MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Transendoscopic Therapies for Gastroesophageal Reflux Disease (GERD)**
Policy Number	**7.01.45**
Category	**Technology Assessment**
Original Effective Date	**02/21/01**
Committee Approval Date	**02/21/02, 01/16/03, 11/20/03, 10/20/04, 08/18/05, 06/15/06, 05/17/07, 05/14/08, 05/28/09, 05/27/10**
Current Effective Date	**03/23/23**
Deleted Date	**N/A**
Archived Date	**05/19/11**
Archive Review Date	**05/24/12, 05/23/13, 05/22/14, 05/28/15, 05/25/16, 05/18/17, 05/17/18, 05/16/19, 03/19/20, 03/18/21, 03/24/22, 03/23/23**
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 or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

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

II. Based upon our criteria and the 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, therefore, is considered **investigational**.

III. Based upon our criteria and the lack of peer-reviewed literature, endoluminal fundoplication (e.g., ELF, EsophyX) and transoral incisionless fundoplication (TIF) as treatments of GERD have not been medically proven to be effective and, therefore, are considered **investigational**.

IV. Based upon our criteria and the 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, therefore, is considered **investigational**.

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

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

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; it can significantly affect the quality of patients' lives. Initial

treatment of GERD is geared toward reducing esophageal refluxes via medical therapies (dietary and lifestyle 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 three 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 and, thereby, 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 LES 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 a treatment for GERD (*Refer to Rationale below*).

Pyrolytic carbon-coated beads (Durasphere), which have been approved by the United States Food and Drug Administration (FDA) as a submucosal urethral bulking agent, are being investigated in the treatment of mild-to-moderate GERD, due to their success in the treatment of urinary incontinence resulting from 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), also known as transesophageal (or transoral) incisionless fundoplication (TIF), is designed to restore the antireflux barrier by recreating the valve at the GEJ. 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 three-to-five cm, serosa-to-serosa flap.

RATIONALE

The Bard Endocinch Suturing System received Section 510(k) premarket clearance from the FDA on March 20, 2000. The Stretta System received Section 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 evidence of serious adverse effects related to the incorrect transmural injection of the product into vital organs, which had gone 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 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.

The American College of Gastroenterology (ACOG) provided updated guidelines in January of 2005, identifying three 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. ACOG noted that all of these techniques seemed to produce an improvement in reflux symptoms, although significant changes in lower esophageal sphincter pressure had not been demonstrated, and fewer than 35% of patients had demonstrated normalization

of their intraesophageal acid exposure (measured by pH testing). When results of the available studies were critically examined, many issues remained unresolved, including: long-term durability, safety and efficacy of the 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, as well as outside clinical trials in certain well-informed patients with well-documented GERD that is responsive to PPI therapy.

EsophyX (EndoGastric Solutions, Inc.), an endoluminal fundoplication device, received FDA clearance in 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 who were referred for laparoscopic surgery, but 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, at three months, the pH scores reflecting distal esophageal acid exposure normalized in 10 of 11 treated patients studied. 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. In 2016, the EsophyX Z Device with SerosaFuse Fasteners was cleared for marketing by the FDA through the Section 510(k) process for use in transoral tissue approximation, full-thickness plication, ligation in the gastrointestinal tract, narrowing of the gastroesophageal junction, and reduction of hiatal hernias of two cm or less in patients with symptomatic chronic 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 Section 510(k) process for expanded indications, including patients who require and respond to pharmacologic therapy and patients with hiatal hernias larger than two cm when a laparoscopic hiatal hernia repair reduces a hernia to two cm or less.

Richter et al. (2018) performed a systematic review and network meta-analysis of randomized, controlled trials completed as of May 10, 2017, to compare the relative efficacies of transoral incisionless fundoplication (TIF) versus laparoscopic nissen fundoplication (LNF) in patients with GERD. The meta-analysis reviewed seven trials comprising 1,128 patients using Bayesian methods under random-effects, multiple-treatment comparisons. The comparative results from direct and network meta-analysis included the following results: TIF had the highest probability of increasing patients' health-related quality of life (0.96), followed by LNF (0.66), a sham procedure (0.35), and PPIs (0.042). LNF had the highest probability of increasing percent time at pH<4 (0.99), followed by PPIs (0.64), TIF (0.32), and the sham procedure (0.05). LNF also had the highest probability of increasing LES pressure (0.78), followed by TIF (0.72) and PPIs (0.01). Patients who underwent the sham procedure had the highest probability for persistent esophagitis (0.74), followed by those receiving TIF (0.69), LNF (0.38), and PPIs (0.19). The meta-analysis did not review adverse effects/harm, as it was not reported consistently across all of the studies. The authors concluded that LNF is superior to TIF and PPIs for improving physiologic parameters of chronic GERD, including increased LES pressure and decreased percent time pH. TIF was not recommend as a long-term alternative to PPI or LNF treatment of GERD, as long-term efficacy has not been demonstrated.

Ongoing clinical trials and studies of transesophageal endoscopic therapies for the treatment of GERD continue to be conducted, which include TIF, application of radiofrequency energy, and injection/implantation of prosthetic devices or bulking agents. Large-scale, long-term controlled studies of these three transendoscopic techniques are needed to establish the safety and efficacy of these procedures.

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)**	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

HCPCS Codes

Code	Description
none	

ICD10 Codes

Code	Description
K21.0	Gastro-esophageal reflux disease with esophagitis
K21.9	Gastro-esophageal reflux disease without esophagitis

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*Key Article

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/view/lcd.aspx?lcdid=35080&ver=53&keyword=GERD&keywordType=starts&areaId=all&docType=F,P&contractOption=all&sortBy=relevance&bc=1
There is currently a Local Coverage Determination (LCD) for the Stretta procedure (E/I). Please refer to the following LCD website for Medicare Members:
https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34540&ContrId=239&ContrVer=1&CntrctrSelected=239*1&Cntrctr=239&name=CGS+Administrators%2c+LLC+(15101%2c+MAC+-+Part+A)&DocType=2&LCntrctr=239*1&bc=AgACAACAAAAA&=