Endoscopic Treatments for Gastroesophageal Reflux Disease (GERD)

MEDICAL POLICY NUMBER: 124

Effective Date: 2/1/2025

Last Review Date: 1/2025

Next Annual Review: 1/2026

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Upper Endoscopy for GERD or DYSPESIA Symptoms: Guideline Note D12.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Notes:

- This policy does not address the per-oral endoscopic myotomy (POEM) or magnetic esophageal ring (i.e., LINX® Reflux Management System) procedures. See "Policy Cross-References" for additional information.

I. Transoral incisionless fundoplication (TIF) (i.e., EsophyX) is considered **not medically necessary** for the treatment of gastroesophageal reflux disease.

II. Other endoscopic treatments for gastroesophageal reflux disease are considered **not medically necessary**, including but not limited to the following (A.-D.):

A. Transesophageal radiofrequency ablation of the gastroesophageal junction (e.g. Stretta®)
B. Endoscopic suturing (e.g. EndoCinch™ Suturing System)
C. Endoluminal gastroplasty
D. Endoscopic implantation of a prosthesis or bulking agent (e.g. Gatekeeper™ Reflux Repair System, Durasphere™)

Link to Evidence Summary

POLICY CROSS REFERENCES

- Peroral Endoscopic Myotomy (POEM), MP191
- Gastroesophageal Reflux Disease: Magnetic Esophageal Ring, MP125

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

Gastroesophageal Reflux Disease (GERD)

GERD is the most common principal gastroenterology-related diagnosis, with 8.9 million cases diagnosed annually in the U.S., and it is the fifth most common hospital discharge diagnosis at 4.4 million. GERD involves the abnormal reflux of gastric contents into the esophagus. Chronic GERD can lead to mucosal damage. Causes of GERD include weakness or relaxation in the lower esophageal sphincter (LES), presence of a hiatal hernia (HH), and/or changes in gastroesophageal pressure. Initial therapy includes acid-suppressive medications and lifestyle modifications (e.g., elevated sleeping, reducing fat intake, weight loss). Pharmacogenetic therapy includes proton pump inhibitors (PPIs) and histamine-2 receptor antagonists (H2Ras). "For patients who wish to discontinue use of these medications or for patients whose GERD is refractory to pharmacologic treatment, an open or laparoscopic Nissen fundoplication may be considered.

Endoscopic Treatments for GERD

Endoscopic treatments for GERD are intended to alter the structure of the gastroesophageal junction (GEJ) in order to prevent reflux of gastric contents. These techniques are less invasive than Nissen fundoplication and are intended to provide an option for patients who are refractory to pharmacologic GERD therapy. Endoscopic therapies for GERD are typically classified into three caftegories:

(1) Radiofrequency energy (RFE) delivered to the GEJ (e.g., Stretta™)
    - RFE is applied to the lower esophageal sphincter (LES) muscle in order to thicken the musculature and increase the size and amount of smooth muscle fibers for better barrier function and fewer transient LES relaxations.

(2) Endoscopic plication or suturing of the proximal stomach to the esophagus (e.g., EsophyX™)
    - Transoral incisionless fundoplication (TIF) is used to recreate a barrier against reflux by retracting the tissue at the LES and attaching implantable fasteners (EsophyX™) or staples (MUSE™).

(3) Polymer injection or implantation of bulking agents into the gastric cardia or distal esophagus (e.g., Gatekeeper™ Reflux Repair System)
    - Bulking agents are implanted into the submucosa of the distal esophagus in order to restrict the dimensions of the esophagus; therefore, limiting the aperture through which gastroesophageal reflux must flow.[1]

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

Devices for the endoscopic treatment of gastroesophageal reflux disease have been approved by the FDA as class II devices under the 510(k) premarket notification process or as class III devices under the premarket approval (PMA) process. The table below may not be exhaustive. Additional information is available by searching the FDA 510(k) or PMA database.

Note: The Gatekeeper™ Reflux Repair System is not an FDA-approved device.

Device Name and Manufacturer	Indications for Use
Stretta® by Mederi®[2]	Intended for general use in the electrosurgical coagulation of tissue and intended for use specifically in the treatment of Gastroesophageal Reflux Disease (GERD).
EsophyX™ by EndoGastric Solutions (EGS)[3]	The EndoGastric Solutions (EGS) EsophyX™ System with SerosaFuse™ Fastener is indicated for use in endoluminal, transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated 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.
EndoCinch™ Suturing System by Bard®[4]	For endoscopic placement of suture(s) in the soft tissue of the esophagus and stomach and for approximation of tissue for the treatment of symptomatic gastroesophageal reflux disease.
Medigus™ Ultrasonic Surgical Endostapler (MUSE™) System[5]	The Medigus Ultrasonic Surgical Endostapler (MUSETM) System is intended for endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach in order to create anterior partial fundoplication for treatment of symptomatic chronic Gastro Esophageal Reflux Disease in patients who require and respond to pharmacological therapy.
Durasphere™ by Advanced UroScience, Inc.	• Durasphere is indicated for use in the treatment of adult women with stress urinary incontinence (SIU) due to intrinsic sphincter deficiency (ISD). • **There is no FDA indication for the treatment of GERD.**

CLINICAL EVIDENCE AND LITERATURE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of endoscopic treatments for gastroesophageal reflux disease (GERD). Below is a summary of the available evidence identified through December 2024.

An evidence review on the endoscopic implantation of a prosthesis or bulking agent (e.g., Gatekeeper™ Reflux Repair System, Durasphere) was not conducted as these therapies have not met the safety and efficacy requirements to receive FDA approval for the treatment of gastroesophageal reflux disease.

Systematic Reviews

- In 2023, ECRI updated an evidence review evaluating the safety and efficacy of the EsophyX for the treatment of gastroesophageal reflux disease.[6] Searching the literature through April 2023, ECRI examined evidence from five systematic reviews (SRs) that provided data to address EsophyX's safety and effectiveness for treating GERD. Outcomes of interest included health-related quality of life (HRQL) and GERD symptom indices, PPI reduction/cessation and adverse events.

  - HRQL and GERD symptom indices: GERD symptoms and quality of life were shown to improve in one SR with TIF, have no improvement in 3 other meta-analyses of RCTs.

  - PPI reduction and cessation: Results of PPI use varied across SRs. One review found reduction in PPI post-TIF. Two others found no difference in cessation rates between patients treated with Esophyx and other procedures, while another meta-analysis found more patients treated with LINX ceased use of PPI than Esophx.

  ECRI found a number of limitations in the evidence, including:

  - None of the SRs included studies that performed head-to-head comparisons between EsophyX and other GERD devices.
  - High heterogeneity across studies for most outcomes
  - All combined results from studies with widely differing follow-up times, thereby possibly combining outcomes for short-term and long-term follow-up.
  - Differing study inclusion and exclusion criteria
  - Data are at high risk of bias due to lack of randomization, blinding, and control groups.

  ECRI concluded that, “EsophyX is safe and improves symptoms and quality of life in most patients with persistent GERD symptoms despite PPI therapy, based on evidence from five systematic reviews (SRs); however, the studies assess too few patients per comparison to determine how well it works compared with LNF or other minimally invasive procedures and devices, such as magnetic sphincter augmentation (MSA) with LINX (Ethicon, Inc.), radiofrequency ablation with Stretta (Restech), and TIF with MUSE (Medigus Ltd.). Randomized controlled trials (RCTs) that directly compare EsophyX with other devices and procedures for treating GERD and report on long-term patient-oriented outcomes would be useful to support stronger conclusions.”

  ECRI gave EsophyX for treating GERD a ‘somewhat favorable” rating.

- In 2019, the Oregon Health Evidence Review Commission (HERC) published a coverage guidance addressing new interventional procedures for the treatment of GERD.[7] Investigators limited their

evidence review to 2 systematic reviews, Huang et al. (2017),[8] and one of which is discussed in the ECRI review discussed below (Richter et al. (2018)).[9] On the basis of these studies, HERC concluded that transoral incisionless fundoplication (TIF) performed with the EsophyX device appears to improve GERD-related quality of life and reduces/eliminates the need for chronic PPI therapy, although the durability of this improvement beyond 3-years was uncertain. Evidence was judged insufficient to suggest that TIF reduces the rate of incident Barrett's esophagus or complications of GERD. Investigators ultimately issued a "weak recommendation" for transoral incisionless fundoplication (TIF) on the basis of "low-certainty" evidence. A "weak recommendation" signifies that the therapy's desirable effects "probably outweigh the undesirable effects…but [that] further research or additional information could lead to a different conclusion." HERC also issued "strong recommendation" against repeat TIF for patients who have recurrent symptoms or fail the initial TIF procedure.

- In 2018, McCarty and colleagues conducted a systematic review and meta-analysis evaluating the safety and efficacy of TIF for the treatment of GERD.[10] Independent investigators systematically searched the literature through March 2017, identified eligible studies, assessed study quality, extracted data and pooled results. Outcomes of interest included immediate technical success rate and serious adverse events. Symptomatic improvement was measured using GERD Health-related quality of life (HRQL), gastroesophageal reflux symptom score (GERSS), and Reflux Symptom Index (RSI). Objective success was determined by hiatal hernia reduction and pH monitoring. Mean follow-up time was 15.8 months.

  In total, 32 studies evaluating 1475 patients were included for review. TIF success rate was 99% (95% confidence interval [CI] 97 to 100; P < 0.001), with an adverse event rate of 2% (95%CI 1 to 3; P < 0.001). Patients' HRQL, GERSS, and RSI all improved significantly post-TIF (mean difference 17.72, 95 %CI 17.31 to 18.14; mean difference 23.78, 95% CI 22.96 to 24.60; mean difference 14.28, 95 %CI 13.56 to 15.01; all P < 0.001, respectively). Hernia reduction occurred in 91% of patients (95 %CI 83 to 98; P < 0.001). Moreover, PPI therapy was discontinued post-procedure in 89% of patients (95%CI 82 to 95; P < 0.001). Limitations included reviewed studies' heterogeneous patient populations, lack of long-term of follow-up, and varying generations of devices assessed. Authors also noted that no studies directly compared TIF with laparoscopic Nissen fundoplication. This comparison may be inappropriate, however, as the two procedures are performed in distinct patient populations and form different degrees of fundoplication (i.e. 220 degrees versus 360 degrees).

<u>Randomized Controlled Trials (RCTs)</u>

- In 2018, Trad and colleagues reported findings at 5-year follow-up for GERD patients who had been treated with transoral incisionless fundoplication (TIF).[11] In total, data were reported for 44 of the initial 63 chronic GERD sufferers with symptoms refractory to proton pump inhibitor (PPI) therapy. At 5-year follow-up, troublesome regurgitation was eliminated in 80 percent of patients and GERD Health-related quality-of-life improved significantly. No serious adverse events reported. Limitations included the study's small sample size, lack of comparator groups, and high attrition rate (30%). Moreover, 34% of patients assessed at 5-year follow-up continued to use daily PPI therapy, which undermines conclusions regarding the stand-alone efficacy of TIF.

- The evidence review identified four additional RCTs evaluating the Stretta or EsophyX endoscopic devices for treating GERD.[12-16] RCTs were limited by one or more of the following: small sample sizes, lack of long-term follow-up and heterogeneous treatment parameters.

CLINICAL PRACTICE GUIDELINES

American College of Gastroenterology (ACG)

In 2022, the ACG published evidence-based guidelines for the diagnosis and management of gastroesophageal reflux disease.[17]

- For Esophyx, the guidelines state, "For patients who have regurgitation as their primary PPI-refractory symptom and who have had abnormal gastroesophageal reflux documented by objective testing, we suggest consideration of antireflux surgery or TIF (conditional recommendation, low level of evidence).

  Two randomized trials with TIF also demonstrate better improvement in regurgitation with TIF compared with high-dose PPIs, although the magnitude of improvement was not as great as with MSA… Randomized trials have shown that TIF is effective for treating troublesome regurgitation (180,231), but the long-term benefit of TIF is not established and questionable (217)."

- For Stretta, the guideline states, "Because data on the efficacy of radiofrequency energy (Stretta) as an antireflux procedure is inconsistent and highly variable, we cannot recommend its use as an alternative to medical or surgical antireflux therapies (conditional recommendation, low level of evidence).

  "The Stretta procedure is difficult to evaluate, in part because it is not totally clear how it functions as an antireflux therapy. Initially, it was believed to control reflux by inducing swelling and mechanical alteration at the esophagogastric junction. However, an early, sham-controlled trial found that, 6 months after treatment, Stretta had significantly improved GERD symptoms and quality of life, but it did not decrease esophageal acid exposure (227). This raised the possibility that the procedure might alleviate GERD symptoms by altering sensation in the distal esophagus. Systematic reviews and meta-analyses have arrived at contradictory conclusions regarding Stretta's efficacy. One meta-analysis that evaluated only RCTs found that Stretta did not produce significant changes in esophageal acid exposure, quality of life, or the ability to stop PPIs (228), whereas another meta-analysis that included both controlled and cohort studies concluded that Stretta significantly reduced esophageal acid exposure, improved quality of life, and decreased PPI usage (229). Nevertheless, in 2013, the Society of American Gastrointestinal and Endoscopic Surgeons gave Stretta a strong recommendation for use in patients who refuse laparoscopic Nissen fundoplication."

American Society of General Surgeons (ASGS)

The ASGS released a position statement on the basis of a non-systematic review of evidence. Authors stated that "the ASGS supports the use of transoral fundoplication by trained General Surgeons for the treatment of symptomatic chronic gastroesophageal reflux disease (GERD) in patients who fail to

achieve satisfactory response to a standard dose of Proton Pump Inhibitor (PPI) therapy or for those who wish to avoid the need for a lifetime of medication dependence."[18]

American Gastroenterological Association (AGA)

In 2022, the AGA published a clinical practice update on the personalized approach to the evaluation and management of GERD based on expert review.[19]
"In patients with proven GERD, laparoscopic fundoplication and magnetic sphincter augmentation are effective surgical options, and transoral incisionless fundoplication is an effective endoscopic option in carefully selected patients."

National Institute for Health and Care Excellence (NICE)

The 2013 evidence-based NICE guideline for endoscopic radiofrequency ablation (e.g., Stretta™) for gastroesophageal reflux disease stated the following:

> "The evidence on the safety of endoscopic radiofrequency ablation for gastro-oesophageal reflux disease (GORD) is adequate in the short and medium term but there is uncertainty about longer-term outcomes. With regard to efficacy, there is evidence of symptomatic relief but objective evidence on reduction of reflux is inconclusive. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research."[20]

The 2023 evidence-based NICE guideline for endoluminal gastroplication (e.g., EsophyX™) for gastroesophageal reflux disease stated the following:

> "1.2 Evidence on the safety of endoluminal gastroplication for gastrooesophageal reflux disease is adequate. However, evidence on its efficacy is inadequate in quality, particularly in terms of patient selection and long-term outcomes. Therefore, this procedure should be used only in research. Find out what only in research means on the NICE interventional procedures guidance page.
> 1.2 Further research should include suitably powered randomised controlled trials with details of patient selection, physiological measurements, and long-term outcomes. [21]

The 2007 evidence-based NICE guideline for the endoscopic augmentation of the lower esophageal sphincter using hydrogel implants (e.g., Gatekeeper™ Reflux Repair System) for the treatment of gastroesophageal reflux disease stated the following:

> "There is limited evidence of short-term efficacy on endoscopic augmentation of the lower oesophageal sphincter using hydrogel implants for the treatment of gastro-oesophageal reflux disease (GORD). This evidence also raises concerns about the procedure's safety. Therefore, this procedure should not be used without special arrangements for consent and for audit."[22]

The 2004 evidence-based NICE guideline for the endoscopic injection of bulking agents (e.g., Durasphere™) for gastroesophageal reflux disease stated the following:

> "Current evidence on the safety and efficacy of endoscopic injection of bulking agents for gastro-oesophageal reflux disease does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research."[23]

Society of American Gastrointestinal Endoscopic Surgeons (SAGES)

The 2017 SAGES clinical spotlight review on endoluminal treatments for gastroesophageal reflux disease gave the following recommendations for transoral incisionless fundoplication (TIF) using the EsophyX™ device:

> "Based on existing evidence, TIF can be performed with an acceptable safety risk in appropriately selected patients. The procedure leads to better control of GERD symptoms compared with PPI treatment in the short term (6 months), but appears to lose effectiveness during longer term follow-up and is associated with moderate patient satisfaction scores. Objective GERD measures improve similarly after TIF 2.0 compared with PPI. No comparative, controlled trials exist between TIF and surgical fundoplication, but preliminary evidence suggests that the latter can be used safely after TIF failure. (Level of evidence +++, strong recommendation)"[24]

The clinical spotlight review gave the following recommendation for radiofrequency ablation of the lower esophageal sphincter using the Stretta™ device:

> "Based on existing evidence, Stretta significantly improves health related quality of life score, heartburn scores, the incidence of esophagitis, and esophageal acid exposure in patients with GERD, but does not increase lower esophageal sphincter basal pressure. In addition, it decreases the use of PPI by approximately 50%. The effectiveness of the procedure diminishes some over time, but persistent effects have been described up to 10 years after the procedure in appropriately selected patients with GERD. Stretta is more effective than PPI, but less so than fundoplication. Stretta is safe in adults and has a short learning curve. (Level of evidence +++, strong recommendation)"[24]

Although SAGES provides strong recommendations for both the EsophyX™ and Stretta™ devices, the reliability of these conclusions are limited due to the following:

- The guideline is not peer-reviewed or published; and
- The conclusions are based on poor quality randomized controlled trials (RCTs). All trials had very small sample sizes (n< 150) and short follow-up periods (no longer than 2 years). Several authors also had significant conflicts of interest and all studies were funded by the device manufacturers; and
- The authors did not provide the full methodological details of their study; therefore, it is difficult to thoroughly evaluate the quality of their purported systematic review.

EVIDENCE SUMMARY

Evidence is insufficient to support the safety and efficacy of endoscopic treatments for GERD. Although several randomized controlled trials support the short-term clinical utility (within 2 years) of endoscopic treatments, longer-term (5 years or more) randomized controlled trials that compare these devices to

laparoscopic Nissen fundoplication are required. Well-defined treatment parameters and patient selection criteria are also necessary to definitively establishing medical necessity. Additionally, clinical practice guidelines have only conditionally recommended the use of endoscopic therapies for the treatment of GERD based on low level evidence. Therefore, endoscopic treatments are considered not medically necessary for treatment of GERD.

BILLING GUIDELINES AND CODING

CODES*		
CPT	43192	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance
	43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance
	43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed
	43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance
	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
	43499	Unlisted procedure, esophagus

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
4/2024	Annual update. Change denial from investigational to not medically necessary for criterion II.
2/2025	Annual update. No changes to criteria or coding.