KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Fundoplication Surgery & Treatment of Gastroesophageal Reflux Disease

- CR BARD's Endoscopic Suturing System
- Endoscopic Placement of a Bulking Material at the Lower Esophageal Sphincter
- LINX Reflux Management System
- Stretta Procedure
- Transoral (Endoluminal) Gastroplication or Suturing (Esophyx)

Criteria

For Medicare members

Procedure(s):	CPT Code(s)	CMS Coverage Guidelines – NCD, LCD, LCA	Kaiser Permanente Medical Policy
Fundoplication Surgery	43280, 43281, 43282, 43325, 43328, 43334, 43335, 43336, 43337, 43327, 43332,43333	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use non-Medicare Clinical Review Criteria, ***Fundoplication Surgery*** for medical necessity determinations. Refer to the Non-Medicare criteria below.	Requires Level of Care Review **AND** Kaiser Permanente has elected to use the Fundoplication and Hiatal Hernia Repair, by Laparoscopy (KP-S-505 02012025) MCG* Care Guideline for medical necessity determinations.
Transesophageal radiofrequency energy ***Examples:*** CSM Stretta™ System, or the Stretta procedure	43257	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use non-Medicare Clinical Review Criteria, ***Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta)*** for medical necessity determinations. Refer to the Non-Medicare criteria below.	Kaiser Permanente has elected to use the Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta) (A-0209) MCG* Care Guideline for medical necessity determinations. This service is not covered per MCG guidelines.
Transoral incisionless fundoplication (TIF) ***Examples:*** EsophyX	43210	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use non-Medicare Clinical Review Criteria, ***Transoral***	Defer to Kaiser Permanente Medical Policy (see below)

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		(Endoluminal) Gastroplication or Suturing for medical necessity determinations. Refer to the Non-Medicare criteria below.	
LINX® Reflux Management System	43284, 43285	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use non-Medicare Clinical Review Criteria, ***Implantable Magnetic Esophageal Ring (Linx)*** for medical necessity determinations. Refer to the Non-Medicare criteria below.	Defer to Kaiser Permanente Medical Policy (see below)
Endoscopic injection of a bulking agent ***Examples:*** pyrolytic carbon-coated zirconium oxide spheres (Durasphere®)	43192, 43201	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria of "insufficient evidence" for medical necessity determinations. Use the Non-Medicare criteria below.	Kaiser Permanente Medical Policy of insufficient evidence (see below).
Endoscopic submucosal implantation or injection of a biocompatible polymer ***Examples:*** • Enteryx, • polymethylmethacrylate [PMMA] beads (1) the Gatekeeper Reflux Repair system	43192, 43201	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria of "insufficient evidence" for medical necessity determinations. Use the Non-Medicare criteria below.	Kaiser Permanente Medical Policy of insufficient evidence (see below).
Transesophageal endoscopic gastroplasty ***Examples:*** • EndoCinch • Plicator • StomaphyX	No specific codes – *often submitted using 43499*	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria of "insufficient evidence" for medical necessity determinations. Use the Non-Medicare criteria below.	Kaiser Permanente Medical Policy of insufficient evidence (see below).

For Non-Medicare members

Service	Criteria
Implantable Magnetic Esophageal Ring (LINX® Reflux Management System)	Procedure is indicated for typical symptomatic GERD (e.g., heartburn, regurgitation, dental erosions) with **ALL** of the following:

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	▪ Confirmation of diagnosis on endoscopy, ambulatory pH monitoring, or barium swallow study ▪ Unresponsive to lifestyle modification* ▪ Failure**, contraindication or intolerance of an adequate trial of medical therapy*** ▪ Documentation supports the need for LINX® versus traditional fundoplication procedures When the following exclusions are not present: ▪ Complete failure of the lower esophageal sphincter ▪ Dysphagia ▪ Previous endoluminal anti-reflux procedure ▪ Barrett's esophagus **Definitions:** ***Lifestyle Modifications** include weight loss, avoidance of trigger foods, avoidance of late meals and elevation of the head of the bed. ****Failure** is defined as lack of response of conservative therapy or inadequate response with significant residual functional limitations due to symptoms. *****An adequate trial of medical therapy** would be at least 4 concurrent months of Proton Pump Inhibitor (PPI) use. ******Paraoesophageal Hernia**: Unlike a type 1 hiatus hernia (sliding hernia), a paraesophageal hernia is a true hernia with a hernia sac composed of peritoneum and characterized by an upward dislocation of the gastric fundus through a focal defect in the phrenoesophageal membrane . For definition of Type II-IV see below.
Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta)	Kaiser Permanente has elected to use the Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta) (A-0209) MCG* Care Guideline for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
Transoral (Endoluminal) Gastroplication or Suturing (Esophyx)	Procedure is indicated for typical symptomatic GERD (e.g., heartburn, regurgitation, dental erosions) with **ALL** of the following: ▪ Confirmation of diagnosis on endoscopy, ambulatory pH monitoring, or barium swallow study ▪ Unresponsive to lifestyle modification* ▪ Failure**, contraindication or intolerance of an adequate trial of medical therapy*** When the following exclusions are not present: ▪ Prior transoral incisionless fundoplication ▪ Hiatal hernia greater than 2 cm ▪ Esophagitis LA grade >B ▪ Barrett's esophagus > 2 cm ▪ Achalasia ▪ Esophageal ulcer ▪ BMI > 35 **Definitions:** ***Lifestyle Modifications** include weight loss, avoidance of trigger foods, avoidance of late meals and elevation of the head of the bed.

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	****Failure** is defined as lack of response of conservative therapy or inadequate response with significant residual functional limitations due to symptoms. *****An adequate trial of medical therapy** would be at least 4 concurrent months of Proton Pump Inhibitor (PPI) use. ******Paraoesophageal Hernia**: Unlike a type 1 hiatus hernia (sliding hernia), a paraesophageal hernia is a true hernia with a hernia sac composed of peritoneum and characterized by an upward dislocation of the gastric fundus through a focal defect in the phrenoesophageal membrane . For definition of Type II-IV see below.
Fundoplication Surgery	Requires Level of Care Review **AND** Kaiser Permanente has elected to use the Fundoplication and Hiatal Hernia Repair, by Laparoscopy (KP-S-505 02012025) MCG* Care Guideline for medical necessity determinations.
• CR BARD's Endoscopic Suturing System (EndoCinch Therapy, Endoluminal Plication) • Endoscopic Placement of a Bulking Material at the Lower Esophageal Sphincter	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.

***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)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information 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 common disease worldwide with an estimated prevalence of 10-20% in the Western population. It is defined as a condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications. GERD has a wide clinical spectrum ranging from mild reflux symptoms to severe regurgitation but is typically characterized by heartburn and acid regurgitation. Other symptoms of GERD include epigastric pain, dysphagia, chronic cough, chronic laryngitis, and asthma (Vakil 2006, Zhang 2016, Savarino 2017).

Therapeutic approaches to GERD included lifestyle modification, medical therapy with gastric acid secretion inhibitors, and surgical interventions. Proton pump inhibitors (PPIs) are the standard medical therapy and aim at suppressing the normal acid production in the stomach to alleviate the acid reflux symptoms. PPIs can only inhibit gastric acid secretion, but do not prevent reflux nor address the incompetent lower esophageal sphincter (LES). It is reported that up to 40% of the GERD patients fail to respond either partially or completely to PPIs and will continue to have reflux symptoms or endoscopic evidence of esophagitis (Reynolds 2016, Saino 2016, Chen 2017).

Laparoscopic Nissen fundoplication (LNF) is currently the gold standard surgical treatment for patients who fail medial therapy. Nissen fundoplication reconstructs the defective LES to restore its normal function as an anti-reflux barrier. The surgery is safe and very effective in reducing GERD symptoms. However, the procedure is technically demanding and requires significant anatomical disruption to mobilize the gastric fundus and wrap it around the esophagus. It may also be associated with side effects including difficulty swallowing, bloating, early satiety, and inability to vomit or belch. As a result, only very few GERD patients will opt for the surgery (Saino 2015, Reynolds 2016, Zadeh 2018).

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The Magnetic sphincter augmentation device (MSA) (LINX®, Torax Medical Shoreview, MN) was introduced in 2008 as a potential less invasive anti-reflux surgical option for patients with uncomplicated GERD who do not respond to PPIs, and still have some LES function. I.e. it is not indicated for patients with complete LES failure or with complicated GERD. The MSA device is a small expandable bracelet- like string of consisting of 10 or more beads with a magnetic core and interlinked with independent titanic wires. The device is laparoscopically placed around the gastroesophageal junction (GEJ) with minimal dissection of the hiatus to preserve the native LES. The magnetic attraction between the beads augments the existing LES barrier function to prevent reflux, and the mobile wires connecting the beads allow the device to expand during swallowing, belching, or vomiting (Reynolds 2017, Siddiqi 2017, Zadeh 2018, Guidozzi 2019).

The LINX® device should not be placed in patients with suspected or known allergies to titanium, stainless steel, nickel or ferrous material, or in those with pacemakers, defibrillators or metallic implants in the abdomen. In addition, it may not be appropriate for patients with a history of dysphagia, previous upper abdominal surgery, previous endoluminal anti-reflux procedures, large sliding hiatal hernia, or Barrett's esophagus. Reported adverse events and complications associated with magnetic sphincter augmentation include inability to belch or vomit, bloating, and dysphagia. The latter is the most common complication of the MSA, and severe cases may require a second surgery for dilatation, and removal of the device if endoscopic dilatation fails. Other reported adverse events include device failure, device migration, device erosion, and ring eroding into the esophageal lumen (Fass 2017, Chen 2017, Zadeh 2018, Guidozzi 2019).

The LINX® Reflux Management System received U.S. Food and Drug Administration (FDA) approval on March 22, 2012 for patients with GERD as defined by abnormal pH testing, and who continue to have chronic symptoms despite the use of a maximum medical therapy.

Medical Technology Assessment Committee (MTAC)

CR BARD's Endoscopic Suturing System (EndoCinch Therapy, Endoluminal Plication) for the Treatment of GERD

BACKGROUND

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 EndoCinch (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

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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.

02/13/2003: MTAC REVIEW
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 anti reflux 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. Gastrintest 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. Pharmaco-therapy 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 non-biodegradable substances injected into the submucosa or muscle,

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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 biles 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

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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 1. Summary of events by source

Source of data	# of events included in analysis	Breakout
Clinical literature	32	• 9 device removal • 20 esophageal dilation • 3 hospital readmissions
MAUDE database	20	• 19 device removal (includes US and OUS) • 1 device erosion
Manufacturer's database	59	• 8 device removal • 1 intra/perioperative complication • 11 hospital readmissions • 39 esophageal dilation

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-Radiofrequency [RF] Application- Curon Medical Inc's CSM Stretta System) for the Treatment of GERD

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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 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^{o} and 85^{o} 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, an 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

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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.
Articles: The search yielded seven review articles and two empirical studies: (1) An RCT comparing radiofrequency ablation to sham treatment, and (2) A longitudinal non-randomized study comparing the procedure to fundoplication. *Evidence tables were created for these two studies as well as a patient registry published prior to 2003 that was not included in the earlier review:* Corley DA, Katz P, Wo JM, et al. Improvement of gastroesophageal reflux symptoms after radiofrequency energy: A randomized, sham-controlled trial. *Gastroenterol* 2002; 125:668-672. See Evidence Table. Richards WO, Houston HL, Torquati A, et al. Paradigm shift in the management of gastroesophageal reflux disease. *Ann Surg* 2003; 237:638-649. See Evidence Table. Wolfsen HC, and Richards WO. The Stretta procedure for the treatment of GERD: A registry of 558 patients. *J Laparoendoscp Adv Surg Tech* 2002; 6:395-402. 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.*

EndoGastric Solutions Stomaphy X™ Endoluminal Fastener, InScope™ Tissue Apposition System, Transoral Incisionless Fundoplication

BACKGROUND
Over the last two decades, several less invasive endoluminal /endoscopic techniques have been developed for the management of GERD. These procedures include radiofrequency ablation (Stretta system), magnetic sphincter augmentation (LINX procedure), and transoral incisionless fundoplication, among others.

Transoral incisionless fundoplication (TIF) using the (EndoGastric Solutions, Inc., Redmond, WA) has been proposed as a less invasive alternative to traditional surgical procedures. Similar to the NF, TIF attempts to decrease the reflux of stomach acid into the esophagus through the reconstruction of an anti-reflux barrier. It involves wrapping a portion of the stomach around the esophagus without requiring any incisions.

TIF is performed in an outpatient setting under general anesthesia, and involves inserting the EsophyX™ device transorally, under direct endoscopic visualization, into the stomach and positioning it 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 fundus of the stomach is folded up and around the distal esophagus utilizing the tissue mold and chassis of the device. Next, an integrated suction apparatus grasps the distal esophagus and positions it below the diaphragm. H-shaped fasteners, made of polypropylene, are then delivered through apposed layers of esophageal and fundus tissue to anchor the repair. This process is repeated to create a full thickness, partial circumference, and gastroesophageal fundoplication. Approximately 20 fasteners are implanted during the procedure resulting in the recreation of an omega shaped full-thickness gastroesophageal valve from inside the stomach 3-5 cm in length and 200-300° in circumference. This procedure may also reduce hiatal hernias that are < 2 cm in size through the use of a built-in vacuum invaginator (Jafri 2009, Louis 2010, Hunter 2015, Testoni 2014, Trad 2014, Witteman 2015).

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TIF 1.0 utilizing the EsophyX™ device was first performed in 2005 and received United States Food and Drug Administration (FDA) initial 510(k) clearance in 2007. The EsophyX device is indicated for endoluminal, transoral tissue approximation, full thickness plication and ligation in the GI tract for the treatment of symptomatic chronic gastroesophageal reflux disease in
patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia < 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease (FDA website accessed June 2020).

The EsophyX technology underwent several modifications along the years. Currently, there are three generations of the device; the original EsophyX® device, EsophyX2®, EsophyX Z®. Over the same timeline, four different fundoplication procedures using the EsophyX have emerged. The initial device was used to perform the endoluminal gastro–gastric fundoplication, called “ELF”. The second procedure TIF 1.0, was a longitudinally oriented plication of gastric cardia onto the distal esophagus just proximal to the gastroesophageal junction. The third procedure TIF 2.0, incorporated a rotational wrap of the cardia and fundus around the circumference of the distal esophagus in addition to providing a 2–4 cm length of the wrap over the intra-abdominal distal esophagus. This results in tightening and reinforcing the sling fibers of the proximal stomach (the lower portion of the LES), accentuating the cardiac notch, steepening the angle of His, and reestablishing the flap valve mechanism. The fourth procedure is a combined laparoscopic hiatal hernia repair with transoral incisionless fundoplication 2.0 (HH-TIF). Each of TIF procedures described is markedly different from the others and have different clinical outcomes. The TIF-2 procedure is believed to be the most similar procedure to NF morphologically and physiologically and is accomplished by using the third generation EsophyX® Z, launched in 2015 and cleared by the FDA in 2016 (Chang 2020, Ihde 2020).

Reported adverse events associated with the procedure include gastrointestinal bleeds, esophageal laceration, pleural effusion, mediastinal abscess, and potential failure of the procedure due to the pull on the fastener used to create the valve.

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, Willams M. Transoral incisionless fundoplication offers high patient satisfaction and relief

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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.*

07/13/2020: MTAC REVIEW
Transoral Incisionless Fundoplication with Esophyx
Conclusion:

- The published RCTs evaluating the safety and efficacy of TIF 2.0 using EsophyX compared the procedure versus a sham therapy or PPI and not to laparoscopic Nissen fundoplication (LNF), the most appropriate comparator.
- There is no direct published evidence, to date, to determine the safety and effectiveness of TIF 2.0 using EsophyX compared LNF, the gold standard for the management of patients with refractory GERD.
- Indirect comparison suggests the LNF is superior to TIF 2.0 in esophageal acid control, healing of esophagitis and increasing in LES pressure.
- There is insufficient published evidence to determine the effects of TIF using EsophyX on net health outcomes, and whether it will lead to protection from long-term adverse events of GERD and Barrett's esophagus.
- TIF may be superior to sham therapy (i.e. no therapy), but not PPIs in reducing percent time pH <4.
- TIF may be superior to sham therapy in improving the quality of life, but not in reducing the incidence of persistent esophagitis.
- The published studies and MAs indicate that the efficacy of TIF may decrease over time and that most patients may still need to use PPIs, but maybe at a lower dose.
- Open label trials found significant improvements with TIF 2.0 in subjective measures, but no difference in objective outcome measures of pH normalization and esophagitis when compared with PPI therapy. This may suggest a potential placebo effect of TIF 2.0.
- There is insufficient published data to determine the long-term safety of TIF 2.0 using EsophyX in patients with GERD.

Articles:
The literature search identified 6 RCTs, one non-randomized comparative study, and over 20 noncomparative observational studies published between 2011 and 2018. The search also revealed 4 meta-analyses (MAs) of exclusively RCTs or RCTs together with observational studies. One of the meta-analyses also included a network MA (NMA). Of the published RCTs, only one trial (Svoboda et al, 2011) compared TIF vs. LNF, 2 trials compared TIF to sham therapy, and two compared the procedure to different PPIs. The Svoboda trial was a small trial (N=52) that used 2 generations of the devices and different techniques for the TIF group along the study (Plicator® method for 18 patients, and the EsophyX® in16 patients). The study was thus not included in any of the published meta-analyses as combining results of studies using different procedures and generations of the device would lead to incorrect conclusions on effectiveness of the procedure in treating reflux disease.

The meta-analysis with the more valid methodology and most inclusive of published RCTs (Huang et al, 2017) as well as the Richter and colleagues' systematic review with both a direct and network meta-analysis were selected for critical appraisal. The published RCTs that compared TIF 2.0 versus LNF, sham therapy, or PPIs were summarized in a table format. See Evidence Table.

The use of Transoral Incisionless Fundoplication with Esophyx does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/08/2019: MTAC REVIEW
Magnetic Sphincter Augmentation (MSA) (LINX® Reflux Management System) for Gastroesophageal Reflux Diseases
Conclusion:

- There is no published evidence, to date, from randomized controlled trials to determine the comparative safety and effectiveness of MSA and laparoscopic Nissen fundoplication in patients with GERD refractory to maximal medical therapy.
- Low quality evidence from short-term non-randomized comparative observational studies suggest that MSA may be associated with better postoperative ability to belch and vomit and less bloating compared to fundoplication in patients with GERD.

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- There is insufficient evidence to determine the long-term safety or effectiveness of MSN in patients with medically refractory GERD.

Articles: The literature search for recently published studies after the December 2017 MTAC review did not identify any randomized controlled trial that compared magnetic sphincter augmentation (LINX® Reflux Management System) versus Nissen fundoplication. The search revealed only one RCT that compared MSA versus double-dose PPIs in patients with moderate to severe GERD who failed once daily PPI therapy for 8 weeks (Bell, 2019). One qualitative systematic review (Stanak 2018) and two more recent systematic reviews with meta-analyses (Ailofi 2018, and Guidozzi 2019) that pooled the results of nonrandomized comparative observational studies, were also identified, as well as a small retrospective study (Richards 2018) of patients who underwent the procedure by a single surgeon. The RCT comparing magnetic sphincter augmentation to double-dose PPI was excluded as the aim of the review was to compare the device to Nissen fundoplication the gold standard procedure for patients with GERD-related symptoms despite the use of a maximum medical therapy. The most recent meta-analyses of studies comparing LINX® reflux management system with Nissen fundoplication were reviewed. No evidence tables referenced for this report.

The use of Magnetic Sphincter Augmentation (MSA) in the treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Haye's Technology Assessment

Laparoscopic Surgery for Gastroesophageal Reflux Disease Refractory to Medical Therapy
April 21st, 2023
Based on a review of full-text clinical practice guidelines and position statements, guidance appears to confer **strong support for** laparoscopic surgery for gastroesophageal reflux disease (GERD) refractory to medical therapy. This level of support includes five guidelines were identified with varying levels of support in favor of laparoscopic surgery for GERD.

Hayes. Hayes Technology Assessment. Laparoscopic Surgery for Gastroesophageal Reflux Disease Refractory to Medical Therapy. Dallas, TX: Hayes; April 21, 2023.
https://evidence.hayesinc.com/report/earb.laparoscopic1509

Applicable Codes

LINX® Reflux Management System
Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® Codes	Description
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed
43285	Removal of esophageal sphincter augmentation device

Radiofrequency Energy Delivery to Gastroesophageal Junction/Transesophageal radiofrequency energy (Ex: CSM Stretta) - Considered Not Medically Necessary:

CPT® Codes	Description
43257	Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease

Transoral (Endoluminal) Gastroplication or Suturing/Transoral incisionless fundoplication (TIF) (Ex: Esophyx)
Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® Codes	Description

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43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed

Endoscopic placement of a bulking material at the lower esophageal sphincter - Considered Not Medically Necessary:

CPT® Codes	Description
43192	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance

CR BARD's Endoscopic Suturing System - Considered Not Medically Necessary:

CPT® Codes	Description
No specific codes	

Laparoscopic Fundoplication and Hiatal Hernia Repair
Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Requires** ***Elective Surgical Procedure Level of Care Review

CPT® Codes	Description
43280*	Laparoscopy, surgical, esophagogastric fundoplasty (eg, Nissen, Toupet procedures)
43281*	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh
43282*	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh

Transthoracic Fundoplication and Hiatal Hernia Repair
Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
43325	Esophagogastric fundoplasty, with fundic patch (Thal-Nissen procedure)
43328	Esophagogastric fundoplasty partial or complete; thoracotomy
43334	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; without implantation of mesh or other prosthesis
43335	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; with implantation of mesh or other prosthesis
43336	Repair, paraesophageal hiatal hernia, (including fundoplication), via thoracoabdominal incision, except neonatal; without implantation of mesh or other prosthesis
43337	Repair, paraesophageal hiatal hernia, (including fundoplication), via thoracoabdominal incision, except neonatal; with implantation of mesh or other prosthesis

Abdominal Fundoplication and Hiatal Hernia Repair
Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
43327	Esophagogastric fundoplasty partial or complete; laparotomy
43332	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; without implantation of mesh or other prosthesis
43333	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; with implantation of mesh or other prosthesis

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

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Date Created	Date Reviewed	Date Last Revised
02/13/2003	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 MPC, 01/06/2015MPC, 02/03/2015MPC, 12/01/2015MPC, 10/04/2016MPC, 08/01/2017MPC, 02/06/2018MPC, 06/05/2018MPC, 06/04/2019MPC, 06/02/2020MPC, 06/01/2021MPC, 06/07/2022MPC, 06/06/2023MPC , 09/03/2024MPC	12/03/2024

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
07/21/2016	Added LINX® Medicare Coverage
10/04/2016	MPC approved to adopt Kaiser Permanente criteria for GERD when Medicare is silent
08/06/2019	Added MTAC review for Magnetic Sphincter Augmentation- LINX® management system for GERD
02/04/2020	MPC approved to adopt Transoral (Endoluminal) Gastroplication or Suturing (Esophyx) MCG A-0205 for medical necessity determinations.
06/02/2020	Removed deleted code C9737 (LINX®)
10/06/2020	Added MTAC Review for Transoral Incisionless Fundoplication with Esophyx. MPC approved to retain existing policy of non-coverage.
10/06/2020	MPC approved MCG 24th ed. guideline for Implantable Magnetic Esophageal Ring (LINX®) A-0990
09/03/2024	MPC approved to adopt coverage for Fundoplication surgery using a hybrid guideline, KP-S-505. 60-day notice required; effective February 1, 2025.
12/03/2024	MPC approved to adopt limited criteria for EsophyX™ and LINX® procedures; 60-day notice required, effective May 1, 2025

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