



ENDOSCOPIC TREATMENT OF GERD and BARRETT'S ESOPHAGUS

Effective Date: July 1, 2009

Review Dates: 2/04, 1/05, 12/05, 2/06, 12/06, 12/07,
2/08, 2/09, 2/10

Date Of Origin: February 25, 2004

Status: Current

I. DESCRIPTION:

A. Endoscopic, or endoluminal, therapies for GERD are designed to alter structures at the gastroesophageal junction to prevent reflux of gastric contents. Current endoscopic therapies may be classified into three basic categories: (1) radiofrequency energy or radiofrequency thermal ablation; (2) endoscopic or plication suturing; and (3) polymer injection and implantation techniques.

1. Radiofrequency Energy or Radiofrequency Thermal Ablation:

Thermal energy is delivered to the lower esophageal sphincter (LES) using endoscopically placed needles. Proposed mechanism of action is unknown, although it is likely that there is a resultant scarring or neurolysis in the lower esophageal sphincter.

An example is the Stretta[®] System (Curon Medical, Inc., Fremont, CA).

2. Plication/Suturing Techniques: This procedure is also referred to as Endoluminal Gastric Plication (ELGP). A needle puncture device attached to the endoscope creates pleats through a series of sutures passed by a needle through adjoining proximal fundic folds at the gastroesophageal junction. The proposed action is providing a physical barrier to gastric reflux, possibly by increasing the length of the lower esophageal sphincter (LES), decreasing the esophageal luminal diameter, or decreasing the frequency of transient relaxations of the LES (tLESRs).

An example of a suture plication gastroplasty device is the EndoCinch[™] or Bard Endoscopic Suturing System (BESS) (Bard Endoscopic Technologies, Billerica, MA, a subsidiary of C.R. Bard Inc., Murray Hill, NJ).

The full-thickness Endoscopic Plication[™] System (EPS; NDO Surgical, Inc., Mansfield, MA) is a semiflexible tube that retroflexes upon itself within the stomach and creates a transmural, full-thickness plication. Its proposed mechanism of action is to inhibit



gastroesophageal reflux by placing a transmural plication near the gastroesophageal junction.

The EndoGastric Solutions (EGS) EsophyX™ System with Serofuse™ Fastener is indicated for use in endoluminal, transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia ≤ 2 cm in size in patients with symptomatic chronic gastroesophageal reflux disease

3. **Polymer Injection/Implantation Techniques:** These are referred to as bulking techniques as their proposed mechanism of action is to provide bulking support to the sphincter keeping stomach fluids and acids from backing up into the esophagus. It does not affect the stomach's ability to produce acid or other digestive fluids. The procedure is not reversible.

An example is Enteryx™ which is a liquid polymeric material that is injected into the muscle of the lower esophageal sphincter (LES), through an endoscope. Enteryx™ forms a soft, spongy permanent implant in the sphincter muscle.

*On October 14, 2005 the FDA issued a preliminary public health notification recall of all Enteryx™ Procedure Kits and Single Pack Enteryx™ Injectors to health care practitioners stating serious adverse events, including death, occurred in patients treated with Enteryx™ for GERD (FDA, 2005).

- B. Endoscopically based therapies for Barrett's esophagus (BE) are designed to destroy the damaged tissue in the esophagus associated with BE and thus reduce the risk of esophageal cancer in these individuals. There are currently two endoscopically based therapies for BE: (1) Photodynamic Therapy (PDT); (2) Thermal Ablation.

1. **Photodynamic Therapy (PDT):** PDT using porfimer sodium (Photofrin) is an FDA approved treatment for Barrett's esophagus with high grade dysplasia. Porfimer sodium is a light-sensitizing drug (a photosensitizer) which is administered intravenously or by mouth. The drug concentrates in the Barrett's tissues. The esophageal tissue is then exposed to modified laser light. Photoactivation of the drug then destroys the cells in which it has been absorbed.



2. **Thermal Ablation (TA):** The goal of this therapy is to ablate dysplastic tissue, reversing the histopathological changes characteristic of BE, and initiating squamous re-epithelialization of the esophagus. Using a controller to limit the amount of heat energy generated, a high-frequency electric current is passed through a heater element for less than a second to destroy the innermost layer of esophageal tissue. The HALO³⁶⁰ Coagulation System, which is also referred to as the BARRX device, is an example of this technology.

II. POLICY/CRITERIA:

A. Transoral incisionless fundoplication (TIF) for GERD for individuals with Normal esophageal motility (by either manometry or video esophagogram) is a covered benefit for the any following indications:

1. Persistent GERD symptoms despite PPI therapy.
2. Anatomic disruption of the GE flap valve to a Hill Grade II-III.
3. Evidence of one of the following while on PPI therapy:
 - a. erosive esophagitis (erosions or ulcerations during endoscopy)
 - b. abnormal ambulatory pH study
 - c. Biopsy confirmed changes characteristic of reflux esophagitis
4. Contraindications for TIF include:
 - a. BMI \geq 35
 - b. Hiatal hernia > 2 cm
 - c. Esophagitis grade D or Barrett's esophagitis
 - d. Esophageal ulcer
 - e. Fixed esophageal stricture or narrowing
 - f. Portal hypertension and/or varices
 - g. History of previous resective gastric or esophageal surgery, cervical spine fusion, Zenker's diverticulum, esophageal epiphrenic diverticulum, achalasia, scleroderma or dermatomyositis, eosinophilic esophagitis, > 2 dilations for esophageal stricture, or cirrhosis
 - h. Active esophago-gastro-duodenal ulcer disease
 - i. Gastric outlet obstruction or stenosis
 - j. Gastroparesis or delayed gastric emptying confirmed by solid-phase gastric emptying study if patient complains of postprandial satiety during assessment

B. Priority Health does not provide coverage for other endoscopic treatments* for GERD for the following reasons:

1. The evidence does not permit conclusions on whether endoscopic suturing, radiofrequency energy delivery, or implantation of inert polymers for treatment of gastroesophageal reflux disease improves health outcomes or is as beneficial as established alternatives. Case series data are inadequate to demonstrate improvement in health outcome. The



procedures have not been compared to Nissen fundoplication in controlled trials, and the risks and benefits of the procedures compared to Nissen fundoplication are not established.

2. There is no long-term outcome data to show the durability of these procedures.

**This procedure is considered experimental.*

C. Endoscopic Mucosal Resection or Photodynamic Therapy for Barrett's Esophagus is a covered benefit when the following is present:

1. High-grade dysplasia (HGD) and / or early esophageal adenocarcinoma (EAC) and standard medical therapy (e.g., proton pump inhibitors, H-2 receptor antagonists, or prokinetic agents) has failed and or;
2. unable to undergo esophagectomy.

D. Thermal Ablation treatment for Barrett's esophagus is not a covered benefit

1. Available studies are uncontrolled and involved limited or no patient monitoring after treatment, further studies are needed to demonstrate the efficacy of ablative procedures such as the BARRX procedure and the durability of the benefits they provide.
2. There is no long-term outcome data to show the durability of these procedures.

III. MEDICAL NECESSITY REVIEW:

- Required Not Required Not Applicable

IV. APPLICATION TO PRODUCTS:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*



- ❖ **MEDICARE:** Coverage is determined by the Centers for Medicare and Medicaid Services (CMS).
- ❖ **MEDICAID:** For Medicaid members, this policy will apply.
- ❖ **MICHILD:** For MICHILD members, this policy will apply unless MICHILD certificate of coverage limits or extends coverage.

V. CODING INFORMATION:

Transoral incisionless fundoplication (TIF) for GERD

ICD-9 Codes that may apply:

- 530.10 Esophagitis, unspecified
- 530.11 Reflux esophagitis
- 530.19 Other esophagitis
- 530.81 Esophageal reflux

CPT/HCPCS Codes:

- 43499 Unlisted procedure, esophagus
(Explanatory notes must accompany claims billed with unlisted codes.)

Endoscopic Mucosal Resection or Photodynamic Therapy for Barrett's Esophagus

ICD-9 Codes that may apply:

- 530.85 Barrett's esophagus

CPT/HCPCS Codes:

- 43499 Unlisted procedure, esophagus
(Explanatory notes must accompany claim.)

- 96570 Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); first 30 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of lung and esophagus)
- 96571 Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); each additional 15 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of lung and esophagus)

- J9600 Injection, porfimer sodium, 75 mg

Not covered treatments for GERD, Barrett's Esophagus

ICD-9 Codes:

- 530.10 Esophagitis, unspecified
- 530.11 Reflux esophagitis
- 530.19 Other esophagitis
- 530.81 Esophageal reflux
- 530.85 Barrett's esophagus

CPT/HCPCS Codes:

- 43201 Esophagoscopy, rigid or flexible; with directed submucosal injection(s), any substance



- 43228 Esophagoscopy, rigid or flexible; with ablation of tumor(s), polyp(s), or other lesion(s), not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique
- 43236 Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with directed submucosal injection(s), any substance
- 43257 Upper gastrointestinal endoscopy including esophagus, stomach, and either the 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
- 43258 Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique
- 43499 Unlisted procedure, esophagus
- 43999 Unlisted procedure, stomach
(Explanatory notes must accompany claims billed with unlisted codes.)
- C9724 Endoscopic full-thickness plication in the gastric cardia using endoscopic plication system (EPS); includes endoscopy

VI. BACKGROUND:

Gastroesophageal reflux disease (GERD), also known as reflux esophagitis, is probably the most prevalent clinical condition that arises from the gastrointestinal (GI) tract. There are two principal factors involved in esophageal reflux: (i) the GI contents and (ii) the anti-reflux mechanism, which is comprised of the lower esophageal sphincter (LES) and the anatomic configuration of the gastroesophageal junction. Reflux occurs when the gradient between the LES pressure and the intragastric pressure is compromised as a result of a transient or sustained reduction in the former, or an elevation in the latter. Most patients with GERD have decreased LES pressures. However, some patients have normal LES pressures, but their sphincters relax inappropriately, thus resulting in refluxes.

The initial treatment of GERD is geared toward reducing esophageal refluxes. Antacids, H₂-receptor antagonists, as well as dietary and lifestyle modifications have been used for such purposes. For patients who fail initial treatment, proton pump inhibitors (e.g., lansoprazole and omeprazole) should be tried. When these standard medical therapies fail, surgery may be considered.

Traditional procedures were designed to raise the pressure within the LES by wrapping a portion or all of the cardia stomach around the esophagus. With the advent of laparoscopic anti-reflux surgery, the two most common procedures are the Nissen fundoplication and the Toupet partial fundoplication. Anti-reflux surgery has been reported to have an efficacy rate of 90%. These operations are usually performed on the same day of hospital admission and take approximately 90 minutes. In general, patients are discharged from the hospital on the second



postoperative day and can return to work in 7 to 10 days. Anti-reflux surgery can be associated with complications. The most common complications are dysphagia and an inability to belch or vomit, occurring in 4 to 11% of patients. The ideal candidates for anti-reflux surgery should be young, have typical GERD symptoms (heartburn and regurgitation) with or without a hiatal hernia, have an abnormal ambulatory pH test, have normal esophageal motility studies, and have responded, at least partially, to PPI therapy.

Limitations to the use of fundoplication include the need for surgical expertise, the need for hospitalization and several weeks of postoperative recovery, and the risk of complications and development of new symptoms not present before the surgery. Additionally, many patients treated surgically will need to resume pharmacologic therapy over time as often the surgery does not cure their disease or permanently modify their need for medication use. It is because of the invasiveness, costs, and inherent risks of surgery that an interest in alternative, endoscopic therapies for GERD, has emerged

Endoscopic, or endoluminal, therapies for GERD are designed to alter structures at the gastroesophageal junction to prevent reflux of gastric contents. Current endoscopic therapies may be classified into three basic categories: **(1)** radiofrequency energy or radiofrequency thermal ablation; **(2)** endoscopic or plication suturing; and **(3)** polymer injection and implantation techniques.

The Stretta® System (Curon Medical, Inc., Fremont, CA) is an example of radiofrequent (RF) thermal energy delivered to the LES using endoscopically placed needles. RF thermal injury purportedly results in ablation of nerve pathways responsible for tLESRs and/or tissue tightening or remodeling of the gastroesophageal junction due to heat-induced collagen contraction. Thus, RF energy may improve LES compliance and inhibit tLESRs.

Examples of suture plication (gastroplasty) devices are EndoCinch™ (Bard™ Endoscopic Technologies, Billerica, MA) and the Endoscopic Suturing Device® (ESD; Wilson-Cook Medical, Winston-Salem, NC), also called Sew-Right. These devices sometimes are referred to as miniature or endoscopic “sewing machines.” With this technology, which uses a transoral flexible endoscopic suturing device to create pleats in the gastroesophageal junction, a needle puncture device attached to the endoscope creates pleats through a series of sutures passed by a needle through adjoining proximal fundic folds, thus, providing a barrier to gastric reflux. A third suture plication device, the full-thickness Endoscopic Plication™ System (EPS; NDO Surgical, Inc., Mansfield, MA) has been designed to inhibit gastroesophageal reflux by placing a transmural plication near the gastroesophageal junction under direct endoscopic visualization to enhance the competency of the gastric cardia. The EPS is an enlarged flexible tube that forms a fundic fold fixation with a single pretied suture implant delivered by the instrument, while retroflexed within the stomach and visually monitored through an inserted endoscope. Thus, plication devices may act by restoring the flap mechanism.



The newest plication procedure is The EndoGastric Solutions (EGS) EsophyX™ System with Serofuse™ Fastener is indicated for use in endoluminal, transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia ≤ 2 cm in size in patients with symptomatic chronic gastroesophageal reflux disease

There are several polymer injection techniques under investigation, including Enteryx™ injection therapy (Boston Scientific Corp., Natick, MA), in which inert polymer material is injected deep into the submucosal zone beneath the LES to form a ringlike “bulking” zone to augment sphincter pressure and decrease tLESRs; the Gatekeeper™ Reflux Repair System (Medtronic, Inc., Minneapolis, MN), which allows endoscopic introduction of an expandable hydrogen prosthesis into the submucosa of the LES zone; and the Plexiglas (polymethylmethacrylate [PMMA]) implantation procedure (Röhme GmbH & Co. KG, Darmstadt, Germany), in which PMMA microspheres are injected endoscopically by needle under high pressure into the submucosa of the proximal LES zone to provide “bulking” support to the sphincter. At this time, neither Gatekeeper nor PMMA are FDA approved.

VII. SPECIAL NOTES:

Priority Health's Technology Assessment Committee (TAC) reviewed the Enteryx procedure and recommend non-coverage of this procedure (December 5, 2003). A second review of Enteryx as well as the Stretta procedure and plication devices was reviewed by TAC in December 2005 with the recommendation of non-coverage of all of the endoscopic GERD treatments.

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esophagus version 16.3: October 2008



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