Molina Clinical Policy
Gastroesophageal Reflux Disease (GERD) Treatment
Policy No. 337

Last Approval: 10/08/2025
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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. References included were accurate at the time of policy approval and publication.

OVERVIEW

Gastroesophageal reflux disease (GERD) is a chronic condition characterized by persistent symptoms or mucosal damage caused by an abnormal reflux of gastric contents into the esophagus. Causes of GERD include lower esophageal sphincter (LES) weakness, hiatal hernia (HH), temporary LES relaxation, alterations in the gastroesophageal pressure gradient, and impaired esophageal clearance or motility. Diagnosis of GERD is typically based on clinical symptoms, response to medication therapy and lifestyle modifications, and when needed, minimally invasive testing. A positive response to a proton pump inhibitor (PPI) therapy is often considered presumptive evidence of GERD. Conventional management of GERD includes lifestyle changes (e.g., dietary adjustments, weight loss), pharmacologic therapy (e.g., antacids, histamine 2 receptor antagonists [H2RAs], and PPIs), endoscopic procedures, and surgical intervention.

A number of minimally invasive therapies for GERD have been developed and remain under investigation. These can be broadly classified into the following categories (Hayes 2024; Hayes 2025; Schwaitzberg 2023):

- **Radiofrequency (RF) energy (Stretta procedure)** is delivered to the LES and gastric cardia with the goal of constricting tissue, reducing transient LES relaxations, and strengthening the gastroesophageal barrier. The Stretta procedure, FDA-cleared in 2000, is thought to decrease gastroesophageal junction compliance and promote healing of erosive esophagitis, though its exact mechanism of action remains unclear, and appropriate patient selection criteria have not been well defined (Triadafilopoulos 2023).
- **Endoscopic suturing techniques** such as transoral fundoplication (TIF) use fasteners or staples to remodel the gastroesophageal junction, thereby enhancing the barrier against reflux. Endoscopic stapling involves clamping and stapling the esophagus to the stomach proximal to the gastroesophageal junction (e.g., Bard® EndoCinch, Enteryx, Endoscopic Suturing System or Device, Endoscopic Plication system, Stomaphyx, EsophyX and MUSE).
- **Injection and implantation of bulking agents or magnetic augmentation** may be injected or implanted around the LES to decrease transient relaxations and reduce reflux (e.g., Plexiglas, Durasphere, and insertion of magnetic beads [LINX]).
- **Implanted electrical stimulation devices** are designed to normalize the LES through neuromodulation (e.g., Endostim neurostimulation therapy). The Endostim device consists of a subcutaneously implanted pulse generator connected to a bipolar lead that delivers electrical stimulation to the LES.

COVERAGE POLICY

Minimally invasive therapies 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.

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.

SUMMARY OF MEDICAL EVIDENCE

The overall quality of the evidence supporting minimally invasive therapies for GERD is low. Limitations include small sample size, lack of randomization and/or blinding, short-term follow-up, inconsistent comparators, and methodological flaws. These limitations apply across modalities including radiofrequency techniques, endoscopic suturing and stapling, injection or implantation of bulking agents or magnetic beads, and implanted stimulation devices. Large, well-designed randomized controlled trials (RCTs) comparing these therapies with established surgical options such as laparoscopic fundoplication and optimized medical management strategies (over a long period of follow-up) are needed to establish their safety, efficacy, and appropriate patient selection.

Radiofrequency Energy (Stretta System)

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Kalapala et al. (2017) assessed short outcomes (3 months) from a prospective randomized study comparing the Stretta treatment with proton pump inhibitors (PPIs). A total of 20 patients with symptomatic GERD and abnormal esophageal acid exposure and esophagitis were included in 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. At 3 months, 80% of Stretta patients reported improvement in QOL compared to 40% in the control group. At the end of 3 months, significant improvement in GERD symptom scores for heartburn, regurgitation, chest pain, and cough compared with the control group were observed. After Stretta treatment, 60% of the patients stopped taking 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.

Endoscopic Plication or Suturing or Stapling

Randomized Controlled Trials

Kalapala et al. (2021) conducted a randomized, double-blinded, sham-controlled trial evaluating the GERD-X endoscopic full-thickness fundoplication (EFTP) device in 70 PPI-treated patients with GERD. The primary endpoint was improvement in the Gastroesophageal Reflux Disease–Health Related Quality of Life (GERD-HRQL) score. A ≥50% reduction in GERD-HRQL score at 3 months was defined as treatment success. Secondary outcomes assessed at 3, 6, and 12 months included GERD-HRQL scores, reflux symptom scores, PPI usage, and endoscopic findings. In-person assessments were performed at 3, 6, and 12 months and included GERD-HRQL scoring and esophagogastroduodenoscopy (EGD). High-resolution manometry (HRM) and 24-hour pH impedance monitoring were performed at 3 and 12 months. At 3 months, 65.7% of the EFTP group achieved the primary endpoint compared with only 2.9% in the sham group ($p<0.001$). Significant improvements in GERD-HRQL scores persisted at 6 and 12 months. Although 24-hour pH impedance monitoring in the EFTP group showed partial improvement at both 3 and 12 months, these differences did not reach statistical significance. However, the EFTP arm demonstrated fewer total reflux episodes in 24 hours compared to baseline, with continued improvement through 12 months. When compared to the sham arm, the reduction in reflux episodes in the EFTP group approached significance at 3 months ($p=0.072$) and 12 months ($p=0.051$). By study completion, 63% of patients in the EFTP group had discontinued PPIs versus 11% in the sham group. The average procedure time for EFTP was 17.4 ± 4 minutes. No major adverse events were reported in either group. The authors concluded that while EFTP demonstrated clinical benefit, larger prospective trials with long-term follow-up are needed to establish its role in GERD management.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

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 QOL score (GERD-HRQL) demonstrated total response in both procedures at one, three, six 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 three months and showed a higher rate of complications. There were no deaths. There was healing of esophagitis at three 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.

Trad et al. (2018) described five-year outcomes for the transoral incisionless fundoplication (TIF 2.0) EsophyX vs Medical PPI Open label (TEMPO) clinical trial regarding safety, durability, and cost-effectiveness for 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 one year, 52 at three years, and 44 at five years for evaluation. Troublesome regurgitation was eliminated in 88% of patients at one year, 90% at three years, and 86% at five years. Resolution of troublesome atypical symptoms was achieved in 82% of patients at one year, 88% at three years, and 80% at five years. No serious adverse events occurred. There were three reoperations by the end of the five-year follow-up. At the five-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 five years ($P < .001$). Patient selection had a narrow scope with a focus on ideal surgical candidates that had long-term documentation of reflux, continued symptoms with optimized medical therapy, and a desire for surgical intervention. The authors concluded that in this patient population, the TIF procedure provided safe and sustained long-term elimination of troublesome GERD symptoms. Study limitations include small patient population, stringent patient selection, and non-randomization to another endoscopic procedure or surgical procedure for GERD.

Weitzendorfer et al. (2018) conducted a prospective single-center one-arm trial of 40 patients pre- and post-procedure for full-thickness plication using the GERDx device. The study included patients with one typical reflux symptom that did not respond to > six months of PPI treatment, hiatal hernia < 2 cm, and endoscopic Hill Grade II-III. Patients excluded from this study were less than 18 years, had an American Society of Anesthesiologists physical status classification III-IV, had paraoesophageal or hiatal hernia measuring >2 cm, gastroesophageal flap valve grade IV, any previous esophageal or gastric surgery and were pregnant. The primary focus of the study measured Gastrointestinal Quality of Life Index (GIQLI) scores at baseline and three months post-procedure to determine outcomes. While there were no intraoperative complications, four out of 40 patients developed a post-procedure complication that required intervention. In addition, seven out of 40 patients continued to have persistent symptoms after the initial procedure and required secondary laparoscopic fundoplication within three months of endoscopic plication. These patients did not continue in the study and were not followed. At three months post-procedure 30 patients remained in the study. Three patients remained on daily antireflux medication post-procedure due to complaint of persistent GERD symptoms and did not meet the primary goal of the study to eliminate the need for daily PPI medication. The patients who continued the study did report an improvement in GIQLI score of at least 15 points. Esophageal acid exposure, reflux-specific symptom scores, and perioperative morbidity were secondary outcomes. At this time, the GERDx device continues to require additional investigation that would include a larger sample size and longer-term results.

Injection and Implantation of Bulking Agent or Insertion of Magnetic Beads

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Ayazi et al. (2020) conducted a retrospective review of prospective collected data on 380 patient who underwent magnetic sphincter augmentation (MSA) between 2013 to 2018 at the Allegheny Health Network hospitals (Pittsburgh, PA). Patient selection for the MSA procedure were prescribed antisecretory medications but continued to complain of break-through symptoms. A focus of the study was to identify pre-procedure predictive factors for the development of dysphagia and best-practice management of patients with post-procedure dysphasia. All patients received a pre-procedure clinical evaluation with focus on foregut symptoms including use of acid suppression medications. Pre-procedure testing included esophagogastroduodenoscopy (EGD), high-resolution impedance manometry (HRIM), esophageal pH monitoring, and videoesophagram. Patient inclusion criteria were age 18 years or older with persistent GERD despite maximum antisecretory therapy and demonstrated evidence of reflux disease based on increased esophageal acid exposure on pH monitoring or a positive impedance-pH base. Any patient with a previous history of esophageal or gastric surgery, gross anatomic abnormalities such as esophageal stricture, significant esophageal dysphasia, or a known allergy to titanium were excluded. A control group of patients were offered laparoscopic Nissen fundoplication surgical treatment for post-procedure comparison to the group that received MSA. Initially post-MSA procedure 63.2% of patients reported dysphagia. Patients were evaluated post-procedure and then at two weeks, six weeks, six months, and yearly thereafter. At 11.5 months 15.5% of MSA patients continued to experience persistent post-procedure dysphagia, which was defined as dysphagia > three months. The need for at least one post-procedure dilatation was required in 30.5% of the MSA group, 39.6% of this group had resolution of dysphasia after one dilatation. All patients requiring dilatation (regardless of number of dilatations) was 67%. Early dilatation prior to eight weeks post-

procedure found that only 21% had resolution of symptoms. Dilation protocols were then adjusted in 2017 until symptoms exceeded eight weeks. This decreased the need for dilatation from 50% in 2014 to 30% in 2017.Use of a smaller MSA device was also identified as a potential factor leading to increased risk of development of dysphasia. The protocol for device size was also adjusted and correlated with an additional decrease in need for dilatation to 18% in 2018. A strict diet protocol was implemented with overall improvement in post-procedure results. Removal of the device due to persistent dysphasia occurred in 1.7% of the study participants. The MSA device continues to require further investigation utilizing well-defined patient criteria and post-procedure protocols that address persistent dysphasia in a larger sample size with comparison to other treatment modalities.

Implanted Stimulation Devices

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Kröner et al. (2021) provides an assessment of the medical management of GERD and an updated review of the evidence on lifestyle modifications and pharmacological therapy for the management of GERD. Lifestyle modifications and pharmacologic agents are the cornerstones of GERD medical management. Current evidence shows a link between anti-reflux pharmacologic therapy to adverse events (e.g., kidney injury, metabolic bone disease, myocardial infarction, etc.). The authors performed a systematic search of PubMed/MEDLINE, Embase, and Cochrane Library databases between inception and March 1, 2021. While pharmacological therapy has been associated with potential adverse events, additional research is needed to determine if the link exists. Due to potential safety and efficacy concerns, lifestyle modifications are considered the first-line approach to treatment of GERD; pharmacologic therapy may be considered for patients when lifestyle modifications are not effective, or such modifications cannot be implemented.

Paireder (2019) reported on an observational prospective single-center study for 37 patients who underwent laparoscopic lower esophageal (LES) electrical stimulation therapy (EST) treatment at the Medical University of Vienna. All patients considered for the study met clinical indication for anti-reflux surgery. Initial preoperative evaluation included upper GI endoscopy and esophageal function testing that included high-resolution impedance manometry. This study had some significant limitations including small sample size, the need for hiatal hernia repair for 62.2% of the patients, and technical problems with device malfunction due to lead leakage in four patients requiring device removal and conversion to fundoplication. Malfunction at this high a rate is concerning for the overall safety of the device. The significant limitations of this study do not support the use of LES-EST treatment.

National and Specialty Organizations

The **American College of Gastroenterology (ACG)** published updated *Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease* (GERD) in 2022. The disease continues to be one of the most common seen by gastroenterologists, surgeons, and primary care physicians. Understanding of its presentations and enhancements in diagnosing GERD have evolved along with approaches of patient management. The ACG notes that while PPIs are the standard medical treatment for GERD, several publications have highlight adverse events which lead to concerns about the safety and efficacy of long-term use of PPIs, including overprescribing. Recent data shows promise for surgical and endoscopic interventions, including pharmacologic (Katz et al. 2022).

The AGA published the *AGA Clinical Practice Update on the Personalized Approach to the Evaluation and Management of GERD: Expert Review* to outline a personalized diagnostic and therapeutic approach to GERD symptoms (Yadlapati et al. 2022). Best Practice Advice was developed from expert review consisting of literature along with discussion and expert opinion.

The **Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)** completed a review that assessed outcomes of antireflux surgery versus medical management of GERD in adults and children, robotic versus laparoscopic fundoplication, complete versus partial fundoplication, and minimal versus maximal dissection in pediatric patients. Randomized control and non-randomized comparative studies were identified from 2004-2019 from PubMed, Embase, and Cochrane databases. Of 1473 records identified, 105 studies were included – most had high or uncertain risk of bias (Slater et al. 2021). Anti-reflux surgery was found in association with superior short-term quality of life compared to PPI however short-term symptom control which was not significantly superior. A total of 28% of patients undergoing operative treatment continued PPI treatment. The review also found similar outcomes with robotic and laparoscopic fundoplication. Compared to total fundoplication, partial fundoplication was associated with higher rates of prolonged PPI usage. No statistically significant difference for long-term symptom control or long-term dysphagia was identified; no difference was noted for minimal dissection during fundoplication was associated with lower

reoperation rates than maximal dissection. The conclusion found is that available evidence has high risk of bias – additional high-quality randomized control trials are needed to determine the safety and efficacy for surgical decision making in the treatment of GERD.

The **National Institute for Health and Care Excellence (NICE)** published guidance on the treatment of GERD in their Clinical Guideline, *Gastroesophageal Reflux Disease and Dyspepsia in Adults: Investigation and Management (CG184)*. The guideline does not include information on RF energy, endoscopic suturing techniques, bulking agents, or implanted stimulation devices.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	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

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

10/08/2025	Policy reviewed. No changes to coverage criteria. Updated Overview, Summary of Medical Evidence, and References.
10/09/2024	Policy reviewed, no changes to criteria, updated Summary of Medical Evidence and References. IRO Peer Review on September 9, 2024 by a practicing physician board-certified in Internal Medicine; Gastroenterology.
10/12/2023	Policy reviewed, no changes to criteria, updated Summary of Medical Evidence section.
10/12/2022	Policy reviewed, no changes to criteria, updated Summary of Medical Evidence section.
10/13/2021	Policy reviewed, no changes to criteria, updated Summary of Medical Evidence, and references.
09/16/2020	Policy reviewed, no changes, updated references.
03/11/2019	New policy. AMR Peer Review on January 7, 2019, by a practicing, board certified physician with a specialty in Gastroenterology.

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