

Molina Clinical Policy

Gastroesophageal Reflux Disease (GERD) Treatment:

Policy No. 337

Last Approval: 10/13/2021

Next Review Due By: October 2022



DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members.¹ References included were accurate at the time of policy approval and publication.

OVERVIEW

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 lower esophageal sphincter (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: lifestyle changes (e.g., dietary restriction, weight reduction); pharmaceuticals (e.g., antacids); Histamine 2 receptor antagonists (H2RAs) and Proton pump inhibitors (PPIs); minimally invasive and endoscopic procedures; and surgical treatment. Laparoscopic fundoplication is currently the gold standard treatment for GERD when medical management has failed. Other unproven minimally invasive treatment strategies may be classified into the following categories:²⁻⁸

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

COVERAGE POLICY

Minimally invasive therapy for GERD (e.g., 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 peer reviewed literature.⁹

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

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SUMMARY OF MEDICAL EVIDENCE 7-20,23-38

Overall, the quality of the evidence is low for minimally invasive therapy for GERD 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. This includes radiofrequency techniques, endoscopic suturing and stapling; injection and implantation of bulking agents or insertion of magnetic beads; and implanted stimulation devices. 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)

Noar, et al. 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.¹⁰

Kalapala, et al. 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.¹¹

Endoscopic Plication or Suturing or Stapling

De Moura, et al. 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 QOL 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 QOL 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.¹²

Trad, et al. 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

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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.¹³⁻¹⁶

Kim, et al. reported long-term outcomes from the Zacherl, et al. 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.¹⁷⁻¹⁹

Injection and Implantation of Bulking Agent or Insertion of Magnetic Beads

Louie, et al. 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 HRQL 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 HRQL 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.²⁰

Ganz, et al. 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. Botherome dysphagia was present in 5% at baseline and in 6% at 5 years. Botherome 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.²¹

Chen, et al. 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

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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 other minimally invasive procedures for 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.²²

Implanted Stimulation Devices

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.²³

Rodriguez, et al. 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 percentages 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. 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.²⁴

Rodriguez et al. 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 percent (11 of 15 patients) had normalized their distal esophageal acid exposure at 3 years. The 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.²⁵⁻²⁶

National and Specialty Organizations

The following organizations have published guidelines and other documents regarding this topic:

- American College of Gastroenterology (ACG) – *Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease* ²⁷
- Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) – *Guidelines for Surgical Treatment of Gastroesophageal Reflux Disease (GERD) and Clinical Spotlight Review: Endoluminal Treatments for Gastroesophageal Reflux Disease (GERD)* ²⁸⁻²⁹
- American Gastroenterological Association (AGA) – *Medical Position Statement on the Management of Gastroesophageal Reflux Disease (GERD)* ³⁰
- National Institute for Health and Care Excellence (NICE) – *Gastroesophageal Reflux Disease and Dyspepsia in Adults: Investigation and Management (no. 184); Endoscopic Radiofrequency Ablation for Gastroesophageal Reflux Disease (Interventional Procedure Guidance [IPG] 461); and Endoluminal Gastroplication for Gastroesophageal Reflux Disease (Interventional Procedure Guidance [IPG] 404)* ³¹⁻³³

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SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

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

HCPSC Codes - N/A

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/13/2021	Policy reviewed, no changes to criteria, updated Summary of Medical Evidence and references.
9/16/2020	Policy reviewed, no changes, updated references.
3/11/2019	New policy.

REFERENCES

Government Agency

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. <http://www.cms.gov/mcd/search.asp>. Accessed August 15, 2021.

Other Evidence Based Reviews and Publications

2. Hayes. Comparative effectiveness review: Endoscopic therapy for gastroesophageal reflux disease. <https://evidence.hayesinc.com>. Published December 7, 2017. Updated February 24, 2021. Accessed August 15, 2021. Registration and login required.
3. Hayes. Clinical research response: EsophyX device (Endogastric Solutions) versus LINX reflux management system (Torax Medical) – product comparison. <https://evidence.hayesinc.com>. Updated June 25, 2021. Accessed August 15, 2021. Registration and login required.
4. Hayes. Emerging technology report: EndoStim lower esophageal sphincter stimulation system. <https://evidence.hayesinc.com>. Updated August 11, 2017. Archived May 8, 2020. Accessed August 15, 2021. Registration and login required.
5. Hayes. Health technology assessment: Magnetic sphincter augmentation (LINX Reflux Management System) for treatment of gastroesophageal reflux disease. <https://evidence.hayesinc.com>. Published December 6, 2018. Updated February 3, 2021. Accessed August 15, 2021. Registration and login required.
6. Kahrilas P.J. Medical management of gastroesophageal reflux disease in adults. <http://www.uptodate.com>. Updated April 1, 2020. Accessed August 15, 2021. Registration and login required.
7. Schwaitzberg S. Surgical management of gastroesophageal reflux in adults. <http://www.uptodate.com>. Updated February 12, 2020. Accessed August 15, 2021. Registration and login required.
8. Triadafilopoulos G. Radiofrequency treatment for gastroesophageal reflux disease. <http://www.uptodate.com>. Updated May 18, 2021. Accessed August 15, 2021. Registration and login required.

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9. AMR Peer Review. Policy reviewed on January 7, 2019 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the area Gastroenterology.

Peer Reviewed Publications

10. Noar M, Squires P, Noar E, Lee M. Long-term maintenance effect of radiofrequency energy delivery for refractory GERD: a decade later. *Surg Endosc*. 2014 Aug;28(8):2323-33. doi: 10.1007/s00464-014-3461-6. Accessed August 15, 2021.
11. Kalapala R, Shah H, Nabi Z, et al. Treatment of gastroesophageal reflux disease using radiofrequency ablation (Stretta procedure): An interim analysis of a randomized trial. *Indian J Gastroenterol*. 2017 Sep;36(5):337-342. doi: 10.1007/s12664-017-0796-7. Accessed August 15, 2021.
12. De Moura EGH, Sallum RAA, Nasi A, et al. Endoscopic polymer injection and endoluminal plication in treatment of gastroesophageal reflux disease: Evaluation of long-term results. *Endosc Int Open*. 2018 May;6(5):E630-E636. doi: 10.1055/a-0573-1194. Accessed August 15, 2021.
13. Trad KS, Barnes WE, Prevou ER, et al. The TEMPO Trial at 5 years: Transoral fundoplication (TIF 2.0) is safe, durable, and cost-effective. *Surg Innov*. 2018 Apr;25(2):149-157. doi: 10.1177/1553350618755214. Accessed August 15, 2021.
14. Trad KS, Fox MA, Simoni G, et al. Transoral fundoplication offers durable symptom control for chronic GERD: 3-year report from the TEMPO randomized trial with a crossover arm. *Surg Endosc*. 2017 Jun;31(6):2498-2508. doi: 10.1007/s00464-016-5252-8. Accessed August 15, 2021.
15. Trad KS, Simoni G, Barnes WE, et al. Efficacy of transoral fundoplication for treatment of chronic gastroesophageal reflux disease incompletely controlled with high-dose proton-pump inhibitors therapy: a randomized, multicenter, open label, crossover study. *BMC Gastroenterol*. 2014;14:174.
16. Trad KS, Turgeon DG, Deljkich E. Long-term outcomes after transoral incisionless fundoplication in patients with GERD and LPR symptoms. *Surg Endosc*. 2012;26(3):650-660.
17. Domagk D, Menzel J, Seidel M, et al. Endoluminal gastroplasty (EndoCinch) versus endoscopic polymer implantation (Enteryx) for treatment of gastroesophageal reflux disease: 6-month results of a prospective, randomized trial. *Am J Gastroenterol*. 2006 Mar;101(3):422-30. doi: 10.1111/j.1572-0241.2006.00533.x. Accessed August 15, 2021.
18. Kim HJ, Kwon CI, Kessler WR, et al. Long-term follow-up results of endoscopic treatment of gastroesophageal reflux disease with the MUSE™ endoscopic stapling device. *Surg Endosc*. 2016 Aug;30(8):3402-8. doi: 10.1007/s00464-015-4622-y. Accessed August 15, 2021.
19. Zacherl J, Roy-Shapira A, Bonavina L, et al. Endoscopic anterior fundoplication with the Medigus Ultrasonic Surgical Endostapler (MUSE) for gastroesophageal reflux disease: 6-month results from a multi-center prospective trial. *Surg Endosc*. 2015 Jan;29(1):220-9. doi: 10.1007/s00464-014-3731-3. Accessed August 15, 2021.
20. Louie BE, Farivar AS, Shultz D, Brennan C, Vallières E, Aye RW. Short-term outcomes using magnetic sphincter augmentation versus Nissen fundoplication for medically resistant gastroesophageal reflux disease. *Ann Thorac Surg*. 2014 Aug;98(2):498-504; discussion 504-5. doi: 10.1016/j.athoracsur.2014.04.074. Accessed August 15, 2021.
21. Ganz RA, Edmundowicz SA, Taiganides PA, et al. Long-term outcomes of patients receiving a magnetic sphincter augmentation device for gastroesophageal reflux. *Clin Gastroenterol Hepatol*. 2016 May;14(5):671-7. doi: 10.1016/j.cgh.2015.05.028. Accessed August 15, 2021.
22. Chen D, Barber C, McLoughlin P, et al. Systematic review of endoscopic treatments for gastroesophageal reflux disease. *Br J Surg*. 2009;96(2):128-136.
23. Kappelle WF, Bredenoord AJ, Conchillo JM, et al. Electrical stimulation therapy of the lower esophageal sphincter for refractory gastroesophageal reflux disease: Interim results of an international multicentre trial. *Aliment Pharmacol Ther*. 2015 Sep;42(5):614-25. doi: 10.1111/apt.13306. Accessed August 15, 2021.
24. Rodríguez L, Rodríguez P, Gómez B, et al. Long-term results of electrical stimulation of the lower esophageal sphincter for the treatment of gastroesophageal reflux disease. *Endoscopy*. 2013 Aug;45(8):595-604. doi: 10.1055/s-0033-1344213. Accessed August 15, 2021.
25. Rodríguez L, Rodríguez P, Gómez B, et al. Two-year results of intermittent electrical stimulation of the lower esophageal sphincter treatment of gastroesophageal reflux disease. *Surgery*. 2015 Mar;157(3):556-67. <https://doi.org/10.1016/j.surg.2014.10.012>. Accessed August 15, 2021.
26. Rodríguez L, Rodríguez P, Gómez B, et al. Electrical stimulation therapy of the lower esophageal sphincter is successful in treating GERD: long-term 3-year results. *Surg Endosc*. 2016 Jul;30(7):2666-72. doi: 10.1007/s00464-015-4539-5. Accessed August 15, 2021.

National and Specialty Organizations

27. American College of Gastroenterology (ACG). Guidelines for the diagnosis and management of gastroesophageal reflux disease. *American Journal of Gastroenterology*. 2013;108(3), 308-328. doi: 10.1038/ajg.2012.444. Accessed August 15, 2021.
28. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Guidelines for surgical treatment of gastroesophageal reflux disease (GERD). <https://www.sages.org/publications/guidelines/>. Published 2010. Accessed August 15, 2021.
29. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Clinical spotlight review: Endoluminal treatments for gastroesophageal reflux disease (GERD). <https://www.sages.org/publications/guidelines/>. Published May 2017. Accessed August 15, 2021.
30. Kahrlas PJ, Shaheen NJ, Vaezi MF, Hiltz SW, Black E, American Gastroenterological Association (AGA), et al. American Gastroenterological Association medical position statement on the management of gastroesophageal reflux disease. *Gastroenterology*. 2008 Oct;135(4):1383-1391. doi: 10.1053/j.gastro.2008.08.045.
31. National Institute for Health and Care Excellence (NICE). Gastroesophageal reflux disease and dyspepsia in adults: Investigation and management (no. 184). <https://www.ncbi.nlm.nih.gov/books/NBK552570/>. Published 2019. Accessed August 15, 2021.
32. National Institute for Health and Care Excellence (NICE). Endoscopic radiofrequency ablation for gastroesophageal reflux disease (interventional procedure guidance [IPG] 461). <https://www.nice.org.uk/guidance/ipg461>. Published 2013. Accessed August 15, 2021.
33. National Institute for Health and Care Excellence (NICE). Endoluminal gastroplication for gastroesophageal reflux disease (interventional procedure guidance [IPG] 404). <https://www.nice.org.uk/guidance/ipg404>. Published 2011. Accessed August 15, 2021.

Other Peer Reviewed and Professional Organization Publications (used in the development of this policy)

34. Vaezi MF, et al. White paper AGA: Optimal strategies to define and diagnose gastroesophageal reflux disease. *Clin Gastroenterol Hepatol*. 2017 Aug;15(8):1162-1172. doi: 10.1016/j.cgh.2017.03.021.
35. Hu Z, Wu J, Wang Z, Zhang Y, Liang W, Yan C. Outcome of Stretta radiofrequency and fundoplication for GERD-related severe asthmatic symptoms. *Front Med*. 2015 Dec;9(4):437-43. doi: 10.1007/s11684-015-0422-y. Accessed August 15, 2021.

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36. Saino G, Bonavina L, Lipham JC, Dunn D, Ganz RA. Magnetic sphincter augmentation for gastroesophageal reflux at 5 years: final results of a pilot study show long-term acid reduction and symptom improvement. *J Laparoendosc Adv Surg Tech A*. 2015 Oct;25(10):787-92. doi: 10.1089/lap.2015.0394. Accessed August 15, 2021.
37. Liang WT, Yan C, Wang ZG, et al. Early and midterm outcome after laparoscopic fundoplication and a minimally invasive endoscopic procedure in patients with gastroesophageal reflux disease: A prospective observational study. *J Laparoendosc Adv Surg Tech A*. 2015 Aug;25(8):657-61. doi: 10.1089/lap.2015.0188. Accessed August 15, 2021.
38. Noar M, Squires P, Khan S. Radiofrequency energy delivery to the lower esophageal sphincter improves gastroesophageal reflux patient-reported outcomes in failed laparoscopic Nissen fundoplication cohort. *Surg Endosc*. 2017 Jul;31(7):2854-2862. doi: 10.1007/s00464-016-5296-9. Accessed August 15, 2021.
39. Testoni PA, Testoni S, Mazzoleni G, Vailati C, Passaretti S. Long-term efficacy of transoral incisionless fundoplication with EsophyX (TIF 2.0) and factors affecting outcomes in GERD patients followed for up to 6 years: A prospective single-center study. *Surg Endosc*. 2015 Sep;29(9):2770-80. doi: 10.1007/s00464-014-4008-6. Accessed August 15, 2021.
40. Nicolau AE, Lobonțiu A, Constantinoiu S. New minimally invasive endoscopic and surgical therapies for gastroesophageal reflux disease (GERD). *Chirurgia (Bucur)*. Jan-Feb 2018;113(1):70-82. doi: 10.21614/chirurgia.113.1.70. Accessed August 15, 2021.
41. Louie BE, Smith CD, Smith CC, et al. Objective evidence of reflux control after magnetic sphincter augmentation: One year results from a post approval study. *Ann Surg*. 2019 Aug;270(2):302-308. doi: 10.1097/SLA.0000000000002789. Accessed August 15, 2021.
42. Reynolds JL, Zehetner J, Nieh A, et al. Charges, outcomes, and complications: A comparison of magnetic sphincter augmentation versus laparoscopic Nissen fundoplication for the treatment of GERD. *Surg Endosc*. 2016 Aug;30(8):3225-30. doi: 10.1007/s00464-015-4635-6. Accessed August 15, 2021.
43. Reynolds JL, Zehetner J, Wu P, Shah S, Bildzukewicz N, Lipham JC. Laparoscopic magnetic sphincter augmentation vs laparoscopic Nissen fundoplication: A matched-pair analysis of 100 patients. *J Am Coll Surg*. 2015 Jul;221(1):123-8. doi: 10.1016/j.jamcollsurg.2015.02.025. Accessed August 15, 2021.
44. Riegler M, Schoppman SF, Bonavina L, Ashton D, Horbach T, Kemen M. Magnetic sphincter augmentation and fundoplication for GERD in clinical practice: One-year results of a multicenter, prospective observational study. *Surg Endosc*. 2015 May;29(5):1123-9. doi: 10.1007/s00464-014-3772-7. Accessed August 15, 2021.
45. Yan C, Liang WT, Wang ZG, et al. Comparison of Stretta procedure and Toupet fundoplication for gastroesophageal reflux disease-related extra-esophageal symptoms. *World J Gastroenterol*. 2015;21(45):12882-12887. doi: 10.3748/wjg.v21.i45.12882. Accessed August 15, 2021.
46. Hunter JG, Kahrilas PJ, Bell RC, et al. Efficacy of transoral fundoplication vs omeprazole for treatment of regurgitation in a randomized controlled trial. *Gastroenterology*. 2015 Feb;148(2):324-333.e5. doi: 10.1053/j.gastro.2014.10.009. Accessed August 15, 2021.
47. Yadlapati R, Vaezi MF, Velo MF, et al. Management options for patients with GERD and persistent symptoms on proton pump inhibitors: Recommendations from an expert panel. *Am J Gastroenterol*. 2018 Jul;113(7):980-986. doi: 10.1038/s41395-018-0045-4. Accessed August 15, 2021.
48. Patti MG. An evidence-based approach to the treatment of gastroesophageal reflux disease. *AMA Surg*. 2016 Jan;151(1):73-8. doi: 10.1001/jamasurg.2015.4233. Accessed August 15, 2021.

APPENDIX

Reserved for State specific information (to be provided by the individual States, not Corporate). Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.