

## Corporate Medical Policy

### Gastroesophageal Reflux Disease, Transendoscopic Therapies

**File Name:** gastroesophageal\_reflux\_disease\_transendoscopic\_therapies  
**Origination:** 5/2001  
**Last CAP Review:** 10/2011  
**Next CAP Review:** 10/2012  
**Last Review:** 10/2011

#### 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 devices for fundoplication, application of radiofrequency 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. The following four different procedures have been investigated:

- 1.) Transesophageal endoscopic gastroplasty or gastroplication is an outpatient procedure. During this procedure, sutures(s) are placed in the lower esophageal sphincter. The sutures are designed to strengthen and lengthen the sphincter to decrease reflux.

Currently, three endoscopic suturing devices have received FDA 510(k) marketing clearance for use in the treatment of GERD:

- EndoCinch™ (CR Bard, Murray Hill, NJ) is a suture technique for partial-thickness plication, approved January 2001
  - NDO Plicator™ (Ethicon Endo-Surgery, Chicago, IL) for full-thickness plication, approved May 2003
  - EsophyX® (EndoGastric Solutions, Redmond, WA) for full-thickness plication, approved September 2007
- 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. The CSM Stretta® system [Conway Stuart] 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. Stretta® is currently manufactured by Mederi Therapeutics, Greenwich, CT.) 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.
  - 3.) Submucosal injection or implantation of a prosthetic or bulking agent to enhance the volume of the lower esophageal sphincter. On contact with the tissue, the polymer precipitates into a spongy mass. The mechanism of action in reducing gastroesophageal reflux is not precisely known. One polymer, Enteryx™, received FDA approval in 2003 through the premarket approval (PMA) process for the treatment of symptomatic gastroesophageal reflux disease. However, on

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September 23, 2005, Boston Scientific Corporation issued a recall of Enteryx due to the device polymerizing shortly after injection into a spongy material that cannot be removed. Serious adverse events involved unrecognized transmural injections of Enteryx into structures surrounding the esophagus, potentially resulting in serious injury or death.

Another bulking agent, pyrolytic carbon-coated zirconium oxide spheres (Durasphere®), is being evaluated. Durasphere® is a bulking agent approved for treatment of urinary and fecal incontinence (see policy number 7.01.19). 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.”

The Gatekeeper Reflux Repair System (Medtronic, Shoreview, MN) 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.

Endoscopic submucosal implantation of polymethylmethacrylate beads into the lower esophageal folds has also been investigated.

***\*\*\*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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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 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.

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## Policy Guidelines

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There is insufficient evidence at present to establish the safety and efficacy of these procedures, particularly in the long term. Some of the unresolved issues include questions about the safety and durability of the device/treatment, and lack of consistent improvement in objective measures (esophageal acid exposure) using these devices. A number of these devices (e.g., EndoCinch™, NDO Plicator™, Gatekeeper, Enteryx™) are no longer marketed or actively evaluated due to lack of efficacy and/or safety issues. For procedures that are still in development, high-quality data from large randomized controlled trials are needed to compare endoscopic procedures with both sham controls and with the currently accepted treatments for GERD, namely drug therapy and laparoscopic fundoplication. Well-designed trials should use standardized outcome measures to examine whether subjective improvement, such as discontinuation of medication therapy and GERD-HRQL scores, is supported by objective improvement, such as esophageal acid exposure. Until such studies demonstrate improved net health outcomes for patients with GERD, the policy statements are unchanged. These techniques are considered investigational.

## 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, 43257*

*There is no specific code for transesophageal endoscopic gastroplasty. Endoscopic submucosal injection of a bulking agent would most likely be coded 43201.*

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.

ECRI. (2003) Endoscopic liquid polymer implantation (enteryx) for gastroesophageal reflux disease (gerd). TARGET database. Retrieved on 5/6/2004 from [http://www.ecri.org/summary/detail.aspx?doc\\_id=1762&q=enteryx&anm=wynneb](http://www.ecri.org/summary/detail.aspx?doc_id=1762&q=enteryx&anm=wynneb).

BCBSA Technology Evaluation Center. (2004, February). Transesophageal endoscopic treatments for gastroesophageal reflux disease. Retrieved 5/18/2005 from [http://www.bcbsa.com/tec/vol18/18\\_20.html](http://www.bcbsa.com/tec/vol18/18_20.html).

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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 treatment of gastroesophageal reflux disease (GERD). Retrieved 11/9/2005 from <http://www.fda.gov/cdrh/safety/101405-enteryx.html>.

Specialty Matched Consultant Advisory Panel - 4/2006

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

Specialty Matched Consultant Advisory Panel - 4/2008

American Gastroenterological Association. Medical position statement on the management of gastroesophageal reflux disease. Available at [www.gastro.org/wmspage.cfm?parm1=4453](http://www.gastro.org/wmspage.cfm?parm1=4453).

National Institute for Clinical Excellence (NICE). Endoscopic radiofrequency ablation for gastro-oesophageal 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

## 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".  |
| 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.  |

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- 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)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.