MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**TRANSENDOSCOPIC THERAPIES FOR GASTROESOPHAGEAL REFLUX DISEASE (GERD)**
Policy Number	**7.01.45**
Category	**Technology Assessment**
Effective Date	**10/18/01**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT

I. Based upon our criteria and lack of peer-reviewed literature, *transesophageal radiofrequency* applications to the gastroesophageal junction (e.g., Stretta procedure) as a treatment of GERD has not been medically proven to be effective and is therefore considered **investigational**.

II. Based upon our criteria and lack of peer-reviewed literature, *endoscopic gastroplasty/gastroplication* (e.g., EndoCinch, Sew- Right, Plicator™ System, Syntheon ARD Plicator) as a treatment of GERD has not been medically proven to be effective and is therefore considered **investigational**.

III. Based upon our criteria and lack of peer-reviewed literature, *endoluminal fundoplication* (e.g., ELF, EsophyX™) or *transoral incisionless fundoplication* (TIF) as a treatment of GERD has not been medically proven to be effective and is therefore considered **investigational**.

IV. Based upon our criteria and lack of peer-reviewed literature, injection/implantation of biocompatible material (e.g., endoscopic submucosal implantation of Plexiglas beads, Durasphere®, Enteryx or use of the Gatekeeper System) as a treatment of GERD has not been medically proven to be effective and is therefore considered **investigational**.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

Refer to Corporate Medical Policy #7.01.89 regarding Magnetic Esophageal Ring/Magnetic Sphincter Augmentation for the Treatment of Gastroesophageal Reflux Disease (GERD).

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

GERD is defined as symptoms (e.g., heartburn, regurgitation, pain, and dysphagia) and/or tissue damage that results from the abnormal reflux of gastric contents into the esophagus and can significantly affect the quality of patients' lives. Initial treatment of GERD is geared toward reducing esophageal refluxes via medical therapies (dietary and life style modifications, medications). When standard medical therapies fail, surgery may be considered. The quest for minimally invasive surgical techniques has led to the development of transendoscopic treatments for GERD. Endoscopic therapies

can be classified into 3 categories: thermal methods, endoscopic suturing/stapling and injection of implants made up of inert biocompatible material.

The *Stretta* procedure utilizes an endoscope and radiofrequency ablation to create thermal lesions in the submucosa of the gastroesophageal junction. Reduction in reflux is reported to occur due to heat-induced collagen retraction, delayed thermal resorption due to wound healing and afferent nerve pathway disruption at the gastroesophageal junction.

Endoscopic gastroplasty or *gastroplication* involves the suturing of the lower esophageal sphincter to strengthen and lengthen the sphincter in order to reduce reflux. Examples of gastroplication devices include the EndoCinch Suturing Device, the Sew-Right Device®, the Syntheon ARD Plicator and the NDO Plicator ™ System.

Another method of endoscopic treatment for GERD is the injection of inert, biocompatible material at or above the cardia. Polymethylmethacrylate (PMMA) or Plexiglas microspheres are injected into the lower esophageal folds. These microspheres, or beads, implant in the submucosa to augment the bulking of tissues and reduce reflux and symptoms of GERD. The Gatekeeper System uses the injection of a hydrogel prosthesis that, once expanded, allows augmentation of the lower esophageal sphincter (LES) by forming a soft pliable lower-esophageal sphincter barrier. Enteryx, a polymer in the form of an injectable solution of ethylene vinyl alcohol that when injected into the LES solidifies into a spongy mass that forms a ring to reduce reflux, is no longer commercially available as treatment for GERD (see rationale statement). Pyrolytic carbon-coated beads (Durasphere®), FDA approved as a submucosal urethral bulking agent, are being investigated in the treatment of mild-moderate GERD due to their success in the treatment of urinary incontinence due to intrinsic bladder deficiency. The beads are injected endoscopically in the region of the gastroesophageal junction (GEJ) with the intent to close/tighten the GEJ lumen .

Endoluminal fundoplication (ELF) is designed to restore the antireflux barrier by recreating the valve at the gastroesophageal junction. The fundoplication device is passed transorally under direct visualization by an endoscope. A proprietary esophageal invaginator incorporated into the device is used to engage the distal esophagus at the level of the Z-line to reduce the hiatal hernia, if present. Gastric tissue from the fundus is then drawn between the body of the device and the tissue mold used to shape each portion of the gastroesophageal valve. Finally, several polypropylene fasteners are delivered across the mold tissue to create a 3-5 cm long serosa-to-serosa flap.

RATIONALE

The Bard Endocinch Suturing System received 510(k) premarket clearance from the FDA on March 20, 2000. The Stretta System received 510(k) premarket clearance from the FDA on April 18, 2000. Enteryx received FDA clearance on April 22, 2003 for the treatment of patients with GERD who require and respond to proton pump inhibitors (PPIs). In October 2005, in a joint decision by the FDA and Boston Scientific, a voluntary recall was initiated of all Enteryx Procedure Kits and injector products from commercial distribution. This action was initiated by Boston Scientific based upon growing data of serious adverse effects that occurred related to the incorrect transmural injection of the product into vital organs that went unrecognized at the time of the procedure. On April 29, 2003 NDO Surgical announced that it had received clearance from the FDA for the Plicator device for the treatment of GERD. The Sew-Right Device®, the Syntheon ARD Plicator and Plexiglas beads currently do~~es~~ not have FDA approval for use in an anti-reflux application. The Gatekeeper System was actually withdrawn in late 2005 before FDA approval and is not expected to be marketed.

Improvement in the net health outcome has not been proven with transendoscopic techniques in the treatment of GERD. In one study of endoscopic gastroplasty, patients appeared to have marginal GERD problems and it is unlikely that these patients would be candidates for a minimally invasive procedure as a primary course of treatment. Long-term outcomes are not available for any of the procedures.

The effectiveness of transendoscopic treatments for GERD has not been demonstrated outside the investigational setting. There is little published data from controlled studies in peer-reviewed literature in regard to transendoscopic treatments of GERD. Studies performed generally have not been placebo effect controlled. Large scale controlled studies of the three transendoscopic techniques are needed to establish the safety and efficacy of these procedures.

The American College of Gastroenterology provided updated guidelines in January of 2005: There are 3 broad categories of endoscopic therapy: radiofrequency application to the LES area, techniques designed to decrease reflux using

endoscopic sewing devices, and techniques using an injection into the LES region. All these techniques seem to produce an improvement in reflux symptoms, although significant changes in lower esophageal sphincter pressure have not been demonstrated and less than 35% of patients have been demonstrated to have normalization of their intraesophageal acid exposure (measured by pH testing). When results of the available studies are critically examined, many issues remain unresolved, including: long-term durability, safety and efficacy of these procedures performed outside of clinical trials and efficacy in atypical presentations of GERD, among others. Systematic reviews were unable to identify any clear indications for these techniques, but did support their use in clinical trials and outside clinical trials in certain well-informed patients who have well documented GERD that is responsive to PPI therapy.

EsophyX ™ (EndoGastric Solutions, Inc), an endoluminal fundoplication device, received FDA clearance September 2007. The 2006 Society of American Gastrointestinal Surgeons (SAGES) national meeting was the stage for several presentations describing ELF. The clinical data presented was from 17 GERD patients referred for laparoscopic surgery who were treated with an ELF procedure instead. GERD-HRQL scores at three months post-treatment improved 53% and PPI use was eliminated in 15 of 17 subjects at a mean of 5.5 months after the intervention. Importantly, the investigators (Cadiere, Rajan) reported that the pH scores reflecting distal esophageal acid exposure normalized in 10 of 11 treated patients studied at three months. Adverse events included moderate throat irritation and epigastric pain, resolving within one week, with one admission for pain assessment with spontaneous resolution without determined cause. Further investigations are in progress; long-term outcomes data and a sham-controlled study are necessary to determine its efficacy and safety as a technique for the treatment of GERD.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
43192 **(E/I)**	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance
43201 **(E/I)**	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43210 **(E/I)**	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed
43236 **(E/I)**	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43257 **(E/I)**	Upper gastrointestinal endoscopy including esophagus, stomach and either duodenum and/or jejunum as appropriate; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease

HCPCS Codes

Code	Description
none	

ICD10 Codes

Code	Description
K21.0	Gastro-esophageal reflux disease with esophagitis

Code	Description
K21.9	Gastro-esophageal reflux disease without esophagitis

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KEY WORDS

ELF, Endocinch, endoluminal fundoplication, Enteryx, EsophyX, Gastroplication, Gatekeeper, NDO Plicator System, Stretta.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for the endoscopic treatment of GERD. Please refer to the following LCD website for Medicare Members:
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35080&ver=33&CntrctrSelected=298*1&Cntrctr=298&name=National+Government+Services%2c+Inc.+(13201%2c+A+and+B+and+HHH+MAC%2c+J+-+K)&s=All&DocType=Active&bc=AggAAAQBAAAA&