

Subject: Gastroesophageal Reflux Disease (GERD) Treatment		Original Effective Date: 3/11/2019
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DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL ⁵⁴⁻⁵⁵

Gastroesophageal reflux disease (GERD) is defined by the presence of chronic symptoms or mucosal damage caused by an abnormal reflux of gastric contents into the esophagus. Causes include a weakness in the LES, presence of a hiatal hernia (HH), temporary LES relaxation, alterations in the gastroesophageal pressure gradient, and esophageal factors such as poor clearance and changes in motility. Medical management of GERD includes life style changes (dietary restriction, weight reduction), pharmaceuticals such as antacids, Histamine 2 receptor

antagonists (H2RAs) and Proton pump inhibitors (PPIs), minimally invasive and endoscopic procedures, and surgical treatment. Laparoscopic fundoplication at the current time is the gold standard treatment for GERD when medical management has failed.

Other unproven minimally invasive treatment strategies may be classified into these categories:

- Radiofrequency (RF) energy applied to the lower esophageal sphincter and gastric cardia, which constricts the tissue to decrease lower esophageal sphincter relaxations and improve the gastroesophageal barrier, (e.g. Stretta procedure)
- Endoscopic suturing techniques (e.g. transoral fundoplication (TIF), which uses fasteners to remodel the tissue, providing an improved esophageal barrier against reflux; and endoscopic stapling; (e.g. Bard® EndoCinch, Enteryx, Endoscopic Suturing System or Device, Endoscopic Plication system, Stomaphyx, Esophyx and MUSE) which involve clamping and stapling the esophagus to the stomach proximal to the gastroesophageal junction (GEJ)
- Injection and implantation of bulking agents (e.g. Plexiglas, Durasphere) or insertion of magnetic beads (e.g. LINX) around the lower esophageal sphincter to impede reflux by decreasing transient relaxations which can cause reflux
- Implanted stimulation devices, (e.g. Endostim neurostimulation therapy) which is designed to normalize the function of the lower esophageal sphincter through neuromodulation. The Endostim device is implanted under the skin of the abdomen and a bipolar lead delivers electrical stimulation therapy to the lower esophageal sphincter.

RECOMMENDATION

Minimally invasive therapy for GERD (i.e. radiofrequency techniques, endoscopic suturing and stapling, injection and implantation of bulking agents or insertion of magnetic beads, and implanted stimulation devices) are considered experimental, investigational and unproven due to insufficient evidence in the peer reviewed literature.

SUMMARY OF MEDICAL EVIDENCE⁹⁻⁵³

Overall, the quality of the evidence is low for minimally invasive therapy for GERD (i.e. radiofrequency techniques, endoscopic suturing and stapling, injection and implantation of bulking agents or insertion of magnetic beads, and implanted stimulation devices), due to insufficient studies with design limitations, lack of randomization and/or blinding, small sample size, generally short-term follow-up, and lack of and inconsistent comparators. Large randomized controlled trials comparing minimally invasive therapy for GERD with laparoscopic fundoplication or other medical management strategies, over a long period of follow-up are needed to evaluate their indications, outcomes safety and efficacy.

A summary of the most relevant and valid studies is provided below.

Radiofrequency Energy (Stretta System)²⁰⁻³¹

Noar et al. (2017) prospectively assessed and compared patient-reported outcomes in 18 patients refractive to laparoscopic Nissen fundoplication (LNF) and 81 patients with gastrointestinal reflux disease (GERD)

refractory to medical management that all underwent Stretta during 10-year follow-up. Patient-reported outcomes measured were GERD-HRQL (health-related quality of life), patient satisfaction scores, and daily medication requirements. The refractory LNF subset demonstrated median improvements in GERD-HRQL, satisfaction, and medication use at all follow-up time points ≥ 6 months to 10 years, which was significant from a baseline of both on- and off-medications ($p < 0.05$). Specifically at 10 years, median GERD-HRQL decreased from 36 to 7 ($p < 0.001$), satisfaction increased from 1 to 4 ($p < 0.001$), and medication score decreased from 7 to 6 ($p = 0.040$). Nine patients decreased medication use by half at 10 years. No significant differences existed between refractory LNF and standard refractory GERD subsets at any follow-up time point ≥ 6 months to 10 years ($p > 0.05$) after Stretta. At 10 years, no significant differences were noted between refractory LNF and standard Stretta subsets regarding medication use ($p = 0.088$), patient satisfaction ($p = 0.573$), and GERD-HRQL ($p = 0.075$). Stretta procedures were completed without difficulty or significant intraoperative or long-term adverse events. The authors concluded that within a small cohort of refractory LNF patients, Stretta resulted in sustained improvement over 10 years with equivalent outcomes to non-LNF standard Stretta patients. Study limitations include non-randomization and small patient population. ³⁰

Kalapala et al. (2017) assessed short-outcomes (3 months) from a prospective randomized study comparing the Stretta treatment with controls receiving proton pump inhibitors (PPIs). Patients ($n = 20$) with symptoms of heartburn, regurgitation, abnormal esophageal acid exposure ($\geq 4\%$), and endoscopically confirmed esophagitis were included into the study. The primary measure was improvement in quality of life (QOL) and decrease in the frequency and severity of GERD symptoms. The mean age of the patients was 39 (± 15) years and controls were 34 (± 11) years. Three months after Stretta, 80% reported improvement in QOL compared to 40% in the control group. At the end of 3 months, significant ($p < 0.05$) improvement in GERD symptom score for heartburn, regurgitation, chest pain, and cough compared with the control group was observed. After Stretta treatment, 60% of the patients were free of PPIs whereas there was no change in the control group. Almost 80% of the patients on Stretta treatment were satisfied with the treatment compared to 30% of the patients in the control group. Randomized controlled trials with larger patient populations and longer follow-up periods are needed to further assess Stretta. ²³

Endoscopic Plication or Suturing or Stapling ³²⁻⁴⁶

De Moura et al. (2018) evaluated long-term results of 47 patients non-responsive to PPIs who underwent endoluminal plication ($n=26$) or polymer injection ($n=21$) for the treatment of GERD. The number of patients with no response to endoscopic treatment with reintroduction of PPIs increased in time for both techniques. There was symptomatic improvement up to 12 months, with progressive loss of this trending up to 60 months for both procedures. Health related quality of life score (GERD-HRQL) demonstrated total response in both procedures at 1, 3, 6 and 12 months. The 60-month analysis showed an increased number of patients with no response in both groups. The quality of life assessment (SF-36) showed benefit in polymer injection up to 3 months and showed a higher rate of complications. There were no deaths. There was healing of esophagitis at 3 months in 45% of patients in polymer injection and 40% in endoluminal plication. There was no improvement in manometric or pH findings. The authors concluded that endoscopic therapies were ineffective in controlling GERD in the long term. ⁴³

Trad et al. (2018) described 5-year outcomes from the previously described TEMPO clinical trial (TIF 2.0). A total of 63 patients with chronic GERD refractory to PPI therapy, absent or ≤ 2 cm hiatal hernia, and abnormal

esophageal acid exposure were randomized to the TIF group or PPI group. Following the 6-month evaluation, all patients in the PPI group elected for crossover to TIF. Of 63 patients, 60 were available at 1 year, 52 at 3 years, and 44 at 5 years for evaluation. Troublesome regurgitation was eliminated in 88% of patients at 1 year, 90% at 3 years, and 86% at 5 years. Resolution of troublesome atypical symptoms was achieved in 82% of patients at 1 year, 88% at 3 years, and 80% at 5 years. No serious adverse events occurred. There were 3 reoperations by the end of the 5-year follow-up. At the 5-year follow-up, 34% of patients were on daily PPI therapy as compared with 100% of patients at screening. The total GERD Health-related quality-of-life score improved by decreasing from 22.2 to 6.8 at 5 years ($P < .001$). The authors concluded that in this patient population, the TIF 2.0 procedure provided safe and sustained long-term elimination of troublesome GERD symptoms. Study limitations include small patient population and non-randomization to another endoscopic procedure or surgical procedure for GERD. ³⁷

Kim et al. (2016) reported long-term outcomes from the Zacherl et al. (2015) MUSE study using the Medigus Ultrasonic Surgical Endostapler (MUSE™). Efficacy and safety data for 37 patients were analyzed at baseline, 6 months, and 4 years post-procedure. In one center (IU), efficacy and safety data were evaluated at baseline, 6 months post-procedure, and then annually up to 4 years. No new complications have been reported in our long-term analysis. The proportions of patients who remained off daily PPI were 83.8 % (31/37) at 6 months and 69.4 % (25/36) at 4 years post-procedure. GERD-Health Related Quality of Life (HRQL) scores (off PPI) were significantly decreased from baseline to 6 months and 4 years post-procedure. The daily dosage of GERD medications, measured as omeprazole equivalents (mean \pm SD, mg), decreased from 66.1 ± 33.2 at baseline to 10.8 ± 15.9 at 6 months and 12.8 ± 19.4 at 4 years post-procedure ($P < 0.01$). The authors conclude that the MUSE™ stapling device appears to be safe and effective in improving symptom scores as well as reducing PPI use in patients with GERD and that the results appeared to be equal to or better than those of the other devices for endoluminal GERD therapy. Future studies with larger patient series, sham control group, and greater number of staples are awaited to further evaluate MUSE. ⁴⁵⁻⁴⁶

Injection and implantation of bulking agent or insertion of magnetic beads ¹⁰⁻¹⁹

Louie et al. (2018) evaluated one-year results from a mandated post-approval multicenter, prospective study of 200 patients with pathologic acid reflux confirmed by esophageal pH testing, who underwent magnetic sphincter augmentation (MSA). Predefined clinical outcomes were assessed at the annual visit including a validated, diseases specific questionnaire, esophago-gastric-duodenoscopy (EGD) and esophageal pH monitoring, and use of proton pump inhibitors. At 1 year, the mean total acid exposure time decreased from 10.0% at baseline to 3.6%, and 74.4% of patients had normal esophageal acid exposure time (% time $\text{PH} < 4 \leq 5.3\%$). GERD Health-Related Quality of Life scores improved from a median score of 26.0 at baseline to 4.0 at 1 year, with 84% of patients meeting the predefined success criteria of at least a 50% reduction in total GERD Health-Related Quality of Life score compared with baseline. The device removal rate at 1 year was 2.5%. There was a report of one erosion, and no serious adverse events were reported. Although the authors conclude that safety and effectiveness of MSA has been demonstrated outside of an investigational setting to further confirm it as treatment for GERD, study limitations include non-randomization and short follow-up period. ¹⁵

Ganz et al. (2016) described the 5-year follow-up evaluation of patients who received a magnetic sphincter augmentation (MSA) device for GERD. The original prospective study at 14 centers in the United States and

the Netherlands was conducted on 100 adults with GERD for 6 months or more, who were partially responsive to daily proton pump inhibitors (PPIs) and had evidence of pathologic esophageal acid exposure. At baseline, the median GERD-HRQL scores were 27 in patients not taking PPIs and 11 in patients on PPIs; 5 years after device placement this score decreased to 4. All patients used PPIs at baseline; this value decreased to 15.3% at 5 years. Moderate or severe regurgitation occurred in 57% of subjects at baseline, but only 1.2% at 5 years. All patients reported the ability to belch and vomit if needed. Bothersome dysphagia was present in 5% at baseline and in 6% at 5 years. Bothersome gas-bloat was present in 52% at baseline and decreased to 8.3% at 5 years. The authors concluded that MSA provides significant and sustained control of reflux, with minimal side effects or complications, which in their opinion validates the long-term safety and efficacy of MSA for patients with GERD. Study limitations include small patient population and non-randomization to another endoscopic procedure or surgical procedure for GERD. ¹³

Chen et al. (2009) conducted a systematic review that included 33 studies examining 7 endoscopic procedures (Stretta procedure, Bard EndoCinch, Wilson-Cook Endoscopic Suturing Device, NDO Plicator, Enteryx, Gatekeeper Reflux Repair System and Plexiglas) Of the three procedures that were compared with sham controls (Stretta procedure, Bard EndoCinch and Enteryx), patient outcomes in the treatment group were either as good as, or significantly better than, those of control patients in terms of heartburn symptoms, QOL, and medication usage. However, for the two procedures that were compared with the laparoscopic fundoplication (Stretta) procedure and the Bard EndoCinch device, outcomes for patients in the endoscopic group were conflicting. Some patients in the endoscopic group experienced comparable outcomes as patients undergoing the laparoscopic approach, while others Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) experienced inferior outcomes. The authors concluded that there is insufficient evidence to determine the safety and efficacy of endoscopic procedures for GERD, particularly over the long term. ¹⁰

Implanted stimulation devices ⁴⁷⁻⁵⁰

In a phase III study, Kappelle et al. described the safety and efficacy of lower oesophageal sphincter electrical stimulation therapy (LES-EST) in GERD patients with incomplete response to proton pump inhibitors (PPIs) in a prospective, international, multicentre, open-label study. Forty-four patients were enrolled and 6-month data from 41 patients are available. Hiatal repair was performed in 16 patients. The primary endpoint of this trial was the incidence of serious device- and procedure-related adverse events. Key efficacy endpoints were reduction in the GERD-HRQL composite score from baseline on- and off-PPIs following 6 months of EndoStim therapy, and improvement in acid reflux episodes. One device-related, one procedure-related and one unrelated severe adverse event were reported. At 6-month follow-up, 21 of 39 evaluable patients reported on the GERD-HRQL that they were “satisfied” with their condition while on PPI therapy, 10 patients were “neutral”, and 8 patients were “unsatisfied”. The authors concluded that these interim results show an acceptable safety record of LES-EST to date, combined with good short-term efficacy in GERD patients who are partially responsive to PPI therapy. Study limitations include small patient population, short term follow-up and non-randomization to another endoscopic or surgical procedure for GERD. ⁴⁷

Rodriguez et al. (2015) evaluated the safety and efficacy of LES stimulation in a single-center feasibility trial that was originally designed with a 6-month follow-up period but this was extended to 2 years. The trial enrolled 25 patients with chronic GERD that was at least partially responsive to PPIs. The primary endpoint was the incidence of serious device- and procedure-related adverse events. Key efficacy endpoints were GERD-

HRQL scores and percentage of 24-hour monitoring in which distal esophageal pH was < 4.0. The mean age of the patient population was 52 years; 14 patients were male and 10 were female. Only 3 of 24 patients had a body mass index within normal limits; the remainder were overweight or obese. At 2-year follow-up, 2 SAEs were reported; both occurred within 3 months of device implantation and both were deemed unrelated to the procedure or the device. A total of 65 AEs (including the 2 SAEs) were reported in 19 patients. Of the 63 non-serious events, 12 were considered related to the device or the procedure. There were no reports of gastrointestinal side effects. Study limitations include small patient population, short term follow-up and non-randomization to another endoscopic or surgical procedure for GERD. ⁴⁹

Rodriguez et al. (2016) assessed the safety and efficacy of LES stimulation in the same cohort as outlined above at 3 years. Fifteen patients completed their 3-year evaluation. Seventy-three % (11/15) patients had normalized their distal esophageal acid exposure at 3 years. Remaining four patients had improved their distal esophageal acid exposure by 39-48 % from baseline. All but four patients reported cessation of regular PPI use (>50 % of days with PPI use); three had normal esophageal pH at 3 years. There were no unanticipated device- or stimulation-related adverse events or untoward sensation reported during the 2- to 3-year follow-up. Study limitations include small patient population and non-randomization to another endoscopic or surgical procedure for GERD. ⁵⁰

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed
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
43289	Unlisted laparoscopy procedure, esophagus
43499	Unlisted procedure, esophagus
43999	Unlisted procedure, stomach

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Review/Revision History

3/11/2019: Policy created

9/16/2020: Policy reviewed, no changes. Updated references and added TOC.