**Clinical Review Criteria**

**Treatment of Gastroesophageal Reflux Disease - GERD**

- Stretta Procedure
- CR BARD’s Endoscopic Suturing System
- Endoscopic Placement of a Bulking Material at the Lower Esophageal Sphincter
- LINX Reflux Management System

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**Criteria**

**For Medicare members**

<table>
<thead>
<tr>
<th>Procedure(s):</th>
<th>CPT Code(s)</th>
<th>CMS Coverage Guidelines – NCD, LCD, LCA</th>
<th>KPWA Medical Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transesophageal radiofrequency energy <strong>Examples:</strong> CSM Stretta™ System, or the Stretta procedure</td>
<td>43257</td>
<td>Non-Covered Services (L35008)</td>
<td>Kaiser Permanente has elected to use the Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta) (A-0209) MCG* for medical necessity determinations. This service is not covered per MCG guidelines.</td>
</tr>
<tr>
<td>Transoral incisionless fundoplication (TIF) <strong>Examples:</strong> EsophyX</td>
<td>43210</td>
<td>Non-Covered Services (L35008) (See also LCA for Non-coverage of Transoral Incisionless Fundoplication (A52885) regarding non-coverage of TIF).</td>
<td>KPWA Medical Policy of insufficient evidence (see below).</td>
</tr>
<tr>
<td>Linx Reflux Management System</td>
<td>C9737, 43284, 43285</td>
<td>Non-Covered Services (L35008)</td>
<td>KPWA Medical Policy of insufficient evidence (see below).</td>
</tr>
<tr>
<td>Endoscopic injection of a bulking agent <strong>Examples:</strong> pyrolytic carbon-coated zirconium oxide spheres (Durasphere®)</td>
<td>43192, 43201, 43499</td>
<td>Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria of “insufficient evidence” for medical necessity determinations. Use the Non-Medicare criteria below.</td>
<td>KPWA Medical Policy of insufficient evidence (see below).</td>
</tr>
<tr>
<td>Endoscopic submucosal implantation or injection of a biocompatible polymer <strong>Examples:</strong> Enteryx,</td>
<td>43192, 43201, 43499</td>
<td>Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria of “insufficient evidence” for medical necessity determinations. Use the Non-Medicare criteria below.</td>
<td>KPWA Medical Policy of insufficient evidence (see below).</td>
</tr>
</tbody>
</table>
For Non-Medicare members
Kaiser Permanente has elected to use the Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta) (A-0209) MCG* for medical necessity determinations. This service is not covered per MCG guidelines.

*The MCG manuals are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:
• Last 6 months of clinical notes from requesting provider &/or specialist (GI, general surgeon)

<table>
<thead>
<tr>
<th>Service</th>
<th>Criteria Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR BARD’s Endoscopic Suturing System</td>
<td>There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.</td>
</tr>
<tr>
<td>(Endocinch Therapy, Endoluminal Plication)</td>
<td></td>
</tr>
<tr>
<td>Endoscopic Placement of a Bulking Material at the Lower Esophageal Sphincter</td>
<td></td>
</tr>
<tr>
<td>Transoral Incisionless Fundoplication</td>
<td></td>
</tr>
<tr>
<td>LINX Reflux Management System</td>
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</tbody>
</table>

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Gastroesophageal reflux disease (GERD) is a one of the most common medical disorders in the United States. It is a chronic disorder that is primarily caused by transient inappropriate relaxation or abnormally low resting pressure of the lower esophageal sphincter (LES). This intermittently exposes the esophagus to gastric acid and enzymes. GERD usually manifests as heartburn, regurgitation, or dysphagia. Patients may have significant daily symptoms with a substantial effect on their quality of life. Complications of the disease include Barrett’s esophagus, esophagitis, laryngeal injury, pneumonia, and esophageal stricture.

Current therapy for GERD begins with lifestyle changes and medical treatment, which proved to be effective in more than three fourths of the patients. Pharmacotherapy reduces the frequency, duration and/or potency of the refluxate. However, the long-term costs are high, and the recurrence of symptoms could be as high as 90% after the cessation of medication. Patients who do not tolerate, or respond well to medical treatment, as well as those who want to avoid life-long treatment, may be candidates for surgery. Surgical approaches are used to create barriers to the reflux. Nissen fundoplication is the most commonly used surgical procedure with a response rate as high as 90% at 5-year follow-up (Lafullarde, 2001).

More recently endoscopic or endoluminal approaches for treating GERD have either been approved or are still under trial. These various methods can be divided in three broad categories:
1. Methods that create a controlled stricture (radiofrequency),
2. Methods that attempt to create a fundoplication,
3. Methods that bulk the gastroesophageal junction (injecting bulking agents).
According to the Montreal Consensus, gastroesophageal reflux disease (GERD) is defined as a condition which develops when the reflux of stomach contents cause troublesome symptoms and/or complications. GERD is a mechanical disorder that is caused by a defective lower esophageal sphincter, a gastric emptying disorder, or failed esophageal peristalsis. Typical symptoms of GERD include heartburn and regurgitation; however, overtime reflux can cause ulceration, Barrett’s esophagus, airway disease, and esophageal cancer. It is estimated that 40% of individuals in the United States suffer from GERD on a monthly basis. Current treatment options for GERD include long-term use of acid suppression medications or surgical intervention. While treatment with acid suppressing medications such as proton pump inhibitors and histamine 2-receptor blockers are effective, they do not treat the underlying mechanical disorder. Additionally, not all patients respond to these therapies (Zagol 2011, Stefanidid 2010).

Surgery is another treatment option for patients with GERD. According to the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), surgical therapy should be considered in patients with a diagnosis of reflux who (Stefanidid 2010):

- Have failed medical management (due to inadequate symptom control, severe regurgitation not controlled with acid suppression, or medication side-effects)
- Opt for surgery despite medical management (due to quality-of-life considerations, lifelong need for medication intake, expense of the medication, etc.)
- Have complications of GERD (e.g., Barrett’s esophagus, peptic stricture)
- Have extra-esophageal manifestations (asthma, hoarseness, cough, chest pains, aspiration)

There are a variety of surgical procedures used for the treatment of GERD. Currently, there is no consensus on the best procedure for all patients. The choice of procedure is often based on anatomic considerations and expertise; however, the laparoscopic Nissen fundoplication has emerged as one of the most widely used techniques. With fundoplication, the gastric fundus is wrapped around the lower end of the esophagus to reduce gastric reflux. The fundal wrap can be either total (360°) or partial (less than 360°). Studies suggest that approximately 90% of patients who undergo Nissen fundoplication achieve symptom relief. Side effects of this procedure include dysphagia, hyperflatulence, inability to belch, bloating, and postsurgery bowel symptoms (AGA 2008, Stefanidid 2010).

Transoral incisionless fundoplication using the EsophyX device (EndoGastric Solutions, Inc., Redmond, WA) has been proposed as a less invasive alternative to traditional surgical procedures. This procedure attempts to decrease the reflux of stomach acid into the esophagus through the reconstruction of an anti-reflux barrier. The EsophyX device is inserted transorally, under direct endoscopic visualization, into the stomach and is positioned at the junction of the stomach and the esophagus. Once positioned, the device uses suction and transmural fasteners to facilitate the recreation of the esophageal gastric valve. The result is an omega shaped valve 3-5 cm in length and 200-300° in circumference. This procedure may also reduce hiatal hernias that are less than 2 cm in size through the use of a built in vacuum invaginator. As this procedure is incisionless and can often be performed on an outpatient basis it is an attractive alternative to conventional surgical procedures (Jafri 2009, Louis 2010).

The EsophyX system had been cleared by the FDA for use in transoral tissue approximation, full-thickness plication and ligation in the gastrointestinal tract for the treatment of GERD in patients with symptomatic chronic GERD who require and respond to pharmacological therapy. This device may also be used to narrow the gastroesophageal junction and reduce hiatal hernia ≤2 cm in size in patients with symptomatic chronic GERD. The EsophyX system has not been previously reviewed by the Medical Technology Assessment Committee and is being review based on request from bariatric surgery and a member appeal.

**Evidence and Source Documents**

- **CR BARD’s Endoscopic Suturing System (Endocinch Therapy, Endoluminal Plication)**
- **Endoscopic Placement of a Bulking Material at the Lower Esophageal Sphincter**
- **LINX Reflux Management System**
- **Stretta Procedure (Electro-Surgical Coag-Radio-Frequency Application- Curon Medical Inc’s CSM)**
- **Transoral Incisionless Fundoplication**

**Medical Technology Assessment Committee (MTAC)**

**CR BARD’s Endoscopic Suturing System (Endocinch Therapy, Endoluminal Plication) for the Treatment of GERD**
Gastroesophageal reflux disease (GERD) is a chronic disorder that affects as many as 14 million Americans. It is primarily caused by transient inappropriate relaxation or abnormally low resting pressure of the lower esophageal sphincter (LES). This intermittently exposes the esophagus to gastric acid and enzymes. GERD usually manifests as heartburn, regurgitation, or dysphagia. Patients may have significant daily symptoms with a substantial effect on their quality of life. Complications of the disease include Barrett’s esophagus, esophagitis, laryngeal injury, pneumonia, and esophageal stricture. Current therapy for GERD begins with lifestyle changes and medical treatment, which proved to be effective in more than three fourths of the patients. Pharmacotherapy reduces the frequency, duration and/or potency of the refluxate. However, the long-term costs are high, and the recurrence of symptoms could be as high as 90% after the cessation of medication. Patients who do not tolerate, or respond well to medical treatment, as well as those who want to avoid life-long treatment, may be candidates for surgery. Surgical approaches are used to create barriers to the reflux. Nissen fundoplication is the most commonly used surgical procedure with a response rate as high as 90% at 5-year follow-up (Lafullarde, 2001). More recently endoscopic or endoluminal approaches for treating GERD have either been FDA approved or are still under investigation. These various methods can be divided in three broad categories: 1. Methods that attempt to create a fundoplication (plicating techniques), 2. Methods that create a controlled stricture (radio frequency), and 3. Methods that bulk the gastroesophageal junction (injecting bulking agents). The ideal procedure should be safe, effective over a long term, and would not affect future surgical options. Currently, there are three plicating devices: The endoCinch (C.R. Bard’s endoscopic suturing system, the ESD, and the Full-Thickness Plicator. The first two have been approved by the FDA, and the last was not approved to date. Endoluminal plication uses mechanical techniques to hinder reflux by approximation of tissue at or below the gastroesophageal junction. The EndoCincher (CR BARD Endoscopic technologies, Massachusetts, USA) system was the first FDA approved endoscopic sewing machine method for treating GERD. It was developed by Swain CP et al in London UK, in the mid-1980s. In the Bard method, an oroesophageal tube (19.7 mm in diameter and 30 cm long) is placed to facilitate passage of the suturing device. The suture capsule, which is similar to a sewing machine, is attached to an endoscope and loaded with a suture. After placing the suture capsule, under vision, over the selected site at the gastroesophageal junction, suction through the external vacuum line is applied. This pulls a fold of tissue into the capsule cavity, and the needle driver places the suture. Suction is released and the tissue is withdrawn from the capsule. The procedure is repeated on an adjoining site. Drawing two sutured sites together creates a plication. It is reported that the procedure is technically difficult, has a steep learning curve, and that the results are likely to be operator-dependent. Conscious sedation might not be sufficient and a general anesthesia may be needed. Adverse effects associated with the procedure include pharyngitis, vomiting, abdominal pain, chest pain, mucosal tear, hypoxia, and bleeding. The Bard’s Endoscopic Suturing system was FDA approved in March 2000, for the treatment of GERD. The ESD (Wilson-Cook Medical, Winston-Salem, N.C.) another endoscopically assisted endoluminal suturing device was also approved by the FDA for soft-tissue apposition. The Full-Thickness Plicator (Ndo Surgical, Inc, Mansfield, Mass) is another plication device that had not been approved by the FDA at time the search was made.

**Endocinch Therapy in the Treatment of GERD**

**Evidence Conclusion:** The studies reviewed show that the procedure is associated with a reduction in the frequency and severity of heartburn and regurgitation symptoms. Patients had an improved quality of life, and there was a significant reduction in the use of antisecretory medications in two of the studies. However, the procedure was performed on a highly selected group of patients (those with hiatal hernia >3 cm, esophageal stricture and Barrett’s esophagus were excluded). Moreover, the follow-up duration of all studies was short, and insufficient to determine the recurrence rate and long term-efficacy of the procedure. Filipi’s study was an RCT, yet the patients were randomized to two different suture configurations of the same procedure and not to an alternative treatment. Randomized controlled studies with long-term follow-up are needed to compare the procedure with other medical and surgical antireflux therapies, and assess the sustained effect of the procedure and the long-term relief from symptoms without using antisecretory medications.

**Articles:** The search yielded 12 articles, all on the Bard technique. There was one randomized controlled trial, one case-control study and one case series. The rest were reviews, tutorials, letters or dealt with the technical aspect of the procedure. There were no published studies on the Wilson-Cook ESD, or the Ndo Full-Thickness Plicator. Evidence tables were created for the three studies identified in the search: Filipi CJ, Lehman GA, Rothstein RI, et al. Transoral flexible endoscopic suturing for treatment of GERD. A multicenter trial. Gastrointest Endosc 2001; 53:416-422. See Evidence Table. Mahmoud Z, McMahon BP, Arfin Q, et al. Endocinch therapy for gastro-esophageal reflux disease: a one year prospective study. Gut 2003, 52:34-39. See Evidence Table. Velanovich V, Ben-Menachem T, and Goel S. Case-control comparison of endoscopic gastroplication, with laparoscopic fundoplication in the management of gastroesophageal reflux disease. Early symptomatic outcomes. Surg Laparosc Endosc Percutan Tech 2002, 12:219-223. See Evidence Table.
The use of Endocinch therapy in the treatment of GERD does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

**Endoscopic Placement of a Bulking Material at the Lower Esophageal Sphincter for the Treatment of GERD**

**BACKGROUND**
Gastro-esophageal reflux disease (GERD) is a chronic disorder that affects as many as fourteen million Americans. It is primarily caused by transient inappropriate relaxation or abnormally low resting pressure of the lower esophageal sphincter (LES). This intermittently exposes the esophagus to gastric acid and enzymes. GERD usually manifests as heartburn, regurgitation, or dysphagia. Patients may have significant daily symptoms with a substantial effect on their quality of life. Complications of the disease include Barrett’s esophagus, esophagitis, laryngeal injury, pneumonia, and esophageal stricture. Current therapy for GERD begins with lifestyle changes and medical treatment, which proved to be effective in more than three fourths of the patients. Pharmacotherapy reduces the frequency, duration and/or potency of the refluxate. However, the long-term costs are high, and the recurrence of symptoms could be as high as 90% after the cessation of medication. Patients who do not tolerate, or respond well to medical treatment, as well as those who want to avoid life-long treatment, may be candidates for surgery. Surgical approaches are used to create barriers to the reflux. Nissen fundoplication is the most commonly used surgical procedure with a response rate as high as 90% at 5-year follow-up ([Lafullarde, 2001]).

More recently endoscopic or endoluminal approaches for treating GERD have either been approved or are still under trial. These various methods can be divided in three broad categories: 1. Methods that create a controlled stricture (radiofrequency), 2. Methods that attempt to create a fundoplication, and 3. Methods that bulk the gastroesophageal junction (injecting bulking agents). The ideal procedure should be safe, effective, with long-term effects, and do not affect future surgical options. Endoscopic injection of an inert material into the submucosa of the distal esophagus has been tried with the intention to impede the reflux. The bulking effect results from both the material injected and the tissue response. Examples of the bulking agents used are bovine collagen, ethylene vinyl alcohol, polytetrafluoroethylene and others. These are injected through long catheters and small gauge needles under endoscopic guidance. In the experiments conducted the resulting improvement in reducing the LES pressure and GERD symptoms were temporary, and did not last long, either due to the biodegradation or migration of the injected material. Other nonbiogradable substances, injected into the submucosa or muscle, and with the use of different application techniques are still under trial. These methods are still in the investigational stage and are not approved by the FDA.

**02/13/2003: MTAC REVIEW**

**Bulking Material in the Treatment of GERD**

**Evidence Conclusion:** There is insufficient evidence to determine the efficacy and safety of endoscopic injection of bulking material for the treatment of GERD.

**Articles:** The search did not yield any study. Two studies were revealed from review articles. Both were pilot studies with no comparison groups. One included only a series of 15 patients (10 in Brussels and 5 in Rome), and the other was a case series with only ten participants.

The use of bulking material in the treatment of GERD does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

**Magnetic Sphincter Augmentation – (LINX® Reflux Management System)**

**BACKGROUND**
Gastroesophageal Reflux Disease (GERD) is an extremely common clinical manifestation of excessive reflux of acidic gastric components. Also referred to as chronic acid reflux, GERD is characterized by a chronic, often progressive dysfunction of the lower esophageal sphincter (LES) allowing acids and bile from the stomach to flow back into the esophagus. Common symptoms include heartburn, regurgitation and dysphagia and can adversely impact the quality of life by interfering with daily activities, disturbing sleep, and reducing productivity. Left untreated GERD can lead to more serious complications such as esophageal stricture, Barrett’s esophagus and esophageal cancer ([Gorecki 2001]). Simple diet and lifestyle modifications can ease some of the symptoms associated with GERD, however, more severe or frequent cases may require pharmaceutical treatment with antacids, H2-receptor antagonists or proton pump inhibitors (PPIs). Some cases of GERD, however, will not respond to medications and may require surgical intervention. Laparoscopic fundoplication (LF), has long been considered the gold standard of antireflux surgery. The technique involves wrapping the upper part of the stomach (gastric fundus) around the lower end of the esophagus in an effort to reinforce the LES. Although LF has a high success rate, the procedure is non-reversible and has been associated with a variety of potential side-effects such as dysphagia, loss of belching and vomiting and increased flatulence and bloating. The LINX® Reflux Management System, developed by Torax® Medical (St. Paul, MN), was designed to prevent back flow into the
esophagus and is suggested as an alternative to anti-reflux surgery. More specifically, the magnetic sphincter augmentation (MSA) device is a series of interlinked magnetic beads implanted laparoscopically at the junction between the esophagus and stomach that acts as a reinforcement of the LES. The device relies on small wires that allow the magnetic beads to expand and allow the flow of foods and liquids into the stomach while preventing reflux at the same time. According to the manufacturer, the LINX Reflux Management System requires less recovery time, provides immediate relief and faster return to solid foods compared with other surgical interventions. To add to this, the device can be removed if side-effects, such as dysphagia, pain and bloating, become unbearable. The LINX® Reflux Management System received US Food and Drug Administration (FDA) approval on March 22, 2012. The device is intended for use in patients with GERD who continue to have symptoms despite the use of a maximum medical therapy for the treatment of reflux. More specifically, it is intended for use in patients who would be considered candidates for anti-reflux surgery. This topic has not previously been reviewed by the Medical Technology Assessment Committee (MTAC) and is currently under consideration due to coverage decision support.

12/15/2014: MTAC REVIEW
LINK Reflux Management System
Evidence Conclusion: A feasibility trial by Lipham and colleagues, included 44 patients and aimed to assess the long-term safety and effectiveness of the LINX Reflux Management System (up to 3.7 years). In this study, patient’s baseline measurements were used as the control for comparison with post-implant measurements. In all outcome measures improvements were seen with reduced esophageal acid exposure, improved GERD-HRQL scores and decreases in use of PPIs. As a result, the investigators concluded that sphincter augmentation with LINX provides long-term clinical benefits with no safety issues (Lipham, DeMeester et al. 2012). Evidence Table 1
In the second study, a pivotal trial by Ganz and colleagues, the investigators sought to evaluate the safety and effectiveness of the LINX Reflux Management System. The study included 100 patients with GERD and assessed esophageal pH as well as manometry and barium esophagography. The investigators report that 64% (95% CI, 54%-73%) of patients achieved success with normalization of esophageal acid exposure, or a ≥50% reduction in exposure at one year. Additional endpoints were also promising with 50% or more improvements seen in 92% of patients on the GERD-Health Related Quality of Life (HRQL) questionnaire. Although the authors concluded that the LINX device resulted in a decreased exposure to esophageal acid, improved reflux symptoms and allowed cessation of PPIs in the majority of patients, they also noted that additional prospective RCTs with appropriate controls are necessary for confirmation. (Ganz, Peters et al. 2013). Finally, the third study, by Riegler and colleagues, evaluated 249 patients who had undergone MSA and LF and completed one-year follow-up. With the overall goal to compare the clinical experience of each procedure, the investigators evaluated patients reflux symptoms, PPI use, side effects and complications. At one year, both groups showed improvement in total GERD-HRQL score (20 vs. 3 in the MSA group and 23 vs. 3.5 in the LF group) and discontinuation of PPIs was higher in the MSA group with 81.8% of patients abstaining and only 63% in the LF group (P=0.009). The investigators concluded that both MSA and LF were comparable but that MSA should be considered as the first-line surgical option Evidence Table 3. Adverse events and complications were documented in all three of the critically appraised publications. In addition, a recent publication from Lipham and colleagues provides a safety analysis of the first 1,000 patients treated with the MSA device. The analysis included safety related events collected from the published literature, FDA databases for device related complications and information provided by the manufacturer for over 1,000 patients treated worldwide between February 2007 and July 2013. This paper was not critically appraised, however, the safety data is generally summarized in table one, below. (Lipham, Taiganides et al. 2014).

<table>
<thead>
<tr>
<th>Source of data</th>
<th># of events included in analysis</th>
<th>Breakout</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical literature</td>
<td>32</td>
<td>• 9 device removal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 20 esophageal dilation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 3 hospital readmissions</td>
</tr>
<tr>
<td>MAUDE database</td>
<td>20</td>
<td>• 19 device removal (includes US and OUS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 1 device erosion</td>
</tr>
<tr>
<td>Manufacturer’s database</td>
<td>59</td>
<td>• 8 device removal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 1 intra/perioperative complication</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 11 hospital readmission</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 39 esophageal dilation</td>
</tr>
</tbody>
</table>

Generally speaking, the body of evidence is limited by small sample sizes, short-term follow-up, as well as a lack of randomization and adequate comparators. Selection bias may be an issue in the third study as the selection of
intervention was ultimately made by the surgeon at the time of surgery. It should also be noted that the majority of studies assessing the LINX Reflux Management System are either funded by the device manufacturer or authored by consultants to the manufacturer. Ultimately the body of evidence provides insufficient evidence to support the safety and effectiveness of the LINX Reflux Management System. Conclusions: There is insufficient evidence to support the effectiveness of the LINX Reflux Management System in patients with refractory GERD. There is insufficient evidence to support the safety of the LINX Reflux Management System in patients with refractory GERD.

**Articles:** The literature search revealed just over 100 publications relating to treatment of GERD using sphincter augmentation many of which were not directly applicable to the objective at hand. No randomized controlled trials (RCTs) were revealed comparing the LINX Reflux Management System with alternative surgical interventions such as LF. The FDA’s 2012 approval relied on two publications, a pivotal clinical trial and a feasibility study, which were selected for critical appraisal. Post-approval studies of the LINX Reflux Management System, required by the FDA, are currently ongoing. In addition to the pivotal and feasibility trial, two additional studies were considered. The first was a recent observational study comparing MSA to laparoscopic fundoplication (LF) and the latter, a safety analysis of the first 1,000 patients treated with MSA (this study was not critically appraised but discussed in the evidence summary). The following articles were selected for critical appraisal: Lipham JC, DeMeester TR, Ganz RA, et al. The LINX® reflux management system: confirmed safety and efficacy now at 4 years. Surgical Endoscopy. 2012;26:2944-2949. See Evidence Table 1. Ganz RA, Peters JH, Horgan S, et al. Esophageal Sphincter Device for Gastroesophageal reflux disease. NEJM. 2013;368(8):719-72. Reigler M, Schoppman, Bonavina L, et al. Magnetic sphincter augmentation and fundoplication for GERD in clinical practice: one-year results of a multicenter, prospective observational study. Surgical Endoscopy. 2014. See Evidence Table 3.

The use of LINX Reflux Management System does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

**Stretta Procedure (Electro-Surgical Coagulation-Radio-Frequency [RF] Application- Curon Medical Inc’s CSM Stretta System) for the Treatment of GERD**

**BACKGROUND**

Gastroesophageal reflux disease (GERD) is one of the most common medical disorders in the United States. It is a chronic disorder that is primarily caused by transient inappropriate relaxation or abnormally low resting pressure of the lower esophageal sphincter (LES). This intermittently exposes the esophagus to gastric acid and enzymes. GERD usually manifests as heartburn, regurgitation, or dysphagia. Patients may have significant daily symptoms with a substantial effect on their quality of life. Complications of the disease include Barrett’s esophagus, esophagitis, laryngeal injury, pneumonia, and esophageal stricture. Current therapy for GERD begins with lifestyle changes and medical treatment, which proved to be effective in more than three fourths of the patients. Pharmacotherapy reduces the frequency, duration and/ or potency of the refluxate. However, the long-term costs are high, and the recurrence of symptoms could be as high as 90% after the cessation of medication. Patients who do not tolerate, or respond well to medical treatment, as well as those who want to avoid life-long treatment, may be candidates for surgery. Surgical approaches are used to create barriers to the reflux. Nissen fundoplication is the most commonly used surgical procedure with a response rate as high as 90% at 5-year follow-up (Lafullarde, 2001). More recently options include injection therapy to the lower esophageal sphincter, endoscopic sewing procedures, and radiofrequency ablation therapy. The ideal procedure should be safe, effective for a long time, and would not affect future surgical options. This review evaluates the radiofrequency techniques. Radiofrequency (RF) energy has been used for the general surgical application of tissue coagulation for more than 70 years. RF energy leads to collagen shrinkage, and in turn tissue contraction and tightening. Recently RF is being used for different clinical purposes, including its application to the gastroesophageal junction. The Stretta System (Curon Medical, Sunnyvale, CA) consists of a RF control module and a flexible Stretta catheter. The catheter has a 20F soft bougie tip and a balloon, which opens in a surrounding basket. On its widest area after balloon inflation, the catheter has four nickel-titanium needle electrodes (5.5 mm long), which can be extended in the LES muscle. The catheter is introduced transorally and positioned at the Z-line (squamocolumnar junction). It aspirates and irrigates the esophageal lumen with water to prevent surface injury. The four electrodes provide 60 to 300 J of RF energy to each needle, heating the surrounding muscle tissue to the target temperature between 65° and 85° C while cooling the mucosal with its irrigation system. 15 to 25 lesion sets are created in the region from 2 cm proximal to 1 cm distal to the Z-line by rotating the catheter 45 degrees and varying its linear position. The RF-induced burns eventually scar down and create a reflux barrier. The mechanism of action of RF is reported to be a reduction in the frequency of LES relaxations, as well as physical alteration in tissue compliance and wall thickness of the gastroesophageal junction. The Curon Medical Inc.’s CSM Stretta System was approved by the FDA on April 18, 2000. Curon recommends the device for mild or moderate cases of GERD only. The Stretta procedure is reported to be easy to learn and apply. However, there is
a concern that if the scars continue to contract, at least some patients will develop a stricture that could be difficult to manage. Other adverse events that may be associated with the procedure include chest pains, fever, mucosal tear, and dysphagia.

12/10/2003: MTAC REVIEW

Electro-Surgical Coagulation (radio-frequency application) in the treatment of GERD

Evidence Conclusion: Of the studies reviewed, a RCT compared Stretta procedure to sham treatment, and a non-randomized longitudinal study compared it to laparoscopic fundoplication. The third was just a survey from a registry with no control or comparison group. Corley et al’s trial was randomized and controlled however, it was a small study, with a high dropout rate, and some baseline differences between the two groups, that were not adjusted for in the analysis. Moreover, the procedure was compared to a sham treatment and not to another intervention e.g. laparoscopic fundoplication. The follow-up duration might have been insufficient to determine the long-term sustained effects, or potential late harms that could be associated with the procedure. In addition, the patients included in the study were highly selected for the trial and may not represent typical GERD patients. Richard et al’s study was not randomized and patients were highly selected for each procedure. It was not blinded, not powered, and the follow-up duration was as short as 2 months for some patients, which is insufficient to determine the long-term durability of benefits or harms of the procedure. Both Corley’s and Richard’s studies were financially supported by Curon Medical, the manufacturer of the Stretta system. The third study reviewed was a retrospective survey of patients who underwent the Stretta procedure in several centers, with no reference to the inclusion/exclusion criteria, or techniques used for performing the procedure. Overall, the results of the studies show that radiofrequency application to the gastroesophageal junction to selected GERD patients is associated with improvement in symptoms and quality of life compared to sham treatment or laparoscopic fundoplication. The heartburn improvement associated with GERD vs. sham treatment was significant in the per protocol analysis but not with the ITT analysis in Corley’s trial.

Articles: The search yielded 9 articles. There were no meta-analyses or randomized controlled trials. There were only three empirical studies all of which were case series. One had a very small sample, and only three months follow-up. The other two with relatively larger sample sizes, and longer follow-up duration were selected for critical appraisal. In December 2001, Curon Medical announced the completion of two major clinical trials, one of which is a RCT of the Stretta vs. sham treatment. To date these studies have not been published. Evidence tables were created for the following studies: Triadafilapoulos G, DiBaise JK, Nostrant T, et al. The Stretta procedure for the treatment of GERD: 6 and 12-month follow-up of the U.S. open label trial. Gastrointest Endosc 2002, 55149-156. See Evidence Table. Houston H, Khaitan L, and Richards WO. First year experience of patients undergoing the Stretta procedure. Surg Endosc 2002, Nov 20. See Evidence Table.

The use of electro-surgical coagulation (radio-frequency application) in the treatment of GERD does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

02/13/2003: MTAC REVIEW

Electro-Surgical Coagulation (radio-frequency application) in the treatment of GERD

Evidence Conclusion: The two case series reviewed show that the Stretta procedure may be a promising treatment for GERD. Patients had significant reduction in the esophageal acid exposure and use of antisecretory medication, as well as significant improvement in their quality of life scores, compared to those before the intervention. However, the studies were case series that provide the lowest grade of evidence. In the studies reviewed, participants were highly selected for the procedure. Only patients with small or no hiatal hernias, no dysphagia, stricture, or Barrett’s disease as well as those whose symptoms are controlled by pharmacological treatment were included in the studies. Moreover, the interpreters of the results were not blinded to the treatment, the follow-up duration was insufficient, dropout rate was high, and there were no comparison or control groups. In conclusion, there is insufficient evidence to determine the efficacy of the Stretta procedure in the treatment of GERD. Prospective randomized studies with larger sample sizes, comparison to another intervention or treatment, and a long follow-up duration will be needed.

The use of electro-surgical coagulation (radio-frequency application) in the treatment of GERD does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

**EndoGastric Solutions StomaphyX™ Endoluminal Fastener, InScope™ Tissue Apposition System, Transoral Incisionless Fundoplication**

**BACKGROUND**

Obesity surgery: The EndoGastric Solutions StomaphyX™ endoluminal fastener and delivery system is a sterile, single-use device for use in transoral tissue approximation and ligation in the GI tract. The system consists of an ergonomic, flexible fastener delivery device and sterile polypropylene fastener implants. The device is introduced into the body through the mouth under endoscopic visualization. Once inside the stomach, the stomach wall is suctioned into the tissue port on the StomaphyX™ creating a large plication. Non-resorbable polypropylene fasteners are then deployed across the fold to hold the tissue in place. Typically 10 to 20 folds are required depending on the patient's anatomy. The pleats created in the stomach will reduce its size, which would potentially lead to early satiety and weight loss. According to the manufacturer, the StomaphyX™ procedure is incisionless, adjustable, and reisible. It is usually performed as an outpatient procedure, and is intended for individuals who want an alternative to invasive weight loss surgery, or those who have had previous gastric bypass surgery and are regaining weight. The EndoGastric Solutions StomaphyX™ endoluminar fastener and delivery system was cleared for marketing by the FDA in February 2007 for use in endoluminal trans-oral tissue approximation and ligation in the GI tract. The InScope™ Tissue Apposition System is a sterile, single patient used disposable suture system for approximating and securing soft tissue within the gastrointestinal tract. It is intended to perform suturing in conjunction with endoscopes having a working channel of 2.8 mm or larger. The system can be used to treat variety of defects endoscopically including ulcers and perforations (FDA Web site). The InScope™ Tissue Apposition System was cleared by the FDA for marketing in January 2007 to be used for the placement of sutures and approximation of soft tissue. GERD: According to the Montreal Consensus, gastroesophageal reflux disease (GERD) is defined as a condition which develops when the reflux of stomach contents cause troublesome symptoms and/or complications. GERD is a mechanical disorder that is caused by a defective lower esophageal sphincter, a gastric emptying disorder, or failed esophageal peristalsis. Typical symptoms of GERD include heartburn and regurgitation; however, overtime reflux can cause ulceration, Barrett’s esophagus, airway disease, and esophageal cancer. It is estimated that 40% of individuals in the United States suffer from GERD on a monthly basis. Current treatment options for GERD include long-term use of acid suppression medications or surgical intervention. While treatment with acid suppressing medications such as proton pump inhibitors and histamine 2-receptor blockers are effective, they do not treat the underlying mechanical disorder. Additionally, not all patients respond to these therapies (Zagol 2011, Stefanidid 2010).

Surgery is another treatment option for patients with GERD. According to the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), surgical therapy should be considered in patients with a diagnosis of reflux who (Stefanidid 2010): Have failed medical management (due to inadequate symptom control, severe regurgitation not controlled with acid suppression, or medication side-effects). Opt for surgery despite medical management (due to quality-of-life considerations, lifelong need for medication intake, expense of the medication, etc.). Have complications of GERD (e.g., Barrett’s esophagus, peptic stricture). Have extra-esophageal manifestations (asthma, hoarseness, cough, chest pains, aspiration). There are a variety of surgical procedures used for the treatment of GERD. Currently, there is no consensus on the best procedure for all patients. The choice of procedure is often based on anatomical considerations and expertise; however, the laparoscopic Nissen fundoplication has emerged as one of the most widely used techniques. With fundoplication, the gastric fundus is wrapped around the lower end of the esophagus to reduce gastric reflux. The fundal wrap can be either total (360°) or partial (less than 360°). Studies suggest that approximately 90% of patients who undergo Nissen fundoplication achieve symptomatic relief. Side effects of this procedure include dysphagia, hyperflatulence, inability to belch, bloating, and postsurgery bowel symptoms (AGA 2008, Stefanidid 2010). Transoral incisionless fundoplication using the EsophyX device (EndoGastric Solutions, Inc., Redmond, WA) has been proposed as a less invasive alternative to traditional surgical procedures. This procedure attempts to decrease the reflux of stomach acid into the esophagus through the reconstruction of an anti-reflux barrier. The EsophyX device is inserted transorally, under direct endoscopic visualization, into the stomach and is positioned at the junction of the stomach and the esophagus. Once positioned, the device uses suction and transmural fasteners to facilitate the recreation of the esophageal gastric valve. The result is an omega shaped valve 3-5 cm in length and 200-300° in circumference. This procedure may also reduce hiatal hernias that are less than 2 cm in size through the use of a built in vacuum invaginator. As this procedure is incisionless and can often be performed on an outpatient basis it is an attractive alternative to conventional surgical procedures (Jafri 2009, Louis 2010). The EsophyX system had been cleared by the FDA for use in transoral tissue approximation, full-thickness plication and ligation in the gastrointestinal tract for the treatment of GERD in patients with symptomatic chronic GERD who require and respond to pharmacological therapy. This device may also be used to narrow the gastroesophageal junction and...
reduce hiatal hernia ≤2 cm in size in patients with symptomatic chronic GERD. The EsophyX system has not been previously reviewed by the Medical Technology Assessment Committee and is being reviewed based on request from bariatric surgery and a member appeal.

04/09/2008: MTAC REVIEW
Endoluminar Fasteners
Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of the EndoGastric Solutions StomaphyX™ endoluminar fastener for weight loss. There is insufficient published evidence to determine the efficacy and safety of the InScope™ Tissue Apposition System for endoscopic gastric sutures.

Articles: The literature search did not reveal any published studies, on the EndoGastric Solutions StomaphyX™ endoluminar fastener and delivery system, or on the InScope™ Tissue Apposition System. Information about the systems was obtained from the FDA and the manufacturer’s Web sites.

The use of endoluminar fasteners in the treatment of obesity does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

08/15/2011: MTAC REVIEW
Endoluminar Fasteners
Evidence Conclusion: Two case-series were selected for review that evaluated the safety and effectiveness of transoral incisionless fundoplication (TIF) for the treatment of GERD. The first study followed 110 subjects for a median of 7 months and the second study followed 86 subjects for 12 months. The primary outcome in both of these studies was GERD Health-Related Quality of Life (GERD-HRQL). Both studies found significant reductions in GERD-HRQL compared to baseline. However, results from these studies should be interpreted with caution as both studies were case-series (lowest-quality evidence). Serious adverse events included two perforations and a post-TIF intraluminal bleeding that required a blood transfusion. Other adverse events included: left shoulder pain, abdominal pain, sore throat, nausea, and epigastric pain (Barnes 2011; Cadière 2008).

Conclusion: There is insufficient evidence to determine the safety and efficacy of transoral incisionless fundoplication for the treatment of GERD.

Articles: To determine the safety and efficacy of transoral incisionless fundoplication using the EsophyX system for the treatment of GERD. Screening of articles: No randomized controlled trials were identified that addressed the safety or efficacy of transoral incisionless fundoplication using the EsophyX system for the treatment of GERD. Studies were not selected for review if they included less than 25 subjects. The largest studies with the longest duration of follow-up were selected for review. The following studies were critically appraised: Barnes WE, Hoddinott KM, Mundy S, Williams M. Transoral incisionless fundoplication offers high patient satisfaction and relief of therapy-resistant typical and atypical symptoms of GERD in community practice. Surg Innov 2011; 18:119-129. See Evidence Table. Cadière GB, Buset M, Muls V, et al. Antireflux transoral incisionless fundoplication using EsophyX: 12-month results of a prospective multicenter study. World J Surg 2008; 32:1676-1688. See Evidence Table.

The use of endoluminar fasteners in the treatment of GERD does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

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<th>Date Created</th>
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<td>02/13/2003</td>
<td>Initiated annual review because of Medicare criteria 05/03/2011 MDCRPC, 09/06/2011 MDCRPC, 07/03/2012 MDCRPC, 05/07/2013 MDCRPC, 03/04/2014 MDCRPC, 01/06/2015 MDCRPC, 02/03/2015 MPC, 12/01/2015 MPC, 10/04/2016 MPC, 08/01/2017 MPC, 02/06/2018 MPC</td>
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MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History

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<tr>
<td>07/21/2016</td>
<td>Added Linx Medicare Coverage</td>
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<tr>
<td>10/04/2016</td>
<td>MPC approved to adopt GH criteria for GERD when Medicare is silent</td>
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Codes

BARD Endoscopic Suturing: no specific codes
Insertion of Bulking Agents: 43192, 43201

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LINX: C9737, 43284, 43285
Stretta: 43257
Transoral Incisionless Fundoplication - EspophyX: 43210