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MEDICAL POLICY – 2.01.38

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

BCBSA Ref. Policy: 2.01.38

Effective Date:	Mar. 1, 2025
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Replaces:	N/A

RELATED MEDICAL POLICIES:

2.01.91	Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia and Gastroparesis
7.01.137	Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

Select a hyperlink below to be directed to that section.

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EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

GERD — gastroesophageal reflux disease — is a long-term medical condition. It's a digestive problem that affects the ring of muscles between the esophagus (the tube that carries swallowed food to the stomach) and the stomach. When food is swallowed, the muscles at the end of the esophagus open so food can pass into the stomach. The muscles then close to prevent acid and stomach contents from backing up into the esophagus. In GERD, however, the ring of muscles is too weak, and acid can leak back up into the esophagus. GERD is usually treated with changes to lifestyle and diet, or medications, or in some cases a surgery called fundoplication. A number of other treatments have been studied. These include a procedure that is done through the mouth that wraps the upper part of the stomach around the esophagus, the use of radiofrequency energy to try to improve the barrier between the stomach and the esophagus, and the placement of implants or fillers in the esophagus. These procedures are investigational (unproven). More studies are needed to determine if they are as effective as other standard treatments.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Transoral incisionless fundoplication (TIF)	**Transoral incisionless fundoplication (TIF) (e.g., Esophyx: MUSE, GERDX) is considered investigational as a treatment of gastroesophageal reflux disease.**
Transesophageal radiofrequency	**Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (i.e., Stretta procedure) is considered investigational as a treatment of gastroesophageal reflux disease.**
Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent	**Endoscopic submucosal implantation of a prosthesis (i.e., Gatekeeper Reflux Repair System) or injection of a bulking agent (e.g., polymethylmethacrylate beads [PMMA], zirconium oxide spheres [i.e., Durasphere]) is considered investigational as a treatment of gastroesophageal reflux disease.**

Coding

Code	Description
CPT	
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43257	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
43499	Unlisted procedure, esophagus

Related Information

N/A

Evidence Review

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.

Background

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 20% in the United States.[1]

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 individuals 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.[2] 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 H_2-receptor antagonists and prokinetics in both network meta-analyses and direct comparisons.[3]

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.[4] 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 individuals reporting symptom relief, complications can occur and sometimes require conversion to an open procedure. Individuals 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, TIF) 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.

Summary of Evidence

For individuals who have GERD and hiatal hernia of 2 cm or less that is not controlled by PPIs who receive TIF (e.g., EsophyX), the evidence includes two randomized controlled trials (RCTs) comparing TIF with PPI therapy, nonrandomized studies comparing TIF with fundoplication, and case series with longer term follow-up. The relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The highest quality RCT (RESPECT) was sham-controlled that 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 individuals. 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 when compared with PPI therapy. Together, these trial results would suggest a strong placebo effect of the surgery and a modest benefit of TIF in individuals whose symptoms were not controlled by PPIs. For these individuals, 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 with GERD and a hiatal hernia of 2 cm or less that is controlled by PPIs who receive TIF (e.g., EsophyX), the evidence includes two RCTs and observational studies with longer term follow-up. The relevant outcomes are symptoms, change in disease status, quality of life, 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 (e.g., perforation) may be severe. At present, the available evidence does not support the use of this intervention in individuals 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 (e.g., Stretta), the evidence includes two meta-analyses, six small RCTs, two nonrandomized comparative studies, and observational studies with longer term follow-up. The relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The RCTs reported some improvements in symptoms and quality of life following treatment with RF energy compared with sham controls. However, objective measures of GERD and a meta-analysis of four 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 and 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. The relevant outcomes are symptoms, change in disease status, quality of life, 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 (i.e., drug therapy, laparoscopic fundoplication). Well-designed trials should use standardized outcome measures to examine whether subjective improvement (e.g., discontinuation of medication therapy, GERD–HRQL scores) is supported by objective improvement (e.g., esophageal acid exposure). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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
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	Dec 2026
Unpublished			
NCT01118585[a]	Prospective Outcome Evaluation of Transoral Incisionless Fundoplication (TIF) for the Treatment of	278	Dec 2018 (completed)

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Gastroesophageal Reflux Disease (GERD): The TIF Registry Study		
NCT02366169[a]	A Worldwide Post-Market Surveillance Registry to Assess the Medigus Ultrasonic Surgical Endostapler (MUSE) System for the Treatment of GERD	200	Dec 2019 (unknown)

NCT: national clinical trial

[a] Denotes industry-sponsored or cosponsored trial.

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 one physician specialty society (two reviewers) and three academic medical centers while this policy was under review for 2015. Input was mixed on the treatment of GERD with transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (i.e., Stretta). Potential conflicts of interest were noted by two reviewers.

2011 Input

In response to requests for clinical input on TIF using EsophyX, input was received from two physician specialty societies and four 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 (i.e., EsophyX) to be investigational for the treatment of GERD.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the 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 Gastroenterological Association

In 2022, the American Gastroenterological Association issued a clinical practice update on the personalized approach to the evaluation and management of GERD.[47] 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[48]:

- 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 individuals 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.[49] 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 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 end point 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."[50]

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.[51] 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, the 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 …"[52] 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, the 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…"[53]

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

The EsophyX (EndoGastric Solutions) is a transesophageal TIF device that was originally cleared for marketing by the US Food and Drug Administration (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+).[5] 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 individuals with symptomatic chronic GERD.[6] In June 2017, EsophyX2 HD and the third-generation EsophyX Z Devices with SerosaFuse fasteners and accessories were cleared for marketing by FDA through the 510(k) process (K171307) for expanded indications, including individuals who require and respond to pharmacologic therapy and in individuals with hiatal hernias larger than 2 cm when a laparoscopic hiatal hernia repair reduces a hernia to 2 cm or less.[7] 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.[8] A 2024 FDA 510(k) clearance (K240879) updated instructions for use and other device labeling.[9,] 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 individuals 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.[10]. The manufacturer website includes a description for use in the 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. 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. FDA product code: GEI.

Durasphere is a bulking agent approved for treatment of urinary and fecal incontinence . 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 United States.

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History

Date	Comments
01/18/01	Add to Medicine Section - New Policy
01/08/02	Replace Policy - Updated with new references; policy statement expanded.
11/12/02	Replace Policy - Policy updated using 2002 TEC Assessment; policy statement unchanged.
05/13/03	Replace Policy - CPT codes updated.

Date	Comments
01/01/04	Replace Policy - CPT code updates only.
05/11/04	Replace Policy - Policy updated with reference to 2003 Assessment; policy statement amended to include ENTERYX procedure as investigational. New CPT code added. Title changed.
07/13/04	Replace Policy - Policy updated with literature search; references added; policy statement unchanged.
02/08/05	Replace Policy - Policy updated with new CPT category I code for Stretta added and category III code deletion; policy statement unchanged.
03/22/06	Code update - HCPCs code removed only, no other changes.
05/09/06	Replace Policy - Policy updated with literature and research; references added; policy statement enhanced
06/16/06	Update Scope and Disclaimer - No other changes.
09/12/06	Replace Policy - Policy updated with information on Plicator procedure, which was incorporated into the benefit statement as an additional investigational treatment; Rationale updated; references added; no actual change in policy statement.
10/9/07	Replace Policy - Policy updated with literature search through April 2007, policy statement unchanged. Another FDA-cleared device (StomaphyX) added to description. References added.
08/12/08	Replace Policy - Policy updated with literature search, no change to the policy statement. References and code added.
12/16/08	Code Update - 0133T deleted no other changes.
09/15/09	Replace Policy - Policy updated with literature search, no change to policy statement. References added.
01/12/10	Cross Reference Update - No other changes.
04/13/10	Minor update - No other changes.
10/12/10	Replace Policy - Policy updated with literature review, reference numbers 41-52 added. No change in policy statements.
10/11/11	Replace Policy – Policy updated with literature review through May 2011; Rationale section revised; policy statements on biocompatible polymer and PMMA beads combined as bulking agents; remains investigational.
02/14/12	Replace Policy – Clinical input reviewed; reference 3 added and references reordered; policy statements unchanged.
08/27/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
10/18/12	Update Related Policies – Add 7.01.137.

Date	Comments
01/29/13	Replace policy. Policy updated with literature review through September 2012; references 15, 19, 26 and 29 added and references reordered; policy statements unchanged. Add Related Policy 2.01.58.
08/15/13	Update Related Policies. Remove deleted policy 2.01.520 and add 2.01.20.
01/21/14	Replace policy. Policy updated with literature review through October 16, 2013; references added and reordered; policy statements unchanged. CPT coding updated; 43212 added to the policy and descriptors updated on others.ICD-9 diagnosis and ICD-10-CM codes removed; policy not adjudicated by diagnoses.
08/18/14	Update Related Policies. Remove 2.01.20 and 2.01.81 as they were archived.
12/03/14	Update Related Policies. Add 2.01.91.
04/24/15	Annual Review. Policy updated with literature review through October 8, 2014; clinical input reviewed; Rationale revised; references 8, 11, and 17 added and some references removed; NDO Plicator, EndoCinch, and Enteryx removed from policy because they are no longer available in the US. Remove ICD-9 and ICD-10 procedure codes; these are not utilized in policy adjudication.
12/16/15	Update Related Policies. Remove 2.01.58 as it is archived.
12/01/16	Annual Review, approved November 8, 2016. Policy updated with literature review through August 2016. References 5-11, 14,17,19,21,28,30 added. No change to policy statements.
01/01/17	Coding update. Added CPT code 43210, removed 43200, 43212, 43232, and 43266.
12/01/17	Annual Review, approved November 9, 2017. Policy updated with literature review through November 2017. Policy statement unchanged. Updated the Practice Guidelines and Position Statements section.
05/01/18	Annual Review, approved April 18, 2018. Policy updated with literature review through October 2017; new references added. Policy statements unchanged.
02/01/19	Annual Review, approved January 4, 2019. Policy updated with literature review through September 2018; references 10-11, 15, 23, and 30 added; references 42-43 updated. Policy statements unchanged.
02/01/20	Annual Review, approved January 9, 2020. Policy updated with literature review through October 2019; references added. Policy statements unchanged.
07/02/20	Coding update. CPT code 43266 removed.
07/14/20	Coding update. CPT code 43236 removed from policy. This applies to other criteria set.
11/01/20	Coding update. Added CPT 43266 and 43236. Related Policy 2.01.55 Sinus Surgery added.
03/01/21	Annual Review, approved February 2, 2021. Policy updated with literature review through October 20, 2020; references added. Policy statements unchanged.

Date	Comments
03/01/22	Annual Review, approved February 7, 2022. Policy updated with literature review through November 3, 2021; references added. MUSE added for clarification, intent unchanged. Policy statements unchanged.
09/01/22	Coding update. Removed CPT code 43266.
03/01/23	Annual Review, approved February 6, 2023. Policy updated with literature review though October 20, 2022; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
03/01/24	Annual Review, approved February 12, 2024. Policy updated with literature review though October 18, 2023; references added. Policy statements unchanged. Updated Related Policy 2.01.91 – title changed from "Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia" to "Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia and Gastroparesis".
03/01/25	Annual Review, approved February 10, 2025. Policy updated with literature review though October 18, 2024; references added. Added GERDX to the examples noted in the policy statement: "Transoral incisionless fundoplication (e.g., EsophyX, MUSE, GERDX) is considered investigational as a treatment of gastroesophageal reflux disease." Policy intent unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.