



Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Policy # 00123

Original Effective Date: 06/24/2002

Current Effective Date: 03/01/2024

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.

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 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**.*

Based on review of available data, the Company considers transoral incisionless fundoplication (ie, EsophyX; MUSE) 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 (ie, Stretta procedure) 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

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for complications of GERD. The prevalence of GERD has been estimated to be 10% to 20% in the Western world, with a lower prevalence in Asia.

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.

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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 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 Gatekeeper™ 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.

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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. The most recent 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." FDA product code: ODE.

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.

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.

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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 federal 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, 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

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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 2 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. 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.

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

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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, Gastroesophageal Reflux Disease Health-Related Quality of Life [GERD-HRQL] 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

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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 Gastroenterological Association

In 2022, the American Gastroenterological Association issued a clinical practice update on the personalized approach to the evaluation and management of GERD.⁴² 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 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:

- 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 Society for Gastrointestinal Endoscopy

In 2015, the American Society for Gastrointestinal Endoscopy published guidelines on endoscopic procedures for GERD. In its review of the EsophyX and Stretta procedures, the Society noted some positive findings but discrepancies between subjective and objective outcome measures or a lack of

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objective outcome measures in reported trials, concluding that these techniques represent “potentially new therapeutic indications for GI endoscopy”, but that prospective trials using objective measures of GERD as the primary endpoint could be useful in defining the clinical role of these procedures.

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.”

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?

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- 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 2011, NICE issued guidance on endoluminal gastroplication for GERD, concluding that "The evidence on endoluminal gastroplication for gastroesophageal reflux disease raises no major safety concerns. Evidence from a number of RCTs [randomized controlled trials] shows a degree of efficacy in terms of reduced medication requirement in the short term, but changes in other efficacy outcomes are inconsistent, and there is no good evidence of sustained improvement in esophageal pH measurements...."

U.S. Preventive Services Task Force Recommendations

Not applicable.

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.

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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 2030
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	Dec 2026
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)

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NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Policy History

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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
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

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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.
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

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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.

Next Scheduled Review Date: 02/2025

Coding

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

Code Type	Code
CPT	43201, 43210, 43236, 43257, 43499 Add code effective 03/01/2024: 43192
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:

- 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
- 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:

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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.

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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.

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