MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Transendoscopic Therapies for Gastroesophageal Reflux Disease (GERD)**
Policy Number	**7.01.45**
Category	**Technology Assessment**
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), 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 STATEMENT

I. Based upon our criteria and lack of the peer-reviewed literature, the following transendoscopic procedures have not been medically proven to be effective and, therefore, 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., Medigus Ultrasonic Surgical Endostapler [MUSE], EndoCinch, Syntheon ARD Plicator, GERDx-System),
   C. Transoral incisionless fundoplication (TIF) (e.g., MUSE, EsophyX),
   D. Injection/implantation of biocompatible bulking agents (e.g., submucosal implantation of plexiglas or polymethylmethacrylate [PMMA] beads, Durasphere).

Refer to Corporate Medical Policy #7.01.89 Magnetic Esophageal Ring/Magnetic Sphincter Augmentation for the Treatment of Gastroesophageal Reflux Disease (GERD)

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

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.

RATIONALE

Clinical trials and studies of transesophageal endoscopic therapies for the treatment of GERD continue to be conducted, which includes the application of radiofrequency energy, gastroplication, transoral incisionless fundoplication (TIF), and injection/implantation of prosthetic devices or bulking agents. Large-scale, long-term controlled studies of these transendoscopic techniques are needed to establish the safety and efficacy of these procedures.

Transesophageal Radiofrequency

The Stretta System received Section 510(k) premarket clearance from the 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.

Ma et al. (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 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.

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.

Endoluminal Gastroplication

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.

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. GERDx, Sew-Right Device, and the Syntheon ARD Plicator have not received FDA approval.

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 stated that "large, prospective trials with long-term follow-up are required to conclude the benefits of this procedure after 1 year."

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 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)

TIF can be performed with Medigus Ultrasonic Surgical Endostapler (MUSE), or EsophyX.

Rausa et al (2023) published a network meta-analysis of RCTs comparing TIF (n=188) to anterior partial fundoplication (n=322), laparoscopic Toupet fundoplication (n=1120), laparoscopic Nissen fundoplication(n=1740), and PPI therapy (N=80) in patients with recalcitrant GERD. The outcomes of interest were differences in the rate of heartburn, regurgitation, dysphagia, bloating, and PPI discontinuation. TIF did not differ significantly from the other treatments in the pooled network analysis for any outcome. Treatment failure was not included in the quantitative analysis due to the considerable heterogeneity across studies.

Testoni et al. (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.

Testoni et al. (2021) published a systematic review and meta-analysis focusing on long-term (≥3 years) outcomes of patients with GERD undergoing TIF (using either EsophyX or MUSE). Outcomes of interest included patient satisfaction, QOL, and PPI use. The mean follow-up time across studies was 5.3 years (range, 3 to 10 years). Daily PPI use was 100% in 5 studies, 97% in 1 study, and was not provided in the other 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.

Richter et al. (2018) performed a systematic review and network meta-analysis of randomized, controlled trials completed as of May 10, 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.

Esophageal Bulking Agents

GERDX-System, Durasphere, Plexiglas currently do not 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.

The evidence on the injection of bulking agents includes case series. 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 both subjective (e.g., GERD-HRQL scores) and objective (e.g., esophageal acid exposure) effects on health outcomes.

Professional Guidelines

In 2023, multi-society consensus guidance was published on the diagnosis and treatment of GERD (Slater et al., 2023). Recommendations for endoscopic or medical treatment of GERD include:

- 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).
- Adult patients with GERD may benefit from TIF 2.0 over continued PPI (conditional recommendation, moderate certainty of evidence).
- Adult patients with GERD may benefit from fundoplication over Stretta (conditional recommendation, very low certainty of evidence).
- Adult patients with GERD may benefit from Stretta over PPI. (conditional recommendation, low 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 et al., 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 GERD management recommendations (Katz et al., 2022):

- 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).
- 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).

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT codes

Code	Description
43192 **(E/I*)**	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance (*****E/I when used to report injection of a bulking agent or any other submucosal injection to treat GERD) *Excludes*: Injection of sclerosis esophageal varices: Flexible, transoral (43204); Rigid, transoral (43192, 43499)

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

HCPCS Codes

Code	Description
none	

ICD-10 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

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*Key Article

KEY WORDS

Transoral Incisionless Fundoplication (TIF)/Endoluminal fundoplication (ELF), Endocinch, Enteryx, EsophyX, Gastroplication, Gatekeeper, NDO Plicator System, Stretta, Medigus Ultrasonic Surgical Endostapler (MUSE).

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) (L35080), Select Minimally Invasive GERD Procedures, for the endoscopic (endoluminal) treatment of GERD. Please refer to the following LCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35080&ver=53&keyword=GERD&keywordType=starts&areaId=all&docType=F,P&contractOption=all&sortBy=relevance&bc=1] accessed 02/27/24.

There is currently a Local Coverage Determination (LCD) (L34540) for the Stretta procedure. Please refer to the following LCD website for Medicare Members:
[https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34540&ContrId=239&ContrVer=1&CntrctrSelected=239*1&Cntrctr=239&name=CGS+Administrators%2c+LLC+(15101%2c+MAC+-+Part+A)&DocType=2&LCntrctr=239*1&bc=AgACAACAAAAA&=] accessed 02/27/24.