoscopic gastroplication (EndoCinch). Gut. 2005 Jun;54(6):752-8.

Schiefke I, et al. Use of an endoscopic suturing device (the "ESD") to treat patients with gastroesophageal reflux disease, after unsuccessful EndoCinch endoluminal gastroplication: another failure. Endoscopy. 2005 Aug;37(8):700-5.

Slater BJ, et al. Multi-society consensus conference and guideline on the treatment of gastroesophageal reflux disease (GERD). Surg Endosc. 2023 Feb;37(2):781-806.

Sowa P, Samarasena JB. Nonablative radiofrequency treatment for gastroesophageal reflux disease (STRETTA). Gastrointest Endosc Clin N Am. 2020 Apr;30(2):253-265.

Testoni SGG, et al. Long-term outcomes of transoral incisionless fundoplication for gastro-esophageal reflux disease: systematic-review and meta-analysis. Endosc Int Open. 2021 Feb;9(2):E239-E246.

Testoni SGG, et al. Transoral incisionless fundoplication with Medigus ultrasonic surgical endostapler (MUSE) for the treatment of gastro-esophageal reflux disease: outcomes up to 3 years. Surg Endosc. 2022 Jul;36(7):5023-5031.

Testoni PA, et al. Transoral incisionless fundoplication with EsophyX for gastroesophageal reflux disease: clinical efficacy is maintained up to 10 years. Endoscopy International Open. 2019; 07: E647–E654.

Trad KS, et al. The TEMPO trial at 5 years: transoral fundoplication (TIF 2.0) is safe, durable, and cost-effective. Surgical Innovation 2018;25(2):149–157.

Triadafilopoulous G, et al. Radiofrequency energy delivery to the gastroesophageal junction for the treatment of GERD. Gastrointest Endosc. 2001 Apr;53(4):407-15.

Triadafilopoulous G, et al. The Stretta procedure for the treatment of GERD 6 and 12 month follow-up of the US open label trial. Gastrointest Endosc. 2002 Feb;55(2):149-56.

Weitzendorfer M, et al. Clinical feasibility of a new full-thickness endoscopic plication device (GERDx) for patients with GERD: results of a prospective trial. Surg Endosc. 2018 May;32(5):2541-2549.

Wolfsen HC, et al. The Stretta procedure for the treatment of GERD: a registry of 558 patients. J Laparosc Adv Surg Tech A. 2002 Dec;12(6):395-402.

Xie P, et al. Efficacy of different endoscopic treatments in patients with gastroesophageal reflux disease: a systematic review and network meta-analysis. Surg Endosc. 2021 Apr;35(4):1500-1510.

Yadlapati P, et al. AGA clinical practice update on the personalized approach to the evaluation and management of GERD: expert review. Clin Gastroenterol Hepatol. 2022 May;20(5):984-994.e1.

Yao L, et al. Efficacy of different endoscopic treatments for gastroesophageal reflux disease: a systematic review and network meta-analysis. J Gastrointest Surg. 2024 Jul;28(7):1051-1061.

Zerbib F, et al. Randomised clinical trial: oesophageal radiofrequency energy delivery versus sham for PPI-refractory heartburn. Aliment Pharmacol Ther. 2020 Aug;52(4):637-645.

SEARCH TERMS

Not applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Select Minimally Invasive GERD Procedures (LCD L35080) [accessed 2025 Feb 05]

Stretta Procedure (LCD L34540) [accessed 2025 Feb 05]

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	
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	
Date	**Summary of Changes**
03/20/25	• Annual review, policy intent unchanged
01/01/25	• Summary of changes tracking implemented.
10/18/01	• Original effective date