Endoscopic Procedures for Gastroesophageal Reflux Disease (GERD)

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee's specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member's EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
# POLICY DESCRIPTION:

This policy describes the use of endoscopic procedures for the treatment of Gastroesophageal Reflux Disease (GERD). These are minimally invasive procedures using an endoscope rather than external incisions to reach the affected area of the digestive tract.

Traditional treatments for GERD involve lifestyle and diet changes as the first line of treatment. If these changes don’t work, medications can be used. Surgical options, open or laparoscopic fundoplication, are also available.

Endoscopic procedures for GERD are designed to alter structures at the gastroesophageal junction to prevent reflux of gastric contents. There are three types of procedure for endoscopic treatment of GERD.

1. **Suturing Methods.** These methods use stitches, or sutures, at the lower end of the esophagus in a procedure called endoluminal gastric plication. The Endocinch is like a little sewing machine.

2. **Radio Frequency Method.** This method uses heat from radio frequencies to alter the muscles in the lower esophagus. Stretta is approved by the FDA for this purpose.

3. **Injection Method.** For this method, inert chemical or biochemical compounds were injected into the tissue of the lower esophagus. Enteryx was the component of choice, but is no longer approved by the FDA.

Endoscopic treatments have only been available for a few years, so not much research is available on long-term effectiveness and safety of such procedures. Therefore, these procedures are considered investigational and/or experimental for the management of patients with GERD. Traditional surgeries for GERD still have a higher long-term success rate than the newer endoscopic treatments.

## COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

- Radiofrequency ablation, as an alternative to esophagectomy, is considered **MEDICALLY NECESSARY** in individuals with:
  1. Barrett’s esophagus with high-grade dysplasia, confirmed by endoscopy, or
  2. Barrett’s esophagus with low-grade dysplasia (LGD), confirmed by a biopsy finding of LGD

Endoscopic radiofrequency ablation is considered **INVESTIGATIONAL AND EXPERIMENTAL** and therefore **NOT MEDICALLY NECESSARY** for Barrett’s esophagus without dysplasia.

**Note:** Local Coverage Determination for Endoscopic Treatment of GERD (L30473), CMS addresses that benefits are not available for radiofrequency energy delivered to the smooth muscle of the lower esophageal sphincter (LES) to treat GERD, as these procedures are not considered reasonable and necessary. See the Regulatory Status/CMS/LCD section.

- Endoscopic implantation of Inert Polymers or polymethylmethacrylate (PMMA) beads (e.g., LINX Reflux Management System sphincter augmentation device), is considered **MEDICALLY NECESSARY** for the treatment of severe or life threatening Gastro Esophageal Reflux Disease (GERD), in individuals whose conditions have been resistant to medical treatment, and who also present any of the following clinical situations:
  1. Have esophageal involvement with progressive systemic sclerosis, or
  2. Have foreshortening of the esophagus such that insufficient tissue exists to permit a valve
reconstruction, or
3. Are poor surgical candidates for a valvuloplasty procedure, or
4. Have failed previous attempts at surgical treatment with valvuloplasty procedures.

• The following transesophageal endoscopic therapies and procedures are considered EXPERIMENTAL AND/OR INVESTIGATIONAL for the management of patients with gastro-esophageal reflux disease (GERD) and all other indications:

1. Endoscopic gastroplasty/gastroplication suturing
   - Bard EndoCinch Suturing System (Bard Endoscopic Technologies)
   - Endoscopic Suturing Device® (Wilson-Cook Medical)
   - EsophyX or StomaphyX System, EsophyX2 System, SerosaFuse Fastener (transoral incisionless fundoplication procedure) (EndoGastric Solutions)
   - Endoscopic Plicator System (NDO Surgical, Inc.)
   - Syntheon ARD Plicator (Syntheon)

2. Radiofrequency energy delivery
   - Stretta® System (Curon Medical Inc.)

3. Implantation of Inert Polymers or polymethylmethacrylate (PMMA) beads
   - Durasphere (Carbon Medical Technologies)
   - Gatekeeper™ Reflux Repair System (Medtronic, Inc.)
   - The Plexiglas (polymethylmethacrylate microspheres [PMMA]) (Röhm GmbH & Co. KG, Darmstadt, Germany)
   - Enteryx® Procedure Kit (Boston Scientific Corporation)
   - LINX Reflux Management System sphincter augmentation device (Torax Medical).
   **Note:** CMS has medical necessity benefits guidance for the LINX Reflux Management System. See the Regulatory Status/CMS/LCD section, National Coverage Determination for endoscopic implantation of Anti-Gastroesophageal Reflux Device (100.9).

4. Angelchik anti-reflux prosthesis

The safety and efficacy of endoscopic therapies for the treatment of GERD have not been established in the published peer-reviewed medical literature. Well designed studies are needed to support the use of any minimally invasive transesophageal endoscopic procedures/therapies for GERD and to establish long-term improved patient health outcomes by eliminating symptoms, preventing recurrence of symptoms or progression of disease, healing esophagitis, and reducing the need for pharmacologic therapy.

**Clinical Considerations:**
Relative contraindications include:
- Atypical GERD symptoms,
- Other associated foregut pathology (specifically, gastroparesis)
- Psychoemotional disorders
- Functional esophageal disease
- Bleeding disorders
- Esophageal strictures/varices
- High-grade dysplasia or cancer
- Shortened esophagus
- Collagen vascular disease
- Peptic stricture
- Patients who are pregnant
- Poor surgical candidates
- Morbidly obese

**BACKGROUND:**

Gastroesophageal reflux disease (GERD) affects 10% to 20% of the world population. This chronic disorder is associated with a risk of significant morbidity, substantially impacting quality of life (QOL), and the possibility of mortality from complications. Approximately 44% of the American population experience gastroesophageal symptoms at least once a month, and up to 10% experience symptoms on a daily basis. The prevalence of GERD in the United States is estimated at 19 million cases per year, with an associated total cost of care of $9.8 billion. The single largest component of the cost of care of these patients is drug costs, estimated at $5.8 billion (Sandler et al., 2002; Dent et al., 2005).

GERD is due to recurring reflux, or regurgitation, of the stomach contents into the esophagus, which results in the classic symptoms of heartburn—a burning, acidic feeling in the throat and chest. In its mildest form, GERD is an annoyance necessitating control with lifestyle modification, antacids, or over-the-counter (OTC), acid-secretion suppressive medications. However, while reflux typically manifests itself as heartburn, regurgitation, or difficulty swallowing (dysphagia), it also can lead to complications such as esophagitis, an inflammatory condition caused by chronic irritation of the esophageal lining by stomach acids and enzymes; esophageal erosion, or ulceration; esophageal stricture; and Barrett’s esophagus, a premalignant condition to esophageal adenocarcinoma.

In patients with GERD, the lower esophageal sphincter (LES) maintains insufficient tension to prevent reflux from the stomach into the esophagus. Inappropriate transient relaxations of the LES (tLESRs), increasing the frequency and duration of esophageal reflux, are responsible for reflux events in patients with normal LES pressure. Other factors that may contribute to the development of GERD include hiatal hernia, esophageal motility disorders, decreased salivary clearance of reflux, decreased secretion of bicarbonate in the esophagus, increased susceptibility of the esophageal lining to damage by gastric secretions, and delayed gastric emptying. Besides the classic symptoms of heartburn and acid regurgitation, other atypical signs and symptoms of GERD, such as chest pain, hoarseness, nausea, chronic cough, pain on swallowing, dental enamel loss, and asthma, may be present.

Diagnosis of GERD accompanied by classic symptoms usually can be made on the basis of history, clinical presentation, and response to acid-suppressing medications. While there is no gold standard for diagnosing GERD, ambulatory 24-hour pH monitoring is the accepted standard for establishing or excluding its presence. In patients with nonerosive reflux disease or symptomatic reflux esophagitis, this test has a sensitivity and specificity of 70% to 96%. The test involves placement of a pH monitor in the esophagus above the LES, with measurements taken periodically. The patient keeps a journal, and the pH value, patient activity, and symptoms for each time point are correlated. Endoscopy is the gold standard for assessing esophageal complications of GERD, although this procedure lacks sensitivity for the diagnosis of GERD, itself. Esophageal manometry testing, which involves pressure measurements across the LES,
generally is used in severe cases or when a patient with reflux is being considered for surgery.

The primary treatment goals of GERD are relief of symptoms, prevention of symptom relapse, healing of erosive esophagitis, and prevention of GERD-related complications. In patients with reflux esophagitis, treatment is directed at acid suppression through the use of lifestyle modifications and pharmacologic agents. Lifestyle modifications include elevating the head of the bed, modifying the size and composition of meals, weight loss, smoking cessation, and avoiding a reclining position 3 hours after eating. Pharmacologic agents include acid suppressants and antacids, histamine-2 receptor antagonists (H2RAs), or proton pump inhibitors (PPIs). Pharmaceutical agents can lose their effectiveness over time, requiring progressively higher dosing. Adults affected by GERD who no longer respond adequately to drugs or those who wish to discontinue use of these medications have the option of laparoscopic antireflux surgery, commonly referred to as laparoscopic Nissen fundoplication. While this surgery has long proven to be effective in treating the disease, the procedure is invasive and potential side effects of the fundoplication procedure may compromise otherwise excellent postsurgical results. A transoral incisionless fundoplication procedure was developed to mimic anti-reflux surgery, as a minimally invasive alternative procedure with potentially fewer side effects.

Endoscopic, or endoluminal, therapies for GERD are designed to alter structures at the gastroesophageal junction to prevent reflux of gastric contents. These therapies are to provide an option for patients who would prefer nonpharmacologic therapy but wish to avoid anti-reflux surgery. Current techniques are less invasive than antireflux surgery and are performed in the outpatient setting. They may be classified into three basic categories:

1. Endoscopic or plication suturing of the proximal stomach (Bard EndoCinch Suturing System)
2. Radiofrequency energy delivered to the gastroesophageal junction (Stretta System)
3. Polymer injection or implantation of bulking agents into the cardia or distal esophagus (EsophyX System with SerosaFuse Fastener)

**Bard EndoCinch Suturing System:**
This is the first approved endoscopic suturing procedure. It requires two endoscopes and an overtube, and involves placing sutures just below the gastroesophageal junction to create an internal plication of the stomach, “tightening” the cardiac component of the LES and imposing a barrier to reflux. Stitches are placed into adjoining proximal gastric folds (not into the muscular portion) to create pleats. The first endoscope carries the metal sewing capsule on its tip, and the second endoscope cinches the sutures using a catheter device that deploys a ceramic plug and ring through which the sutures are threaded. Target tissue is drawn into the sewing chamber via suction, and two sutures are placed into the tissue. An extracorporeally tied knot then is advanced through the endoscope to create a single plication, formed by the two sutures. A short overtube, which is reusable, allows for repeated intubations (approximately 10). Two to three plications usually are performed longitudinally, radially, or spirally at the side of the cardia with lesser curvature within 1 cm below the squamocolumnar junction. The EndoCinch device has both single use and reusable components. The procedure typically is performed on an outpatient basis using either conscious or deep sedation and takes approximately 60 minutes. The patient resumes normal activities the next day. Considerable endoscopic skill and expertise is needed to perform the procedure, and endoscopists are required to undergo manufacturer training at an animal facility (Falk et al., 2006b).

**Stretta System:**
The Stretta Procedure is endoscopically-guided and minimally invasive. Radiofrequency energy delivery requires a special single-use catheter and radiofrequency energy generator. The flexible delivery catheter is
made up of a soft shaft and a balloon-basket assembly with four electrodes positioned radially around the balloon. The generator delivers radiofrequency energy to the catheter in an automated fashion under temperature control using thermocouple monitoring, and the power output is regulated by computer algorithm. When the catheter is positioned and the needles deployed into the circular muscle of the gastroesophageal junction, energy is delivered to each electrode to create a series of thermal lesions in the muscle of the LES and gastric cardia. Target tissue and mucosal temperature are achieved and maintained through a special suction and irrigation system.

The Stretta procedure usually is performed on an outpatient basis in the endoscopy unit or ambulatory surgery center with the use of intravenous conscious sedation. Radiofrequency energy is delivered while the mucosa is cooled with irrigation, using the previously described temperature-controlled radiofrequency generator system. The procedure generally takes under 40 minutes, and the patient typically resumes normal activity the next day. Patients undergo endoscopy immediately after delivery of radiofrequency energy to assess the post radiofrequency appearance of the mucosa. Typically, collagen contraction is observed immediately after radiofrequency energy delivery with tightening of the gastroesophageal junction.

**EsophyX System with SerosaFuse Fastener:**

The EsophyX/SerosaFuse system consists of sterile polypropylene fastener implants and a flexible fastener delivery device. The SerosaFuse fasteners and EsophyX delivery device are provided sterile and are for single use. The polypropylene fasteners are proprietary and function only with the EGS delivery devices. The transoral incisionless fundoplication procedure using the EsophyX/SerosaFuse system creates full-thickness serosa-to-serosa plications and constructs valves 3 to 5 cm (centimeters) in length and 200° to 300° in circumference. The procedure is performed with the patient under general anesthesia, typically by a team of physicians. One physician controls the implantation of fasteners using the EsophyX device, and the other ensures continuous direct visualization with an endoscope. The surgery generally takes less than an hour, and most patients go home the next day. Patients are instructed to consume a liquid diet during the first 2 weeks and a soft diet during the following 4 weeks. In general, proton pump inhibitors are discontinued 7 days after the procedure. The EsophyX/SerosaFuse system is indicated for the treatment of symptomatic chronic GERD 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 GERD.

**Transesophageal Endoscopic Injection and Implantation techniques:** Endoscopic injection and implantation techniques involve endoscopic injection or implantation of inert polymer material into the submucosa of the proximal lower esophageal sphincter (LES) zone to provide bulking support to the sphincter to help prevent acid reflux. Usually performed in an endoscopy suite or ambulatory surgery center using intravenous conscious sedation, these procedures are intended for patients with symptomatic GERD.

There are three endoscopic injection and implantation techniques (also referred to as bulking techniques) currently under investigation:

- The Plexiglas (polymethylmethacrylate [PMMA]) procedure which involves injection of an inert polymer material into the submucosa of the proximal lower esophageal sphincter zone to provide bulking support to the sphincter and decrease transient relaxations of the lower esophageal sphincter (tLESRs).
- The Gatekeeper Reflux Repair System 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. These agents are not commercially available in the United States.

- The bulking agent, pyrolytic carbon-coated beads (Durasphere®), is being evaluated for treatment of GERD. Durasphere is approved by the U.S. Food and Drug Administration (FDA) as a submucosal urethral bulking agent. Use of this product for esophageal reflux would be considered off-label use.

The LINX™ Reflux Management System is an implant that consists of a ring that fits around the esophagus and is intended to prevent reflux of bile and acid from the stomach into the esophagus. According to the company Web site, the LINX system is a small flexible band of interlinked titanium beads with magnetic cores. The magnetic attraction is intended to help the lower esophageal sphincter (LES) resist opening to gastric pressures, preventing reflux from the stomach into the esophagus. A surgeon uses a laparoscopic incision to implant the device around the patient’s esophagus just above the stomach while the patient is under general anesthesia.

**Radiofrequency ablation (RFA), using the HALO system (BÂRRX Medical Inc., Sunnyvale, CA):** Barrett’s esophagus (BE) is a condition in which the normal squamous epithelium of the esophagus is replaced by an abnormal, specialized columnar type epithelium, similar to the lining of the intestine. This process is called intestinal metaplasia. Intestinal metaplasia is a precursor to esophageal adenocarcinoma and persons with BE are at a 40-fold increased risk for developing this disease compared to the general population. Management of Barrett’s esophagus (BE) is dependent on the progression of the disease and may include treatment of GERD, surveillance, and a number of endoscopic or surgical procedures. Radiofrequency ablation (RFA), using the HALO system (BÂRRX Medical Inc., Sunnyvale, CA), is under investigation as a non-invasive therapy for BE. RFA consists of a sizing balloon, an energy generator, and an ablation catheter, which deliver radiofrequency energy under endoscopic guidance, purportedly removing the diseased tissue lining the esophagus.

### REGULATORY STATUS:

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**
   
   Several endoscopic antireflux (endoluminal) procedures have received approval by the U.S. Food and Drug Administration (FDA) for treatment of gastroesophageal reflux disease (GERD).


EsophyX, EsophyX2: The current generation of EsophyX, EsophyX2, was cleared for marketing as substantially equivalent to the original EsophyX system with minor changes in November 2009 under the U.S. Food and Drug Administration’s (FDA) 510(k) process. The original system was cleared for marketing in September 2007 as substantially equivalent to the predicate devices NDO Surgical Endoscopic Plication System, Bard EndoCinch, and EGS StomaphyX Endoluminal Fasteners and Delivery System. According to the approval summary letter, EsophyX2 is indicated for:

- Use in transoral tissue approximation,
- Full-thickness plication and ligation in the GI tract,
- The treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacologic therapy,
- Narrowing of the gastroesophageal junction, and
- Reduction of hiatal hernia <2 cm in patients with symptomatic chronic gastroesophageal reflux disease.


These products are Class II devices (moderate risk) deemed substantially equivalent to other endoscopic devices utilizing other procedures.

Enteryx™: The Enteryx™, a biocompatible liquid polymer, received FDA approval in 2003 through the premarket approval (PMA) process for the treatment of symptomatic GERD. However, on September 22, 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. See the following Web site for more information:


HALO system (BÂRRX Medical Inc., Sunnyvale, CA): In June 2005, the U.S. Food and Drug Administration (FDA) granted 510(k) clearance for the HALO360 Coagulation System for use in the coagulation of bleeding and nonbleeding sites in the gastrointestinal tract, including the treatment of Barrett’s esophagus (BE). The HALO90 System received FDA approval in April 2006. The HALOFLEX Energy Generator received 510(k) approval in November 2009.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):

National Coverage Determination (NCD):

National Coverage Determination for endoscopic implantation of Anti-Gastroesophageal Reflux Device (100.9): The procedure involves the implantation of this special device around the esophagus under the diaphragm and above the stomach, which is secured in place by a circumferential tie strap. The implantation of this device may be considered reasonable and necessary in specific clinical situations where a conventional valvuloplasty procedure is contraindicated. The implantation of an anti-gastroesophageal reflux device is covered only for patients with documented severe or life threatening gastroesophageal reflux disease whose conditions have been resistant to medical
treatment and who also:

1. Have esophageal involvement with progressive systemic sclerosis, or
2. Have foreshortening of the esophagus such that insufficient tissue exists to permit a valve reconstruction, or
3. Are poor surgical candidates for a valvuloplasty procedure, or
4. Have failed previous attempts at surgical treatment with valvuloplasty procedures.

**Note:** Endoscopic implantation of Inert Polymers or polymethylmethacrylate (PMMA) beads (e.g., LINX Reflux Management System sphincter augmentation device) is a good example.

**Local Coverage Determinations (LCD):**

LCDs addressing endoscopic treatments for GERD exist and compliance with these policies is required where applicable.

- Local Coverage Determination for Endoscopic Treatment of GERD (L30473): Coverage Indications Limitations and/or Medical Necessity Benefits are not available for endoluminal treatment for Gastroesophageal Reflux Disease (GERD) using the Stretta® procedure, the Bard EndoCinch™ Suturing System, Plicator™, Enteryx®, EsophyX™ or similar treatments as these procedures are not considered reasonable and necessary for the diagnosis or treatment of an injury or disease.

Currently, these procedures are considered non-covered due to the fact that current peer-reviewed literature does not support the efficacy of the services. Claims will be denied as "not proven effective."

These procedures are promising for treatment of patients in whom proton pump inhibitor therapy fails. Clinical data from various studies are emerging. At this time, open-label studies or patient registries with short term follow-ups are the dominant source of data. The overwhelming preponderance of reviewers remains equivocal in their support and has called for randomized controlled trials with long-term follow-ups. In the absence of evidence from such studies, and in the absence of wide acceptance, endoscopic treatments for GERD are not proven effective. Therefore, they are not reimbursable even though some of the treatments may have associated CPT™ or OPPS codes.

**3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):**

Minnesota DHS does not have a policy statement regarding endoscopic procedures for the treatment of GERD in its Provider Manual or other specific provider references.

MHCP will cover fundoplication surgeries for the long-term management of adults with chronic GERD as medically necessary. In order for the authorization request to be approved, patients must meet all of the following authorization criteria:

- GERD symptoms are refractory to ongoing medical management for a period of at least six months, which must include both of the following:
  - Treatment with proton pump inhibitors (PPIs)/histamine type 2 receptor antagonists (H2RAs) with appropriate titration of dosing.
  - Non-pharmacologic management, including lifestyle and behavioral modifications, including dietary changes, body positioning, antacid use, and tobacco cessation if applicable.
SUMMARY:

**Bard EndoCinch Suturing System:**

Results of the first prospective multicenter trial on the endoscopic plication suturing technique, EndoCinch, suggested that the procedure was safe and associated with improved symptom control and reduction in the use of medications at the 6-month follow-up in patients with early-stage uncomplicated GERD. Quality of life (QOL), results showed a significant improvement in bodily pain, and there was a reduction in esophageal acid reflux. However, there was no difference in LES pressure measurements (Filipi et al., 2001). Small study size, short follow-up, and lack of a comparison group, as well as a 20% dropout rate and 17% retreatment rate, were limitations of this early study on EndoCinch.

Two small, uncontrolled prospective studies evaluated the efficacy of endoluminal plication suturing after 12 months. The first study reported that endoscopic suturing was a safe procedure, resulting in modest alterations in LES function. These changes were associated with minor, but significant, improvements in reflux control that were sustained at 12 months, including improvement in QOL and reduction in severity of reflux symptoms. However, after 6 months, plication loss was shown in 40% of the patients (Tam et al., 2004). In the second study, beneficial effects of the suturing treatment were reported on GERD symptoms, PPI use, and esophageal acid exposure. However, after 12 months, none of the patients still had correct placement of all of the initial sutures. This was considered a serious failure of the technique (Abou-Rebyeh et al., 2005). Limitations of both studies included size and lack of a control group.

Overall, the evidence from these studies suggests that EndoCinch may improve GERD symptoms and QOL scores, at least in the short term, and may reduce medication use in some patients. However, in the majority of studies, esophageal acid exposure and LES pressure were not improved, and rates of suture loss were high.

**Stretta System:**

Triadafilopoulos et al. (2001) conducted two prospective, multicenter trials in patients with a heterogeneous spectrum of clinical disease severity, but with minimal active esophagitis or hiatal hernia. The first study followed 47 patients for 6 months (Triadafilopoulos et al., 2001), and the second followed 118 patients for 12 months (Triadafilopoulos et al., 2002). Both studies reported that radiofrequency energy delivery significantly improved GERD symptoms, QOL, and esophageal acid exposure, while eliminating the need for antisecretory medications in a majority of patients. However, there were no improvements in other physiological measures such as LES pressure, peristaltic amplitude, and LES length. The procedure was well tolerated, with a low rate of self-limited complications. For both studies, limitations included lack of a comparison group, small to moderate sample size, and short to moderate length of follow-up.
A large, retrospective patient registry study (n=558), which involved a diverse group of patients at multiple centers, reported that the Stretta procedure was safe and resulted in significant GERD symptom control and patient satisfaction (Wolfsen and Richards, 2002). Treatment effect was durable beyond 1 year (for 88 patients who were followed beyond 1 year), and most patients were not taking antisecretory medications at follow-up. The limitations included retrospective study design with potential for selection, recall, and other biases, and short follow-up period for the majority of patients. Additionally, there were no data available on objective outcomes, such as esophageal acid exposure, and LES pressure and length.

A randomized, double-blind, sham-controlled, multicenter trial reported that radiofrequency energy delivery significantly improved GERD symptoms and QOL, compared with the sham procedure, at 6 months follow-up, but it did not decrease esophageal acid exposure, LES pressure, or medication use (Corley et al., 2003). Nevertheless, those individuals who were classified as responders, with > 50% reduction in the HRQL score, experienced significant median decreases in 24-hour acid exposure time. In addition to a 13% dropout rate, a greater than anticipated number of sham patients discontinued their medications, and, therefore, the study was underpowered. The study reported only minor transient adverse events.

Richards et al. (2003) conducted a prospective study that compared the Stretta procedure with a surgical procedure, laparoscopic fundoplication. Both patient groups were highly satisfied and had similar improvements in GERD symptoms and QOL, although follow-up was short term. However, only 58% of Stretta patients were not taking PPI medications post procedure, compared with 97% of surgical patients. More adverse events were reported in the laparoscopic fundoplication group compared with the Stretta group. The authors concluded that the Stretta system appears to be a moderately effective and safe alternative to laparoscopic fundoplication in well-selected patients. This comparative study was not randomized, and patients in the Stretta group had less severe disease, potentially biasing the results.

Two prospective studies suggested that the Stretta system was safe and significantly improved GERD symptoms and QOL, while eliminating the need for PPIs in the majority of patients. However, both studies were methodologically flawed, with small sample sizes, no comparison group, and short-term follow-up (Houston et al., 2003; Tam et al., 2003).

Two prospective studies were preformed to evaluate the long-term efficacy (4 years) of the Stretta procedure in patients with GERD (Noar and Lotfi-Emran, 2007; Reymunde and Santiago, 2007). Both studies concluded that Stretta was a safe, effective, and durable treatment that improved GERD symptoms and QOL, while reducing medication usage during the 4-year period of follow-up. The studies were uncontrolled and did not include objective outcomes.

In a European, multicenter, open-label, prospective study on the efficacy of the Stretta procedure in the treatment of GERD, investigators focused on objective parameters (esophageal acid exposure, manometry, LES pressure, reflux time and DeMeester score) in addition to medication use, GERD-HRQL and SF-36 scores (Meier et al., 2007). After 12 months, the procedure proved to be well tolerated and effective, with a favorable impact on medication use, LES pressure, esophageal acid exposure, and GERD symptoms scores. This study reported positive objective and subjective outcome measures. Lack of a control group was the most important shortcoming of this study.

Overall, the studies on the Stretta procedure reported improved GERD symptoms, QOL scores, and medication use in all studies. The studies monitoring esophageal acid exposure reported improvement or no effect. The largest study, and the studies with the longest follow-up, did not include this outcome measure.
**EsophyX System with SerosaFuse Fastener:**
The literature search revealed seven prospective, mostly small-sized uncontrolled studies that evaluated the feasibility, efficacy, and safety of transoral incisionless fundoplication using the EsophyX/SerosaFuse system in symptomatic GERD patients. The overall GERD population ranged from a very select to a wide case mix of patients. None of the studies included a control or comparison group. While there were some positive findings, the evidence is inconclusive regarding the subjective and objective efficacy of the procedure or to determine its long-term impact on health outcomes. In approximately two-thirds of the patients, recurrence of symptoms resulted in reinstitution of pharmacologic therapy. Surgical reintervention (laparoscopic Nissen fundoplication or repeat transoral incisionless fundoplication) was performed in approximately 13% of the overall study population. The evidence of durability of the procedure was limited. The available evidence showed a rate of serious procedural complications of approximately 6% (14 cases), including esophageal perforations, pleural perforations with pneumothorax, or intraluminal bleeding events.

The overall quality of the evidence is very low since the available studies lack adequate control or comparison groups, and have small populations, and inadequate follow-up times. Additional well-designed, independent comparative clinical trials with long-term follow-up are required to further evaluate the GERD plication procedure using the EsophyX/SerosaFuse system. Future trials need to define which subpopulation may benefit the most from this procedure, the magnitude of the benefits of this procedure, its efficacy relative to other GERD therapies, and its durability since symptom persistence has been problematical with most of the available endoluminal procedures. In addition, future studies must include objective assessment of outcomes such as pH testing and endoscopic evaluation to confirm improvements in health outcomes.

**Transesophageal Endoscopic injection and implantation of polymer material:**
Five studies involving endoscopic injection and implantation techniques were identified in the published, peer-reviewed literature. Of the three studies that evaluated Enteryx, one was a small pilot study and two were larger, multicenter studies by the same group of investigators who used the same study population and reported results separately after 6 and 12 months of follow-up. The following results were reported for Enteryx:

- Significant improvement in GERD symptoms at 6 months14 and 12 months.16,17 (Johnson and Ganz et al, 2003; Fockens and Bruno et al, 2004).
- Significant improvement in quality of life (QOL) at 6 months14 and 12 months. (Johnson and Ganz et al, 2003; Fockens and Bruno et al, 2004).
- Significant reduction in esophageal acid exposure at 6 months15 and 12 months. (Johnson and Ganz et al, 2003).
- Elimination of need for antisecretory medications in most patients.14-16 (Devière and Pastorelli et al, 2002; Johnson and Ganz et al, 2003).
- No significant change in LES pressure. (Devière and Pastorelli et al, 2002).

Only one small prospective study evaluated PMMA implantation in patients followed for 5 to 11 months (mean 7.2 months). (Feretis and Benakis et al, 2001). Results were:

- Significant improvement in GERD symptoms.
• Elimination of need for antisecretory medications in most patients.
• No serious complications; mild transient complications included chest pain, self-limiting bleeding, dysphagia, and gas-bloat syndrome.

Only one study evaluated the Gatekeeper procedure, combining data from two prospective European multicenter trials. (Johnson and Ganz et al, 2003). Results were:
• Significant improvement in GERD symptoms and QOL (physical score only) at 6 months.
• Significant increase in LES pressure at 6 months.
• Significant reduction in esophageal acid exposure at 6 months.
• Data on medication use were not collected systematically at all sites.
• Two serious adverse events (3.0%; pharyngeal perforation and postprandial nausea) occurred, but patients recovered uneventfully; mild complications included sore throat, retrosternal pain, and epigastric pain.

The Angelchik anti-reflux prosthesis: This device was approved (PMA) by the FDA in 1979. It is a soft, collar-shaped, silicone elastomer shell filled with silicone gel, with an internal diameter of 3.1 cm. It is placed around the esophagus under the diaphragm and above the stomach, and is secured by 2 reinforced Teflon straps around the gastro-esophageal junction. The alleged advantage of the Angelchik device is the simplicity of the procedure -- its placement requires only limited dissection, thus decreasing the operating time. Since its introduction, more than 25,000 prostheses have been inserted into patients worldwide. Early faulty design had caused breakage of the circumferential strap, and led to migration of the device. Modification of the original strap to 2 re-inforced, non-circumferential straps by the manufacturer appears to have minimized the migration problem. However, complications as a consequence of implantation of the Angelchik prosthesis have been reported in as many as 10 to 20 % of patients. An American Medical Association’s DATTA evaluation of the Angelchik prosthesis found that this device has not been established as safe and effective for routine use in the treatment of GERD. Long-term studies concluded that the Angelchik device causes long-term dysphagia in many patients, severe enough to require its removal in 25 % of these patients. Thus, its continual use cannot be recommended.

**APPLICABLE CODES:**

*The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.*

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>C9724</td>
<td>Endoscopic full-thickness plication in the gastric cardia using endoscopic plication system (EPS); includes endoscopy</td>
</tr>
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</table>

<table>
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<tr>
<th>ICD-9 Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>530.1x*</td>
<td>Esophagitis</td>
</tr>
<tr>
<td>530.11</td>
<td>Reflux esophagitis</td>
</tr>
<tr>
<td>530.20, 530.21</td>
<td>Esophageal ulceration</td>
</tr>
<tr>
<td>530.3</td>
<td>Esophageal stricture</td>
</tr>
<tr>
<td>530.81</td>
<td>Esophageal reflux, gastroesophageal reflux</td>
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</table>
530.85 | Barrett’s esophagus
553.3 | Hiatal hernia

The x represents a range of codes; it is dependent on the specific diagnosis.

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
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<tr>
<td>K21.0</td>
<td>Gastro-esophageal reflux disease with esophagitis</td>
</tr>
<tr>
<td>K21.9</td>
<td>Gastro-esophageal reflux disease without esophagitis</td>
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<table>
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<tr>
<th>CPT® Code</th>
<th>Description</th>
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<tr>
<td>43228</td>
<td>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</td>
</tr>
<tr>
<td>43257</td>
<td>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</td>
</tr>
<tr>
<td>43258</td>
<td>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</td>
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<tr>
<td>43499</td>
<td>Unlisted procedure, esophagus</td>
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<tr>
<td>43999</td>
<td>Unlisted procedure, stomach</td>
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<tr>
<td>49999</td>
<td>Unlisted procedure, abdomen, peritoneum and omentum</td>
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<tr>
<td>C9724</td>
<td>Endoscopic full-thickness plication of the stomach using endoscopic plication system (eps); includes endoscopy</td>
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REFERENCES:


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<tr>
<td>44. Fennerty MB.</td>
<td>Endoscopic therapy for gastroesophageal reflux disease: what have we learned and what needs to be done? Gastrointest Endosc Clin N Am. 2003b;13(1):201-209.</td>
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61. Hayes Stretta Procedure (Mederi Therapeutics Inc.) for Gastroesophageal Reflux Disease (GERD)


**POLICY HISTORY:**

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<tr>
<td>11/21/2013</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
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<tr>
<td>11/25/2013</td>
<td>Published to UCare.org</td>
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