

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Note: Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence is addressed separately in medical policy 00095.

Note: Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus is addressed separately in medical policy 00261.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers transoral incisionless fundoplication (e.g., EsophyX, MUSE, GERDX) as a treatment of gastroesophageal reflux disease (GERD) to be **investigational**.*

Based on review of available data, the Company considers transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (e.g., Stretta procedure) as a treatment of gastroesophageal reflux disease (GERD) to be **investigational**.*

Based on review of available data, the Company considers endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (polymethylmethacrylate [PMMA] beads, zirconium oxide spheres) as a treatment of gastroesophageal reflux disease (GERD) to be **investigational**.*

Background/Overview

Gastroesophageal Reflux Disease

Gastroesophageal reflux disease (GERD) is a common disorder characterized by heartburn and other symptoms related to reflux of stomach acid into the esophagus. Nearly all individuals experience such symptoms at some point in their lives; a smaller number have chronic symptoms and are at risk for complications of GERD. The prevalence of GERD has been estimated to be approximately 20% in the United States.

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

Pathophysiology

The pathophysiology of GERD involves excessive exposure to stomach acid, which occurs for several reasons. There can be an incompetent barrier between the esophagus and stomach, either due to dysfunction of the lower esophageal sphincter or incompetence of the diaphragm. Another mechanism is 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.

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

Treatment

Guidelines on the management of GERD emphasize initial medical management. Weight loss, smoking cessation, head of the bed elevation, and elimination of food triggers are all recommended in recent practice guidelines. Proton pump inhibitors (PPIs) have been shown to be the most effective medical treatment. In a Cochrane systematic review, van Pinxteren et al (2010) reported that PPIs demonstrated superiority to H₂-receptor antagonists and prokinetics in both network meta-analyses and direct comparisons.

Surgical Treatment

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

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

Other Treatment Options

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

1. Transesophageal endoscopic gastroplasty (gastroplication, transoral incisionless fundoplication) can be performed as an outpatient procedure. During this procedure, the fundus of the stomach is folded and then held in place with staples or fasteners that are

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

deployed by the device. The endoscopic procedure is designed to recreate a valve and barrier to reflux.

2. Radiofrequency energy has been used to produce submucosal thermal lesions at the gastroesophageal junction (this technique has also been referred to as the Stretta procedure). Specifically, radiofrequency energy is applied through 4 electrodes inserted into the esophageal wall at multiple sites both above and below the squamocolumnar junction. The mechanism of action of the thermal lesions is not precisely known but may be related to 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.
3. Submucosal injection or implantation of a prosthetic or bulking agent to enhance the volume of the lower esophageal sphincter has also been investigated. One bulking agent, pyrolytic carbon-coated zirconium oxide spheres (Durasphere), has been evaluated. The GatekeeperTM Reflux Repair System (Medtronic) used a soft, pliable, expandable prosthesis made of a polyacrylonitrile-based hydrogel. The prosthesis was implanted into the esophageal submucosa, and with time, the prosthesis absorbed water and expanded, creating bulk in the region of implantation. However, the only identified RCT was terminated early due to lack of efficacy and it was voluntarily withdrawn by the manufacturer. Endoscopic submucosal implantation of polymethylmethacrylate beads into the lower esophageal folds has also been investigated.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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+). Some of the key Regulatory Status changes are summarized herein. In 2007, EsophyX[®] (EndoGastric Solutions) was cleared for marketing by the FDA through the 510(k) process for full-thickness plication. In 2016, EsophyX[®] Z Device with SerosaFuse Fasteners was cleared for marketing by 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. FDA product code: ODE.

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

The Medigus SRS Endoscopic Stapling System (MUSE, Medigus) 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. FDA product code: ODE.

The GERDX-System (K233240) was cleared through the 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. FDA product code: ODE. The manufacturer website includes a description for use in presence of a hiatal hernia up to 3 cm in size. The device is clinically, biologically, and technologically identical to the NDO Surgical Endoscopic Plication System (K071553) which was approved by the FDA in 2003 and has since been removed from the market due to risk of complications. Technological details of the GERDX-System have been improved from the predicate device to improve safety.

In 2000, the CSM 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. FDA product code: GEI.

Durasphere^{®‡} is a bulking agent approved for the treatment of urinary and fecal incontinence (see medical policy 00095). Use of this product for esophageal reflux would be considered off-label use. The website of Carbon Medical Technologies states that the Durasphere^{®‡} GR product is “intended to treat problems associated with GERD” but is considered an investigational device in the U.S.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Description

Transesophageal endoscopic therapies are being developed for the treatment of gastroesophageal reflux disease (GERD). A variety of procedures are being evaluated, including transesophageal (or transoral) incisionless fundoplication (TIF), application of radiofrequency energy, and injection/implantation of prosthetic devices or bulking agents.

Summary of Evidence

For individuals who have GERD and a hiatal hernia of 2 cm or less that is not controlled by proton pump inhibitors (PPIs) who receive TIF (eg, EsophyX), the evidence includes 2 randomized controlled trials (RCTs) comparing TIF with PPI therapy, nonrandomized studies comparing TIF with fundoplication, and case series with longer-term follow-up. Relevant outcomes are symptoms,

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

change in disease status, quality of life (QOL), medication use, and treatment-related morbidity. The highest quality RCT (RESPECT) was sham-controlled and compared TIF with PPI therapy while the other RCT (TEMPO) compared TIF with maximum PPI therapy. Both trials found a significant benefit of TIF on the primary outcome measure in about 65% of patients. The sham-controlled trial reported improvement in 45% of the sham-controlled group and no benefit on secondary subjective outcome measures. The nonblinded RCT found significant improvements in subjective measures but no difference in objective outcome measures compared with PPI therapy. Together, these trial results would suggest a strong placebo effect of the surgery and a modest benefit of TIF in patients whose symptoms were not controlled by PPIs. For these patients, the most appropriate comparator would be laparoscopic fundoplication. Studies comparing TIF with fundoplication have limitations that include earlier TIF procedures and unbalanced groups at baseline and are inadequate to determine relative efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have GERD and a hiatal hernia of 3 cm or less that is controlled by PPIs who receive TIF (eg, EsophyX), the evidence includes 2 RCTs and observational studies with longer-term follow-up. Relevant outcomes are symptoms, change in disease status, QOL, medication use, and treatment-related morbidity. A sham-controlled trial found that the time to resume PPI therapy was longer following TIF and the remission rate was higher, indicating that TIF is more effective than no therapy. The nonblinded RCT found a benefit of TIF compared with continued PPI therapy for subjective measures, but not for the objective measures of pH normalization and esophagitis. In addition, a single-center, double-blind RCT in individuals with GERD (using GERDX) and a hiatal hernia of 3 cm or less found improved subjective outcomes to 12 months, but objective measures such as esophageal pH control were not significantly improved. These results raise questions about a possible placebo effect for the procedure. Also, observational studies have indicated a loss of treatment effectiveness over time. Adverse events associated with the procedure (eg, perforation) may be severe. At present, the available evidence does not support the use of this intervention in patients whose symptoms are adequately controlled by medical therapy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have GERD who receive endoscopic radiofrequency energy (eg, Stretta), the evidence includes 2 meta-analyses, a network meta-analysis, 6 small RCTs, 2 nonrandomized comparative studies, and observational studies with longer-term follow-up. Relevant outcomes are symptoms, change in disease status, QOL, medication use, and treatment-related morbidity. The RCTs reported some improvements in symptoms and QOL following treatment with radiofrequency energy compared with sham controls. However, objective measures of GERD and a meta-analysis of 4 RCTs found no significant improvements in outcomes, raising questions about the mechanism of the symptom relief. Symptom relief and clinical success is reported to be lower than after fundoplication, and reoperations and other severe adverse events greater. Larger RCTs with longer follow-up, preferably compared with fundoplication, are needed to define the risks and benefits of this procedure better. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

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

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2015 Input

In response to requests for clinical input on transesophageal radiofrequency (Stretta) as a treatment of gastroesophageal reflux disease (GERD), input was received from 1 physician specialty society (2 reviewers) and 3 academic medical centers while this policy was under review in 2015. Input was mixed on the treatment of GERD with transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (ie, Stretta). Potential conflicts of interest were noted by 2 reviewers.

2011 Input

In response to requests for clinical input on transoral incisionless fundoplication (TIF) using EsophyX, input was received from 2 physician specialty societies and 4 academic medical centers while this policy was under review in 2011. Reviewers agreed that TIF differed sufficiently from laparoscopic Nissen fundoplication to warrant evaluation as a separate procedure. Reviewers considered TIF (ie, EsophyX) to be investigational for the treatment of GERD.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Gastroenterology

The American College of Gastroenterology (2022) guidelines on the diagnosis and management of GERD include the following statements regarding TIF and Stretta:

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

- 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 (LA grade C or D) or hiatal hernias >2 cm (conditional recommendation, low level of evidence).
- Because 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).

According to the guideline methods, a conditional recommendation equates to a suggestion, and low level of evidence signifies "very little confidence in the effect estimate to support a particular recommendation, based on the risk of bias of the studies, evidence of publication bias, heterogeneity among studies, directness of the evidence, and precision of the estimate of effect." The guideline additionally noted that if TIF or Stretta is used, such use should be limited to patients with milder forms of GERD.

American Foregut Society

In 2020, recommendations by an expert U.S panel on surgical and endoscopic management options for patients with GERD were published; 16 expert panelists participated in a 2-round survey process that was facilitated by the American Foregut Society. Six interventions were discussed for various patient scenarios: laparoscopic fundoplication with crural repair; laparoscopic magnetic sphincter augmentation with crural repair; TIF; TIF with laparoscopic crural repair; radiofrequency energy delivery; and optimization of medical therapy.

Among patients who were complete responders to PPI therapy, the majority of panelists considered TIF an appropriate treatment option when no clinically significant hiatal hernia was present. Although TIF combined with crural repair received relatively high ratings for patients with a clinically significant hiatal hernia, it did not reach consensus, likely due to the panelists' concerns about limited high-quality supporting evidence. Panelists did not reach consensus regarding the appropriateness of radiofrequency energy delivery for complete responders to PPI therapy patients without a clinically significant hiatal hernia. Some panelists noted, however, that this treatment should not be dismissed entirely, as it remains a potential therapeutic option that does not limit future surgical interventions.

For patients who were partial responders to PPI therapy, most panelists considered TIF an appropriate option when no clinically significant hiatal hernia was present but deemed it inappropriate when such a hernia existed. Overall, TIF combined with crural repair did not achieve consensus across any of the four partial PPI responder patient scenarios. Radiofrequency energy delivery was rated as indeterminate for partial PPI responders experiencing heartburn or regurgitation without a clinically significant hiatal hernia. Panelists noted that randomized controlled trials show inconsistent and low-quality evidence for this therapy in partial responders.

For patients who did not respond to PPI therapy, TIF without crural repair was rated appropriate across all PPI nonresponder scenarios without a clinically significant hernia, independent of impedance-pH testing results. Although TIF with crural repair received relatively high ratings in

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

certain cases, it did not reach consensus for any PPI nonresponder scenarios involving a clinically significant hernia, regardless of impedance-pH outcomes. Although radiofrequency energy delivery was rated favorably for PPI nonresponders without a clinically significant hernia who showed reflux hypersensitivity or elevated reflux burden on impedance-pH testing, it did not fully meet the criteria for agreement. It was ranked as inappropriate for all PPI non-responder scenarios, a clinically significant hiatal hernia.

American Gastroenterological Association

In 2022, the American Gastroenterological Association issued a clinical practice update on the personalized approach to the evaluation and management of GERD. The guideline stated that "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.

American Society for Gastrointestinal Endoscopy

In 2025, the American Society for Gastrointestinal Endoscopy (ASGE) published guidelines on recommendations for the diagnosis and management of GERD. The following statements regarding TIF and Stretta were made.

In patients with confirmed GERD with a small hiatal hernia (≤ 2 cm) and Hill grade I or II who meet any of the following criteria, the ASGE suggests evaluation for TIF as an alternative to chronic medical management (conditional recommendation; low quality of evidence):

- Chronic GERD (≥ 6 months);
- Chronic PPI use (≥ 6 months) for management for GERD symptoms;
- Refractory GERD;
- Regurgitation-predominant GERD;
- Patient prefers to avoid long-term PPI use.

In patients with confirmed GERD with a large hiatal hernia (> 2 cm) and Hill grade III or IV, the ASGE suggests evaluation for combined hiatal hernia repair and TIF in a multidisciplinary review (conditional recommendation, very low quality of evidence).

In patients with confirmed GERD and small hiatal hernias (< 2 cm) and Hill grade I or II, Stretta can be considered when other alternatives (endoscopic/surgical fundoplication) are not available or feasible (best practice advice, conditional recommendation, very low quality of evidence).

American Society of General Surgeons

In 2011, the American Society of General Surgeons issued a position statement on transoral fundoplication stating that "ASGS supports the use of transoral fundoplication by trained General Surgeons for the treatment of symptomatic chronic gastroesophageal reflux disease (GERD) in patients who fail to achieve satisfactory response to a standard dose of Proton Pump Inhibitor (PPI) therapy or for those who wish to avoid the need for a lifetime of medication dependence."

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

Multi-Society Consensus Guidance on GERD

In 2023, consensus guidance was issued by the Society of American Gastrointestinal and Endoscopic Surgery, American Society for Gastrointestinal Endoscopy, American Society for Metabolic and Bariatric Surgery, European Association for Endoscopic Surgery, Society for Surgery of the Alimentary Tract, and The Society of Thoracic Surgeons on the diagnosis and treatment of GERD. The relevant questions and recommendations for TIF and Stretta are as follows:

- Should endoscopic treatment with TIF 2.0 versus fundoplication be used for patients with GERD?
 - 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).
- Should endoscopic treatment with TIF 2.0 versus medical treatment (PPI) be used for patients with GERD?
 - The panel suggests that adult patients with GERD may benefit from TIF 2.0 over continued PPI (conditional recommendation, moderate certainty of evidence).
- Should endoscopic treatment with Stretta versus fundoplication be used for patients with GERD?
 - The panel suggests that adult patients with GERD may benefit from fundoplication over Stretta. (conditional recommendation, very low certainty of evidence).
- Should endoscopic treatment with Stretta versus medical treatment (PPI) be used for patients with GERD?
 - The panel suggests that adult patients with GERD may benefit from Stretta over PPI. (conditional recommendation, low certainty of evidence).

National Institute for Health and Care Excellence

In 2013, NICE updated its guidance on endoscopic radiofrequency treatment for GERD, concluding: "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. With regard to efficacy, there is evidence of symptomatic relief, but objective evidence on reduction of reflux is inconclusive....." The NICE noted "concern on the part of some specialists about the possibility that symptoms may improve as a result of denervation caused by the procedure; if that were the case then failure to recognize and treat reflux might lead to complications in the long term."

In 2023, NICE updated its guidance on endoluminal gastroplication for GERD, concluding that "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."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date (status)
Ongoing			
NCT04306380	Transoral Incisionless Fundoplication Database Repository (TIF)	500	Dec 2040
NCT05066594	Observational Registry of Transoral Incisionless Fundoplication (Creation of a New Gastroesophageal Valve) in Patients With Gastroesophageal Reflux Disease	100	May 2029
NCT03669874	Endoscopic Fundoplication With MUSE System	80	Sept 2026
NCT04795934	Multicenter Single-Blind RCT of CTIF Versus LNF For Treatment of GERD in Patients Requiring Hiatal Hernia Repair Combined With Transoral Incisionless Fundoplication Versus Laparoscopic Nissen Fundoplication for Treatment of Gastroesophageal Reflux Disease in Patients Requiring Hiatal Hernia Repair	142	Jan 2030
Unpublished			
NCT01118585 ^a	Prospective Outcome Evaluation of Transoral Incisionless Fundoplication (TIF) for the Treatment of Gastroesophageal Reflux Disease (GERD): The TIF Registry Study	278	Dec 2018 (completed)
NCT02366169 ^a	A Worldwide Post-Market Surveillance Registry to Assess the Medigus Ultrasonic Surgical Endostapler (MUSE ^{TM+}) System for the Treatment of GERD	200	Dec 2019 (unknown)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

References

1. Shaqran TM, Ismaeel MM, Alnuaman AA, et al. Epidemiology, Causes, and Management of Gastro-esophageal Reflux Disease: A Systematic Review. *Cureus*. Oct 2023; 15(10): e47420. PMID 38022211
2. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. *Am J Gastroenterol*. Mar 2013; 108(3): 308-28; quiz 329. PMID 23419381
3. van Pinxteren B, Sigterman KE, Bonis P, et al. Short-term treatment with proton pump inhibitors, H2-receptor antagonists and prokinetics for gastro-oesophageal reflux disease-like symptoms and endoscopy negative reflux disease. *Cochrane Database Syst Rev*. Nov 10 2010; (11): CD002095. PMID 21069670
4. Khan F, Maradey-Romero C, Ganocy S, et al. Utilisation of surgical fundoplication for patients with gastro-oesophageal reflux disease in the USA has declined rapidly between 2009 and 2013. *Aliment Pharmacol Ther*. Jun 2016; 43(11): 1124-31. PMID 27060607
5. Ihde GM. The evolution of TIF: transoral incisionless fundoplication. *Therap Adv Gastroenterol*. 2020; 13: 1756284820924206. PMID 32499834
6. Food and Drug Administration (FDA). 510(k) Summary: EsophyX (K160960). 2016; https://www.accessdata.fda.gov/cdrh_docs/pdf16/K160960.pdf.
7. Food and Drug Administration (FDA). EsophyX Summary K171307. 2017; https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171307.pdf.
8. Food and Drug Administration (FDA). EsophyX Summary K172811. 2017; https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172811.pdf.
9. Food and Drug Administration (FDA). 510(k) Summary: EsophyX Z+ (K240879). 2024; https://www.accessdata.fda.gov/cdrh_docs/pdf24/K240879.pdf.
10. Food and Drug Administration (FDA). 510(k) Summary: GERDX (K233240). 2024; www.accessdata.fda.gov/cdrh_docs/pdf23/K233240.pdf.
11. McCarty TR, Itidiare M, Njei B, et al. Efficacy of transoral incisionless fundoplication for refractory gastroesophageal reflux disease: a systematic review and meta-analysis. *Endoscopy*. Jul 2018; 50(7): 708-725. PMID 29625507
12. Richter JE, Kumar A, Lipka S, 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*. Apr 2018; 154(5): 1298-1308.e7. PMID 29305934
13. Testoni S, Hassan C, Mazzoleni G, et al. Long-term outcomes of transoral incisionless fundoplication for gastro-esophageal reflux disease: systematic-review and meta-analysis. *Endosc Int Open*. Feb 2021; 9(2): E239-E246. PMID 33553587
14. Rausa E, Ferrari D, Kelly ME, et al. Efficacy of laparoscopic Toupet fundoplication compared to endoscopic and surgical procedures for GERD treatment: a randomized trials network meta-analysis. *Langenbecks Arch Surg*. Jan 21 2023; 408(1): 52. PMID 36680602
15. Haseeb M, Brown JRG, Hayat U, et al. Impact of second-generation transoral incisionless fundoplication on atypical GERD symptoms: a systematic review and meta-analysis. *Gastrointest Endosc*. Mar 2023; 97(3): 394-406.e2. PMID 36402203

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

16. Hunter JG, Kahrilas PJ, Bell RC, et al. Efficacy of transoral fundoplication vs omeprazole for treatment of regurgitation in a randomized controlled trial. *Gastroenterology*. Feb 2015; 148(2): 324-333.e5. PMID 25448925
17. Trad KS, Barnes WE, Simoni G, et al. Transoral incisionless fundoplication effective in eliminating GERD symptoms in partial responders to proton pump inhibitor therapy at 6 months: the TEMPO Randomized Clinical Trial. *Surg Innov*. Feb 2015; 22(1): 26-40. PMID 24756976
18. Trad KS, Fox MA, Simoni G, et al. Transoral fundoplication offers durable symptom control for chronic GERD: 3-year report from the TEMPO randomized trial with a crossover arm. *Surg Endosc*. Jun 2017; 31(6): 2498-2508. PMID 27655380
19. Trad KS, Barnes WE, Prevou ER, et al. The TEMPO Trial at 5 Years: Transoral Fundoplication (TIF 2.0) Is Safe, Durable, and Cost-effective. *Surg Innov*. Apr 2018; 25(2): 149-157. PMID 29405886
20. Håkansson B, Montgomery M, Cadiere GB, et al. Randomised clinical trial: transoral incisionless fundoplication vs. sham intervention to control chronic GERD. *Aliment Pharmacol Ther*. Dec 2015; 42(11-12): 1261-70. PMID 26463242
21. Witteman BP, Conchillo JM, Rinsma NF, et al. Randomized controlled trial of transoral incisionless fundoplication vs. proton pump inhibitors for treatment of gastroesophageal reflux disease. *Am J Gastroenterol*. Apr 2015; 110(4): 531-42. PMID 25823768
22. Toomey P, Teta A, Patel K, et al. Transoral incisionless fundoplication: is it as safe and efficacious as a Nissen or Toupet fundoplication?. *Am Surg*. Sep 2014; 80(9): 860-7. PMID 25197871
23. Frazzoni M, Conigliaro R, Manta R, et al. Reflux parameters as modified by EsophyX or laparoscopic fundoplication in refractory GERD. *Aliment Pharmacol Ther*. Jul 2011; 34(1): 67-75. PMID 21539587
24. Bell RCW, Freeman K, Heidrick R, et al. Transoral incisionless fundoplication demonstrates durability at up to 9 years. *Therap Adv Gastroenterol*. 2021; 14: 17562848211004827. PMID 33948113
25. Canto MI, Diehl DL, Parker B, et al. Outcomes of transoral incisionless fundoplication (TIF 2.0): a prospective multicenter cohort study in academic and community gastroenterology and surgery practices (with video). *Gastrointest Endosc*. Jan 2025; 101(1): 90-102.e1. PMID 39293690
26. Kalapala R, Karyampudi A, Nabi Z, et al. Endoscopic full-thickness plication for the treatment of PPI-dependent GERD: results from a randomised, sham controlled trial. *Gut*. Apr 2022; 71(4): 686-694. PMID 33849942
27. Stefanidis G, Viazis N, Kotsikoros N, et al. Long-term benefit of transoral incisionless fundoplication using the esophyx device for the management of gastroesophageal reflux disease responsive to medical therapy. *Dis Esophagus*. Feb 01 2017; 30(3): 1-8. PMID 27868281
28. Testoni PA, Testoni S, Mazzoleni G, et al. Long-term efficacy of transoral incisionless fundoplication with Esophyx (Tif 2.0) and factors affecting outcomes in GERD patients followed for up to 6 years: a prospective single-center study. *Surg Endosc*. Sep 2015; 29(9): 2770-80. PMID 25480624
29. Testoni PA, Testoni S, Distefano G, et al. Transoral incisionless fundoplication with EsophyX for gastroesophageal reflux disease: clinical efficacy is maintained up to 10 years. *Endosc Int Open*. May 2019; 7(5): E647-E654. PMID 31058207

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

30. Testoni SGG, Cilona MB, Mazzoleni G, 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.* Jul 2022; 36(7): 5023-5031. PMID 34799745
31. Huang X, Chen S, Zhao H, et al. Efficacy of transoral incisionless fundoplication (TIF) for the treatment of GERD: a systematic review with meta-analysis. *Surg Endosc.* Mar 2017; 31(3): 1032-1044. PMID 27495332
32. Lipka S, Kumar A, Richter JE. No evidence for efficacy of radiofrequency ablation for treatment of gastroesophageal reflux disease: a systematic review and meta-analysis. *Clin Gastroenterol Hepatol.* Jun 2015; 13(6): 1058-67.e1. PMID 25459556
33. Arts J, Bisschops R, Blondeau K, et al. A double-blind sham-controlled study of the effect of radiofrequency energy on symptoms and distensibility of the gastro-esophageal junction in GERD. *Am J Gastroenterol.* Feb 2012; 107(2): 222-30. PMID 22108449
34. Aziz AM, El-Khayat HR, Sadek A, et al. A prospective randomized trial of sham, single-dose Stretta, and double-dose Stretta for the treatment of gastroesophageal reflux disease. *Surg Endosc.* Apr 2010; 24(4): 818-25. PMID 19730952
35. Corley DA, Katz P, Wo JM, et al. Improvement of gastroesophageal reflux symptoms after radiofrequency energy: a randomized, sham-controlled trial. *Gastroenterology.* Sep 2003; 125(3): 668-76. PMID 12949712
36. Coron E, Sebillé V, Cadiot G, et al. Clinical trial: Radiofrequency energy delivery in proton pump inhibitor-dependent gastro-oesophageal reflux disease patients. *Aliment Pharmacol Ther.* Nov 01 2008; 28(9): 1147-58. PMID 18616516
37. Fass R, Cahn F, Scotti DJ, 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.* Dec 2017; 31(12): 4865-4882. PMID 28233093
38. Xie P, Yan J, Ye L, et al. Efficacy of different endoscopic treatments in patients with gastroesophageal reflux disease: a systematic review and network meta-analysis. *Surg Endosc.* Apr 2021; 35(4): 1500-1510. PMID 33650003
39. Kalapala R, Shah H, Nabi Z, et al. Treatment of gastroesophageal reflux disease using radiofrequency ablation (Stretta procedure): An interim analysis of a randomized trial. *Indian J Gastroenterol.* Sep 2017; 36(5): 337-342. PMID 29030802
40. Zerbib F, Sacher-Huvelin S, Coron E, et al. Randomised clinical trial: oesophageal radiofrequency energy delivery versus sham for PPI-refractory heartburn. *Aliment Pharmacol Ther.* Aug 2020; 52(4): 637-645. PMID 32656869
41. Liang WT, Yan C, Wang ZG, et al. Early and Midterm Outcome After Laparoscopic Fundoplication and a Minimally Invasive Endoscopic Procedure in Patients with Gastroesophageal Reflux Disease: A Prospective Observational Study. *J Laparoendosc Adv Surg Tech A.* Aug 2015; 25(8): 657-61. PMID 26258269
42. Ma L, Li T, Liu G, et al. Stretta radiofrequency treatment vs Toupet fundoplication for gastroesophageal reflux disease: a comparative study. *BMC Gastroenterol.* May 27 2020; 20(1): 162. PMID 32460696
43. Liang WT, Wang ZG, Wang F, et al. Long-term outcomes of patients with refractory gastroesophageal reflux disease following a minimally invasive endoscopic procedure: a prospective observational study. *BMC Gastroenterol.* Oct 10 2014; 14: 178. PMID 25304252

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

44. Noar M, Squires P, Noar E, et al. Long-term maintenance effect of radiofrequency energy delivery for refractory GERD: a decade later. *Surg Endosc.* Aug 2014; 28(8): 2323-33. PMID 24562599
45. Ganz RA, Fallon E, Wittchow T, et al. A new injectable agent for the treatment of GERD: results of the Durasphere pilot trial. *Gastrointest Endosc.* Feb 2009; 69(2): 318-23. PMID 19185691
46. Feretis C, Benakis P, Dimopoulos C, et al. Endoscopic implantation of Plexiglas (PMMA) microspheres for the treatment of GERD. *Gastrointest Endosc.* Apr 2001; 53(4): 423-6. PMID 11275880
47. Katz PO, Dunbar KB, Schnoll-Sussman FH, et al. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol.* Jan 01 2022; 117(1): 27-56. PMID 34807007
48. Gawron AJ, Bell R, Abu Dayyeh BK, et al. Surgical and endoscopic management options for patients with GERD based on proton pump inhibitor symptom response: recommendations from an expert U.S. panel. *Gastrointest Endosc.* Jul 2020; 92(1): 78-87.e2. PMID 32007519
49. Yadlapati R, Gyawali CP, Pandolfino JE, et al. AGA Clinical Practice Update on the Personalized Approach to the Evaluation and Management of GERD: Expert Review. *Clin Gastroenterol Hepatol.* May 2022; 20(5): 984-994.e1. PMID 35123084
50. Desai M, Ruan W, Thosani NC, et al. American Society for Gastrointestinal Endoscopy guideline on the diagnosis and management of GERD: summary and recommendations. *Gastrointest Endosc.* Feb 2025; 101(2): 267-284. PMID 39692638
51. American Society of General Surgeons (ASGS). Coverage of Transoral fundoplication. 2011; <https://theasgs.org/wp-content/uploads/2016/05/Coverage-of-Transoral-Fundoplication.pdf>.
52. Slater BJ, Collings A, Dirks R, et al. Multi-society consensus conference and guideline on the treatment of gastroesophageal reflux disease (GERD). *Surg Endosc.* Feb 2023; 37(2): 781-806. PMID 36529851
53. National Institute for Health and Care Excellence (NICE). Endoscopic radiofrequency ablation for gastro-oesophageal reflux disease [IPG461]. 2013; <https://www.nice.org.uk/guidance/ipg461>.
54. National Institute for Health and Care Excellence (NICE). Endoluminal gastroplication for gastro-oesophageal reflux disease
Reference number:[IPG753]. 2023; <https://www.nice.org.uk/guidance/ipg753>.

Policy History

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

06/20/2002 Medical Policy Committee review.

06/24/2002 Managed Care Advisory Council approval.

04/01/2004 Medical Director review

04/20/2004 Medical Policy Committee review. Format revision. No substance change to policy.

04/26/2004 Managed Care Advisory Council approval

04/05/2006 Medical Director review

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

04/19/2006	Medical Policy Committee review. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
04/02/2008	Medical Director review
04/16/2008	Medical Policy Committee approval. No change to coverage eligibility.
04/02/2009	Medical Director review
04/15/2009	Medical Policy Committee approval. No change to coverage eligibility. Title changed.
04/08/2010	Medical Policy Committee approval
04/21/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/07/2011	Medical Policy Committee review
04/13/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/12/2012	Medical Policy Committee review
04/25/2012	Medical Policy Implementation Committee approval. Added NDO Plicator and EsophyX procedures as examples of transesophageal endoscopic gastroplasty. Investigational statements were combined on biocompatible polymer and PMMA beads as bulking agents.
04/04/2013	Medical Policy Committee review
04/24/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2014	Medical Policy Committee review
04/23/2014	Medical Policy Implementation Committee approval. Removed the second Investigational statement regarding transesophageal radiofrequency to create thermal lesions of the gastrointestinal junction (i.e., the Stretta procedure) as a treatment of GERD.
04/02/2015	Medical Policy Committee approval
04/20/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Updated rationale and references.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/01/2015	Coding update
01/01/2016	Coding update
04/07/2016	Medical Policy Committee approval
04/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
01/05/2017	Medical Policy Committee approval
01/18/2017	Medical Policy Implementation Committee approval. Removed transesophageal endoscopic gastroplasty from the policy and policy statements.
02/01/2018	Medical Policy Committee review
02/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

02/07/2019	Medical Policy Committee review
02/20/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2020	Medical Policy Committee review
02/12/2020	Medical Policy Implementation Committee approval. Removed biocompatible liquid polymer from the current investigational statement. Added two investigational statements for endoscopic GERD procedures for transoral incisionless fundoplication (TIF) using the Esophyx device and transesophageal radiofrequency using the Stretta device.
05/05/2020	Coding update
09/11/2020	Coding update
02/04/2021	Medical Policy Committee review
02/10/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/30/2021	Coding update
02/03/2022	Medical Policy Committee review
02/09/2022	Medical Policy Implementation Committee approval. MUSE added to the second investigational statement for clarification of transoral incisionless fundoplication as a treatment of gastroesophageal reflux disease. Coverage eligibility unchanged.
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/01/2024	Medical Policy Committee review
02/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2025	Medical Policy Committee review
02/12/2025	Medical Policy Implementation Committee approval. Added the GERDX device to the examples of transoral incisionless fundoplication investigational treatments for gastroesophageal reflux disease. Coverage eligibility unchanged.
02/05/2026	Medical Policy Committee review
02/11/2026	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 02/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	43192, 43201, 43210, 43236, 43257, 43499
HCPCS	No codes
ICD-10 Diagnosis	K21.00-K21.9, R12

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2026

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.