

Medical Coverage Policy



Transesophageal Endoscopic Treatments for Gastroesophageal Reflux Disease

Device/Equipment Drug Medical Surgery Test Other

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| Effective Date: | 4/6/2006 | Policy Last Updated: | 9/18/2012 |
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Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

Note: This policy does not pertain to Barrett's Esophagus which is covered.

Description:

Due 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. Listed below are several transesophageal endoscopic therapies:

Endoscopic gastroplication, or gastroplasty, is an outpatient procedure that takes about one half-hour and does not require general anesthesia. Sutures are placed in the lower esophageal sphincter that are designed to strengthen and lengthen the sphincter in order to decrease reflux. The Endocinch (CR Bard) device has been approved by the FDA for use in endoscopic suturing, and has been investigated as a device used in endoscopic gastroplasty. The StomaphyX™ (equivalent to EndoCinch) device, has been granted FDA approval. Minimal data are available regarding transesophageal suturing published in peer-reviewed journals.

Endoscopic radiofrequency ablation, also known as the Stretta™ procedure, is a transesophageal procedure in which radiofrequency thermal lesions are created in the lower esophageal sphincter. Subsequent scarring is designed to similarly strengthen and lengthen the sphincter. Both the endoluminal gastroplication and the Stretta procedure approach the esophagus from its interior mucosal surface as opposed to the traditional Nissen procedures that approach the esophagus from the exterior or serosal surface.

Endoscopic implantation of inert polymers, known as Enteryx™, is a permanently implanted device made up of a polymer and solvent solution that is implanted by injection into the wall of the lower esophagus. The device is intended to help keep gastric acid from backing up into the lower esophagus by strengthening the muscle that separates the lower esophagus from the stomach.

Endoscopic submucosal implantation of polymethylmethacrylate (PMMA) beads in the low esophageal folds has also been investigated.

The Cook Endoscopy Duette Multi-Bank Mucosectomy Device is used for endoscopic mucosal resection in the upper GI track. Using suction and banding to create esophageal mucosal "pseudopolyps", the pseudopolyps are then removed in a procedure similar to a standard polypectomy. Resecting multiple pseudopolyps allow the physician to perform an endoscopic mucosal resection.

Future comparative studies with predetermined clinically significant end points, validated outcome measures, prolonged follow-up, and complete complication registries will eventually determine the precise role of endoscopic procedures for the patients with GERD.

Medical Criteria:

Not applicable.

Policy:

Transesophageal endoscopic gastroplasty (i.e., Endocinch and the StomaphyX™ devices) and radiofrequency ablation (i.e., Stretta™ procedure), submucosal implantation of polymethylmethacrylate (PMMA) beads, and the Cook Endoscopy Duette Multi-Bank Mucosectomy device are considered **not medically necessary** for the treatment of gastroesophageal reflux disease as there is minimal literature to validate health outcomes of these procedures. The efficacy and safety of these procedures over medical or surgical therapy have not been assessed.

Implantation of inert polymers (Enteryx™) is considered a **contract exclusion** as the FDA has withdrawn its approval following serious complications.

Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for the applicable services that are "Not Medically Necessary" and contract exclusions.

Coding and Reimbursement:

The following CPT Code for the endoscopic radiofrequency ablation is not medically necessary:

43257

The following unlisted code should be used as there are no specific CPT codes for all other procedures:

43499

Also known as:

GERD treatment
Stretta procedure
Endoluminal gastropliation
Endoluminal gastroplasty
Bard Endocinch
Enteryx
PMMA

Related Topics:

None

Published:

Policy Update, September 2001
Policy Update, September, 2004
Policy Update, June 2006
Provider Update, July 2008
Provider Update, September 2009
Provider Update, February 2011
Provider Update, January 2012
Provider Update, November 2013

References:

American College of Gastroenterology. Gastroesophageal Reflux Disease (GERD). Retrieved: <http://www.acg.gi.org/patients/gihealth/grdtrtmnt.asp>.

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Blue Cross and Blue Shield Association TEC Assessment: Vol.18. No.20, February 2004:Transesophageal Endoscopic Treatments for Gastroesophageal Reflux Disease. Retrieved: http://blueweb.bcbs.com/global_assets/special_content/tec_assessments/vol18/18_20.pdf.

Blue Cross and Blue Shield Association Medical Policy Reference Manual #2.01.38. Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease. Retrieved: http://blueweb.bcbs.com/global_assets/special_content/medical_policy/policymanual/policy.html?pnum=20138.

Bonavina L, DeMeester T, Fockens P, et al. Laparoscopic sphincter augmentation device eliminates reflux symptoms and normalizes esophageal acid exposure: One- and 2-year results of a feasibility trial. *Ann Surg*. 2010;252(5):857-862.

Cook Medical. Duette™ Multi-Band Mucosectomy. Retrieved: <http://www.cookmedical.com/esc/resources.do?id=4439>.

Feretic C, et al. *Gastrointest Endosc*. 2001 Apr;53(4):541-5. Endoscopic implantation of Plexiglas (PMMA) microspheres for the treatment of GERD. <http://www.ncbi.nlm.nih.gov/pubmed/11275880>.

Ip S, Bonis P, Tatsoni A, et al. Comparative Effectiveness of Management Strategies for Gastroesophageal Reflux Disease. Evidence Report/Technology Assessment No. 1 (Prepared by Tufts-New England Medical Center Evidence-based Practice Center) Rockville, MD. Agency for Healthcare Research and Quality. AHRQ Publication No. 06-EHC003-EF;December 2005.

Noar MD, Lotfi-Emran S. Sustained improvement in symptoms of GERD and antisecretory drug use: 4-year follow-up of the Stretta procedure. *Gastrointestinal Endoscopy*;2007;65(3):367-372.

Repici A, Fumagalli U, Malesci A, et al. Endoluminal fundoplication (ELF) for GERD using EsophyX: a 12-month follow-up in a single-center experience. *Journal of Gastrointestinal Surgery*;2010 Jan;14(1):1-6.

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