

## Corporate Medical Policy

# Gastroesophageal Reflux Disease, Transendoscopic Therapies

**File Name:** gastroesophageal\_reflux\_disease\_transendoscopic\_therapies

**Origination:** 5/2001

**Last Review:** 11/2022

### **Description of Procedure or Service**

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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 (RF) energy, and injection/implantation of prosthetic devices or bulking agents.

Due in part to the prevalence of gastroesophageal reflux disease (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 (NOTES). Three types of procedures have been investigated:

- 1.) Transesophageal endoscopic gastroplication (gastroplication, transoral incisionless fundoplication [TIF]) is 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 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 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.

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) utilizes a soft, pliable, expandable prosthesis made of a polyacrylonitrile-based hydrogel. The prosthesis is implanted into the esophageal submucosa and with time the prosthesis absorbs water and expands, 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.

### **REGULATORY STATUS**

EsophyX® (EndoGastric Solutions), a TIF device, received 510(k) marketing clearance in 2007 for full-thickness plication. In 2016, EsophyX® Z Device with SerosaFuse Fasteners was cleared for marketing (K160960) by the FDA through the 510(k) process for use in transoral tissue approximation, full thickness plication, ligation in the gastrointestinal tract, narrowing the gastroesophageal junction,

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and reduction of hiatal hernia of 2 cm or less in patients with symptomatic chronic gastroesophageal reflux disease (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 in patients with hiatal hernias larger than 2cm when a laparoscopic hiatal hernia repair reduces a hernia to 2cm or less. The most recent FDA 510(k) clearance (K172811) occurred in 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.

The Medigus SRS Endoscopic Stapling System (MUSE, Medigus) received marketing clearance by the FDA in 2012 and 2014. MUSE is intended for endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach to create anterior partial funduplication for treatment of symptomatic chronic GERD in patients who require and respond to pharmacologic therapy.

The CSM Stretta ® System received 510(k) marketing clearance from the FDA in 2000 for general use in the electrosurgical coagulation of tissue and intended for use specifically in the treatment of GERD. Mederi Therapeutics began manufacturing the Stretta® device. Mederi was acquired by Respiratory Technology Corporation in 2018.

Durasphere® is a bulking agent approved for treatment of urinary and fecal incontinence (see policy titled “Injectable Bulking Agents for the 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 Durasphere® GR is an investigational device in the U.S. “intended to treat problems associated with GERD.”

## **Related Policies**

Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease (GERD)

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

*\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

## **Policy**

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**Transendoscopic Therapies for Gastroesophageal Reflux Disease are considered investigational. BCBSNC does not provide coverage for investigational services or procedures.**

## **Benefits Application**

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## **When transendoscopic therapies for gastroesophageal reflux disease are covered**

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Not applicable.

## **When transendoscopic therapies for gastroesophageal reflux disease are not covered**

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Transoral incisionless fundoplication (TIF) (i.e., Esophyx®) is considered investigational as a treatment of gastroesophageal reflux disease.

Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (i.e., the Stretta procedure) is considered investigational as a treatment of gastroesophageal reflux disease.

Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., polymethylmethacrylate beads, zirconium oxide spheres) is considered investigational as a treatment of gastroesophageal reflux disease.

## Policy Guidelines

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The evidence for individuals who have GERD and a hiatal hernia of 2 cm or less and receive TIF (eg. EsophyX) that is not controlled by proton pump inhibitors (PPIs) 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, medication use, and treatment-related morbidity. The highest quality RCT (RESPECT) was sham-controlled that compared TIF together with PPI therapy while the second 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, but the sham-controlled trial found only a 45% improvement of the group and no benefit on secondary subjective outcome measures. The nonblinded RCT found significant improvements in subjective measures, however, there was no difference in objective outcome measures when compared with PPI therapy. Together, these trials suggest a strong placebo effect of the surgery and a modest benefit of TIF in patients whose symptoms are not controlled by PPI therapy. For these patients, the most appropriate comparator is laparoscopic fundoplication. Studies comparing TIF with fundoplication have limitations that include earlier TIF procedures and unequal groups at baseline and are inadequate to determine relative efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence on transesophageal incisionless fundoplication (TIF) in individuals who have gastroesophageal reflux disease (GERD) and hiatal hernia of 2cm or less that is controlled by proton pump inhibitors (PPIs) includes 2 RCTs and observational studies with longer term follow-up. 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. These results indicate a possible placebo effect for the procedure. In addition, observational studies indicate a loss of treatment effectiveness over time. Adverse events associated with the procedure (eg, perforation) may be severe. Currently, 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 the effects of the technology on health outcomes.

The evidence on endoscopic radiofrequency (RF) energy, (eg, Stretta) in patients who have GERD includes 2 meta-analyses, 6 small RCTs, 2 nonrandomized comparative studies, and observational studies with longer term follow-up. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The RCTs report 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 these studies found no significant improvement in outcomes, therefore the mechanism of symptom relief is uncertain, although symptom relief may be lower than after fundoplication, and reoperations greater. Larger RCTs with longer follow-up are needed to better define the risks and benefits of this procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

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The evidence on esophageal bulking agents in individuals who have GERD is limited to 1 RCT and case series. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The RCT for a single product was terminated early due to lack of efficacy, while other products have only case series to support use. 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–Health-Related Quality of Life scores) is supported by objective improvement (eg, esophageal acid exposure). The evidence is insufficient to determine the effects of the technology on health outcomes.

## **Billing/Coding/Physician Documentation Information**

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 43201, 43210, 43212, 43236, 43257, 43266, 43499, 43659*

*Endoscopic submucosal injection of a bulking agent would most likely be coded using 43201 or 43236. Endoscopic implantation of a prosthesis would most likely be coded using 43212, 43266, or 43499.*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## **Scientific Background and Reference Sources**

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- BCBSA Medical Policy Reference Manual, 12/15/00; 2.01.38
- BCBSA Medical Policy Reference Manual, 11/20/01; 2.01.38
- Specialty Matched Consultant Advisory Panel, 6/2002
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7/17/03, 2.01.38.
- BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.38, 12/17/03.
- Specialty Matched Consultant Advisory Panel - 5/2004
- ECRI. (2003, June) The stretta procedure for gastroesophageal reflux disease (gerd) (Issue No.95). Windows on Medical Technology.
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- BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.38, 4/1/2005
- DeVault KR, Castel DO. (2005) Updated guidelines for the diagnosis and treatment of gastroesophageal reflux disease. *American Journal of Gastroenterology*. 100:190-200.
- U.S Food and Drug Administration. (2005, October). FDA preliminary public health notification \*: Recall of Boston Scientific ENTERYX procedure kits and ENTERYX injector single packs for

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BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.38, 6.14.07

Specialty Matched Consultant Advisory Panel - 4/2008

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National Institute for Clinical Excellence (NICE). Endoscopic radiofrequency ablation for gastroesophageal reflux disease. Interventional procedure guidance 292. London, UK: NICE; March 2009

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.38, 7/9/09

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.38, 8/11/2011

Medical Director review – 10/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.38, 11/10/2011

Specialty Matched Consultant Advisory Panel – 10/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.38, 11/8/2012

Specialty Matched Consultant Advisory Panel – 10/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.38, 11/14/2013

Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. *Am J Gastroenterol* 2013; 108:308–328. Corrigendum. *Am J Gastroenterol* 2013; 108(10):1672. Available online at: <http://gi.org/guideline/diagnosis-and-managemen-of-gastroesophageal-reflux-disease/>. Last accessed January, 2014.

Society of American Gastrointestinal and Endoscopic Surgeons. Endoluminal treatments for gastroesophageal reflux disease (GERD). 2013. Available online at: <http://www.sages.org/publications/guidelines/endoluminal-treatments-for-gastroesophageal-reflux-disease-gerd/>. Last accessed January, 2014.

American Gastroenterological Association. Medical position statement on the management of gastroesophageal reflux disease. Available online at: <http://www.gastrojournal.org/article/PIIS0016508597701689/related>. Last accessed January, 2014.

Specialty Matched Consultant Advisory Panel – 11/2014

Senior Medical Director review-- 12/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.38, 2/12/15

Medical Director review -3/2015

Specialty Matched Consultant Advisory Panel 11/2015

Medical Director review 11/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.38, 11/12/15

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.38, 10/2016

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Specialty Matched Consultant Advisory Panel 11/2017

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BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.38, 11/2018

Specialty Matched Consultant Advisory Panel 11/2019

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Specialty Matched Consultant Advisory Panel 11/2020

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BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.38, 1/2021

Specialty Matched Consultant Advisory Panel 11/2021

Medical Director review 11/2021

Specialty Matched Consultant Advisory Panel 11/2022

Medical Director review 11/2022

## Policy Implementation/Update Information

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5/01	Original policy issued. Coding format change.
1/02	Policy revised under what is not covered section. Investigational indications reworded for clarity and a new investigational indication added.
6/02	Specialty Matched Consultant Advisory Panel. No changes. Approve.
1/04	Information added regarding the Enteryx procedure. Additional information added in the Description section of the policy. Formatted for consistency. Code 0008T added to policy.
6/10/04	Specialty Matched Consultant Advisory Panel review. Coding updated. Added codes 43201 and 0057T, removed 43499. No change to criteria. References added. Notification given 6/10/2004. Effective date 8/12/2004.
10/14/04	Code S2215 added to the Billing/Coding section.
12/23/04	Code 43257 added to Billing/Coding section of policy.
6/16/05	Rationale added to "Policy Guidelines" section. 43200 and 0057T removed from "Billing/Coding" section of policy. References added.
12/1/05	Information added regarding Boston Scientific/FDA recall of Enteryx in the "Description of Service or Procedure".

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- 1/19/06 Added new 2006 CPT code 0133T to "Billing/Coding" section. Deleted HCPCS code S2215 from "Billing/Coding" section
- 5/22/06 Specialty Matched Consultant Advisory Panel review 4/20/2006. No changes to criteria. Removed information in "Policy Guidelines" section related to Enteryx. "Endoscopic Plication System, Gatekeeper Reflux Repair System, SUR6355" added to "Key Words" section. References added.
- 1/3/07 Deleted HCPCS code 0008T from "Billing/Coding" section.
- 7/16/07 Deleted HCPCS code 0133T from "Billing/Coding" section.
- 6/16/08 Specialty Matched Consultant Advisory Panel review 4/30/08. Added additional information to "Description" section; "StomaphyX and the EsophyX were cleared by the FDA 510(k) process in 2007, which indicates they are equivalent to the EndoCinch." No change to policy statement. References added. (btw)
- 6/22/10 Policy Number(s) removed (amw)
- 11/23/10 Description section revised and updated. Policy statement and medical criteria unchanged. Specialty Matched Consultant Advisory Panel review 10/28/10. Policy accepted as written. (adn)
- 11/8/11 Description section updated. *When It Is Not Covered* section was revised to read: "Transesophageal endoscopic gastroplasty is considered investigational as a treatment of gastroesophageal reflux disease (e.g., the EndoCinch™, NDO Plicator™, or EsophyX™ procedures). Transesophageal radiofrequency to create submucosal thermal lesion of the gastroesophageal junction (i.e., the Stretta procedure) is considered investigational as a treatment of gastroesophageal reflux disease. Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., biocompatible liquid polymer, polymethylmethacrylate beads, zirconium oxide spheres) is considered investigational as a treatment of gastroesophageal reflux disease." Rationale updated in the Policy Guidelines section. (adn)
- 10/30/12 Added CPT code 43219 to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 10/17/12. No change to policy statement. (sk)
- 1/15/13 Reference added. Information on transesophageal (or transoral) incisionless fundoplication added to Description section. Related Policies and Related Guideline added. Coding section updated. No change to policy statement. Medical Director review. (sk)
- 12/31/13 Coding update. CPT code 43219 removed from Billing/Coding section. (sk)
- 1/28/14 References added. CPT codes 43212, 43236, and 43266 added to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 10/16/13. No change to policy statement. (sk)
- 1/13/15 References updated. Specialty Matched Consultant Advisory Panel review 11/2014. Senior Medical Director review 12/2014. No change to policy intent. (td)
- 4/28/15 Description Section extensively revised-Regulatory Status section added. When Not Covered section revised to include transoral incisionless fundoplication. Billing/Coding section revised to include codes: 43499, 43659. Policy Guidelines section updated. References updated. Medical Director review 3/2015. (td)
- 10/1/15 Billing/Coding section updated to include C9743 effective October 1, 2015. (td)
- 12/30/15 Billing/Coding section updated to include code 43210; effective 1/1/16. References updated. Specialty Matched Consultant Advisory Panel review 11/18/2015. Medical Director review 11/2015. (td)

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- 1/26/16 Description section updated. Policy Guidelines extensively revised. Policy Statement remains unchanged. References updated. (td)
- 12/30/16 Regulatory status section updated. Specialty Matched Consultant Advisory Panel review 11/2016. Medical Director review 11/2016. (jd)
- 12/15/17 References updated. Specialty Matched Consultant Advisory Panel 11/2017. Medical Director review 11/2017. (jd)
- 1/12/18 Regulatory Status and Policy Guidelines updated. No change to policy intent. References updated. Medical Director review 12/2017. (jd)
- 12/14/18 Minor revisions to regulatory status and related policies. References updated. Specialty Matched Consultant Advisory Panel 11/2018. Medical Director review 11/2018. (jd)
- 2/11/20 References updated. Specialty Matched Consultant Advisory Panel 11/2019. Medical Director review 12/2019. (jd)
- 12/8/20 Specialty Matched Consultant Advisory Panel 11/2020. Medical Director review 12/2020. (jd)
- 11/30/21 Minor revisions and updates to Description section and Policy Guidelines. No change to policy intent. References updated. Specialty Matched Consultant Advisory Panel 11/2021. Medical Director review 11/2021. (jd)
- 11/29/22 Minor revisions and updates to Description section. Billing/Coding and References sections updated. No change to policy statement. Specialty Matched Consultant Advisory Panel 11/2022. Medical Director review 11/2022. (tm)

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