NO. 91483

GASTROESOPHAGEAL REFLUX DISEASE (GERD) AND BARRETT'S ESOPHAGUS

Effective: 06/01/2026
Committee Review: 05/13/2026
Last reviewed: 05/13/2026

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Policy scope: This policy defines the medical necessity criteria and coverage exclusions for the diagnosis and treatment of GERD and Barrett's Esophagus. It addresses standard and advanced interventions, including surgical, endoscopic, and ablative therapies.

Related policies:

- Experimental/Investigational/ Unproven Care/Benefit Exceptions No. 91117
- Genetics: Counseling, Testing and Screening No. 91540

I. MEDICAL NECESSITY CRITERIA

Treatment for gastroesophageal reflux disease (GERD)

A. Transoral incisionless fundoplication (TIF) or Concomitant Transoral Incisionless Fundoplication (cTIF) procedures for gastroesophageal reflux disease (GERD) for individuals with normal esophageal motility (by either

manometry or video esophagogram) may be medically necessary for any of the following indications:

1. Anatomic disruption of the gastroesophageal (GE) flap valve

2. Persistent GERD symptoms despite proton pump inhibitors (PPI) therapy (for at least 6 months).

3. Evidence of one of the following while on PPI therapy:
   a. Erosive esophagitis (erosions or ulcerations during endoscopy)
   b. Abnormal ambulatory pH study
   c. Biopsy confirmed changes characteristic of reflux esophagitis

4. Contraindications for TIF include:
   a. Active esophago-gastro-duodenal ulcer disease
   b. BMI ≥ 35
   c. Hiatal hernia > 2 cm
   d. Esophagitis grade D or Barrett's esophagitis
   e. Esophageal ulcer
   f. Fixed esophageal stricture or narrowing
   g. Gastric outlet obstruction or stenosis
   h. Gastroparesis or delayed gastric emptying confirmed by solid-phase gastric emptying study if patient complains of postprandial satiety during assessment
   i. History of previous resective gastric or esophageal surgery, cervical spine fusion, Zenker's diverticulum, esophageal epiphrenic diverticulum, achalasia, scleroderma or dermatomyositis, eosinophilic esophagitis, > 2 dilations for esophageal stricture, or cirrhosis
   j. Portal hypertension and/or varices

B. **The Stretta** radiofrequency energy procedure for the treatment of GERD may be considered medically necessary for patients 18 years or older when all of the following clinical criteria are met (1 or 2 and 3 below):

1. Member must have all of the following:
   a. Daily gastroesophageal reflux disease (GERD) > 6 months as evidenced by one of the following:
      i. pH study (performed off medication) showing pathologic acid exposure (pH 14.7), **OR**
      ii. upper GI endoscopy showing Grade A or B esophagitis (Los Angeles classification), **OR**
      iii. abnormal reflux as determined by impedance testing, **OR**
      iv. biopsy confirmed reflux esophagitis
   b. Esophageal manometry demonstrating **both** of the following:
      i. normal peristalsis (e.g. lack of frequent large breaks in peristaltic propagation, or bolus clearance > 70%, or contractility > 500); AND
      ii. normal sphincter relaxation (i.e. residual pressure
   c. symptoms of heartburn refractory to daily appropriate dose anti-secretory therapy.
      OR

2. Member has been diagnosed with:
    a. reflux related aspiration pneumonia, OR
    b. laryngopharyngeal reflux
    AND

3. Member does not have any of following:
    a. American Society of Anesthesiologists (ASA) IV classification
    b. Barrett's esophagus
    c. Esophagitis grade C or D (Los Angeles classification)
    d. Hiatal hernia >2cm
    e. Autoimmune disease
    f. Collagen vascular disorder
    g. Coagulation disorder
    h. Current anticoagulant therapy
    i. Life threatening disorder with life expectancy
    j. Achalasia
    k. Current pregnancy

C. Magnetic sphincter augmentation (MSA) with the LINX device may be medically necessary for the treatment of GERD when **all** of the following are met:

1. 18 - 74 years of age

2. Body Mass Index (BMI) less than or equal to 35

3. Documented typical symptoms of GERD for longer than 6 months (regurgitation or heartburn which is defined as a burning epigastric or substernal pain which responds to acid neutralization or suppression)

4. Member is refractory to ideal medical management (requires twice daily proton pump inhibitor or other anti-reflux drug therapy, diet and lifestyle change discussed)

5. Hiatal hernia <3 cm as determined by endoscopy

6. Total Distal Ambulatory Esophageal pH< 4 for ≥ 4.5% of the time with discontinuation of any GERD medications for at least 7 days prior to testing

7. Distal esophageal motility within normal range, as defined by either:
    a. Conventional manometry (average of sensors 3 and 4 is > 35 mmHg peristaltic amplitude on wet swallows or >70% (propulsive) peristaltic sequences; OR,
    b. High resolution manometry (HRM):
        i. Distal contractile integral 500 – 5000 mm Hg cms; AND,
        ii. Distal latency > 4.5 s

8. Symptomatic improvement on PPI therapy demonstrated by

a. GERD-Health-Related Quality of Life (GERD-HRQL) score of ≤ 10 on proton-pump inhibitors and ≥ 15 off PPIs, or
b. ≥ 6-point improvement when comparing their on PPI and off PPI GERD-HRQL score

9. None of the following:
    a. Current electrical implant (e.g., pacemakers and defibrillators) or metallic abdominal implant
    b. Diagnosed with Scleroderma
    c. Diagnosed with an esophageal motility disorder such as but not limited to Achalasia, Nutcracker Esophagus, or Diffuse Esophageal Spasm or Hypertensive LES
    d. Diagnosed psychiatric disorder (e.g., bipolar, schizophrenia, etc.), not including depression on appropriate medication(s), would require statement of clearance from the treating Behavioral Health team
    e. Esophageal or gastric varices
    f. Esophagitis - Grade C or D (Los Angeles Classification)
    g. History of gastroesophageal surgery, anti-reflux procedures, including endoscopic anti-reflux procedures
    h. History of or known esophageal stricture or gross esophageal anatomic abnormalities (Schatzki's ring, obstructive lesions, etc.)
    i. Suspected or confirmed esophageal or gastric cancer
    j. Symptoms of dysphagia more than once per week within the last 3 months
    k. Life expectancy less than 3 years
    l. Pregnant or breastfeeding
    m. Suspected or known allergies to titanium, stainless steel, nickel or ferrous materials

D. Priority Health considers other treatments for GERD as investigational and experimental, or not medically necessary. These include, but are not limited to the following:

1. Endoscopic suturing or implantation of inert polymers for the treatment of gastroesophageal reflux are considered experimental and investigational:
    a. Bard EndoCinch Suturing System (C.R. Bard Inc.)
    b. Angelchik anti-reflux prosthesis
    c. Enteryx
    d. Endoscopic Plicator System (NDO Surgical, Inc.), Syntheon ARD Plicator (Syntheon and GERDx
    e. Durasphere (Carbon Medical Technologies), the Gatekeeper Reflux Repair System (Medtronic, Inc.), an endoscopically-implanted injectable esophageal prosthesis, and the Plexiglas polymethylmethacrylate (PMMA) microspheres (Arkema Inc.)
    f. Non-Invasive Post -Prandial Anti-Reflux Devices (i.e., RefluxStop)
    g. Lower Esophageal Sphincter (LES) Electrical Stimulation (i.e, EndoStim)
    h. Antireflux mucosal intervention (ARMI) procedures (i.e., Antireflux Mucosectomy (ARMS) and Antireflux Mucosal Ablation (ARMA))
    i. Acupuncture

2. The following device is considered experimental and investigational for the treatment of GERD or any other condition:
    a. Reflux Band Upper Esophageal Sphincter Assist Device

Treatment for Barrett's Esophagus (BE)

A. Endoscopic Mucosal Resection and/or Thermal Ablation Treatment (i.e., Barrx) or Photodynamic Therapy for Barrett's Esophagus (BE) is medically necessary when the following is present:
    1. Dysplastic Barrett's Esophagus and/or early esophageal adenocarcinoma (EAC).
    2. The data available at present is insufficient to support these modalities in non-dysplastic Barrett's esophagus.

B. Any of the following ablative or surgical interventions are considered experimental and investigational for the treatment of members with Barrett's Esophagus:
    1. Argon plasma coagulation
    2. Chemoradiation therapy
    3. Cryotherapy
    4. Laser therapy
    5. Multi-polar electro-coagulation
    6. Ultrasonic therapy

C. Any of the following tests are considered experimental and investigational for the diagnosis or management of Barrett's Esophagus:
    1. Capsule endoscopy of the esophagus
    2. Confocal laser endomicroscopy and Fuji Intelligent Chromo Endoscopy (FICE)
    3. Genetic mutation analysis
    4. Methylation biomarkers and microRNA tests
    5. Wide-area transepithelial sampling (WATS-3D)
    6. TissueCypher

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

Note: Some advanced diagnostic laboratory tests may meet criteria for designation as Advanced Diagnostic Laboratory Tests Under the Medicare Clinical Laboratory Fee Schedule (CLFS).

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare

Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
100.3- NCD - 24-Hour Ambulatory Esophageal pH Monitoring (100.3) 100.4- NCD - Esophageal Manometry (100.4)	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	L34540-LCD - Stretta Procedure (L34540) L36021- LCD - MolDX: Molecular Diagnostic Tests (MDT) (L36021) L33949- LCD - Botulinum Toxins (L33949) L35986- LCD - Special Histochemical Stains and Immunohistochemical Stains (L35986)
First Coast Service Options, Inc.	L33583-LCD - Diagnostic and Therapeutic Esophagogastroduodenoscopy (L33583)
National Government Services, Inc.	L35080- LCD - Select Minimally Invasive GERD Procedures (L35080) L33646- LCD - Botulinum Toxins (L33646)
Noridian Healthcare Solutions	L36256 -LCD - MolDX: Molecular Diagnostic Tests (MDT) (L36256) L36353 -LCD - Lab: Special Histochemical Stains and Immunohistochemical Stains (L36353)
Novitas Solutions, Inc.	L35350- LCD - Upper Gastrointestinal Endoscopy (Diagnostic and Therapeutic) (L35350)
Palmetto GBA	L34553- LCD - Stretta Procedure (L34553) L34434- LCD - Upper Gastrointestinal Endoscopy and Visualization (L34434) L39780- LCD - Lower Esophageal Magnetic Sphincter Augmentation (L39780) L35025- LCD - MolDX: Molecular Diagnostic Tests (MDT) (L35025) L35922-LCD - Lab: Special Histochemical Stains and Immunohistochemical Stains (L35922)
WPS Insurance Corporation	L34659- LCD - Endoscopic Treatment of GERD (L34659) L36807- LCD - MolDX: Molecular Diagnostic Tests (MDT) (L36807) L34635- LCD - Botulinum Toxin Type A & Type B (L34635)

	L36805-LCD - Lab: Special Histochemical Stains and Immunohistochemical Stains (L36805)

III. BACKGROUND

GERD

Gastroesophageal reflux disease (GERD)—also called reflux esophagitis—is among the most prevalent conditions of the gastrointestinal (GI) tract. Two principal factors drive reflux: (1) the nature/volume of GI contents and (2) the antireflux mechanism, which includes the lower esophageal sphincter (LES) and the anatomy of the gastroesophageal junction (GEJ). Reflux occurs when the pressure gradient between the LES and the stomach is compromised—either by a transient or sustained fall in LES pressure or a rise in intragastric pressure. Many patients have reduced LES tone, while others have normal LES pressure but inappropriate (transient) LES relaxations, both of which permit reflux.

The initial (conservative**)** management of GERD begins with lifestyle modification and dietary changes, including weight management, meal-timing adjustments, elevating the head of the bed, and avoiding reflux-triggering foods. Pharmacologic therapy typically starts with antacids and H2-receptor antagonists, with proton pump inhibitors (PPIs), such as lansoprazole or omeprazole, used when initial measures fail to adequately control symptoms. Patients who remain symptomatic despite optimized medical therapy may be considered candidates for procedural intervention.

Traditional anti-reflux surgery reinforces the lower esophageal sphincter (LES) by wrapping part or all of the gastric fundus around the distal esophagus, most commonly through laparoscopic Nissen fundoplication or Toupet partial fundoplication. These procedures demonstrate approximately 90% efficacy, are typically completed in about 90 minutes, and allow hospital discharge within two days with return to work in 7–10 days. However, surgery carries risks—including dysphagia and inability to belch or vomit in 4–11% of patients—and is best suited for younger individuals with typical GERD symptoms (heartburn and regurgitation), abnormal pH testing, normal esophageal motility, and partial response to PPI therapy. Limitations include the need for surgical expertise, postoperative recovery (several weeks), and the possibility of recurrent symptoms requiring resumption of medical therapy. Due to these burdens and the invasive nature of surgery, interest has increased in less invasive, endoscopic alternatives for managing refractory GERD.

Endoscopic GERD interventions generally fall into three functional categories. The first category includes radiofrequency (RF) energy delivery, which remodels tissue at the LES and may reduce transient LES relaxations. The second category consists of endoscopic suturing or plication techniques, which recreate valve-like folds at the gastroesophageal junction; this includes systems ranging from transoral incisionless fundoplication (TIF) to full-thickness plication platforms such as GERDx. The third category includes injection or implantation techniques, which use bulking agents or implantable materials to augment LES competence. Other minimally invasive

approaches that complement these categories include magnetic sphincter augmentation, and a range of suturing systems (Loganathan et al., 2024).

Several investigational and emerging techniques are under exploration for patients who remain symptomatic despite conventional therapy. These include injection of bulking agents, implantation of bioprosthetic materials, LES electrical stimulation, and endoscopic mucosal interventions. Additional non-invasive options, such as post-prandial external anti-reflux devices, are also emerging. Antireflux mucosal interventions—including antireflux mucosectomy (ARMS) and antireflux mucosal ablation (ARMA)—are being studied as ways to remodel the mucosa and tighten the gastroesophageal junction. Some complementary approaches, such as acupuncture, are also utilized in certain settings, although evidence remains variable.

Radiofrequency Energy or Radiofrequency Thermal Ablation
Thermal energy is delivered to the lower esophageal sphincter (LES) using endoscopically placed needles. Proposed mechanism of action is unknown, although it is likely that there is a resultant scarring or neurolysis in the lower esophageal sphincter. The Stretta® System is an example of radiofrequent (RF) thermal energy delivered to the LES using endoscopically placed needles. RF thermal injury purportedly results in ablation of nerve pathways responsible for tLESRs and/or tissue tightening or remodeling of the gastroesophageal junction due to heat-induced collagen contraction. Thus, RF energy may improve LES compliance and inhibit tLESRs. The Stretta procedure was reviewed by the Priority Health Technology Assessment Committee in September 2015. This policy reflects the recommendation of the committee.

Plication/Suturing Techniques
Endoluminal gastric plication (ELGP) includes a progression of endoscopic antireflux technologies designed to create tissue folds (plicas) at or near the gastroesophageal junction to reinforce the antireflux barrier. Early systems—such as the EndoCinch™ (Bard Endoscopic Technologies), the Endoscopic Suturing Device® (Sew-Right; Wilson-Cook Medical), and the Syntheon ARD Plicator—used needle-based or stapling mechanisms to place sutures through proximal fundic folds, functioning as miniature endoscopic “sewing machines” and acting by increasing functional LES length, narrowing the esophageal lumen, or reducing transient LES relaxations. Full-thickness plication devices followed, including the Ethicon Plicator (later withdrawn) and the Endoscopic Plication™ System (EPS; NDO Surgical, Inc.), which placed transmural sutures under direct visualization to restore the flap-valve mechanism by enhancing gastric cardia competency.

The EsophyX™ System (EndoGastric Solutions) with Serofuse™ fasteners represents the most established and widely adopted endoluminal plication platform, indicated for transoral tissue approximation and full-thickness plication in symptomatic chronic GERD, including narrowing the gastroesophageal junction and reducing hiatal hernias ≤ 2 cm. During TIF 2.0, the device is advanced transorally to the gastroesophageal valve to construct a 3-cm, 270° valve using 12–23 fasteners. Earlier iterations included endoluminal fundoplication and TIF 1.0. TIF 2.0 is considered most comparable to laparoscopic Nissen fundoplication, the surgical standard (Ihde, 2020), which—although effective—carries risks such as GERD recurrence, need for repeat surgery, dysphagia, gas, bloating, and inability to belch or vomit (Frazzoni et al., 2014). Since its introduction in 2009, TIF 2.0 has served as one of the most established minimally invasive options for GERD not fully responsive to medication.

Among contemporary platforms, the GERDx System (GSURG GmbH) represents the most modern and technologically advanced fullthickness plication device, utilizing a microhydraulic mechanism to manipulate tissue and place pledgetreinforced (ePTFE) sutures at or near the gastroesophageal junction. This endoscopic fullthickness plication (ETFP) approach is intended for patients who continue to require and respond to pharmacologic GERD therapy and provides a minimally invasive alternative to open, laparoscopic, or other endoscopic fundoplication procedures (Hayes, 2025).

In 2025, Hayes completed an Evidence Analysis Research Brief and found that adequate peer-reviewed literature exists to evaluate endoscopic full-thickness plication (ETFP) using the GERDx system for GERD (Hayes, 2025). However, major gastroenterology societies currently provide no clear endorsement for this technology. The American Society for Gastrointestinal Endoscopy (ASGE) reports insufficient high-quality evidence supporting novel endoscopic GERD therapies, including GERDx, and therefore does not recommend for or against their use (ASGE, 2025). The American Gastroenterological Association (AGA) guideline does not address GERDx but identifies laparoscopic fundoplication and magnetic sphincter augmentation as effective surgical options and recognizes transoral incisionless fundoplication (TIF) as an effective endoscopic approach in appropriately selected patients (Yadlapati et al., 2022).

A prospective single-arm clinical trial evaluated the GERDx™ endoscopic full-thickness plication system in 40 patients with GERD who remained symptomatic despite more than six months of proton pump inhibitor therapy, demonstrated pathologic acid exposure, and had hiatal hernias <2 cm with Hill grade II–III anatomy (Weitzendorfer et al., 2018). Baseline and 3-month follow-up assessments included the Gastrointestinal Quality of Life Index (GIQLI), reflux symptom scoring, esophageal manometry, and impedance pH monitoring. The procedure was completed without intraoperative complications; however, 4 patients experienced postoperative complications requiring intervention, and 7 patients required laparoscopic fundoplication within three months due to persistent symptoms. Among the 30 patients available for follow-up, significant improvements were observed in GIQLI (92.45 → 112.03), reflux-specific symptom scores (49.84 → 23.93), and DeMeester scores (46.48 → 20.03) (all $p < 0.001$), while manometric parameters did not significantly change and 3 patients continued daily antireflux medication. The authors concluded that GERDx™ plication improved distal acid exposure, reflux symptoms, and quality of life in appropriately selected patients with minimal short-term adverse effects but noted key limitations, including the single-arm design, 25% loss to follow-up, insufficient power for secondary outcomes, and exclusion of individuals with Barrett's esophagus or esophageal motility disorders. They emphasized that GERDx™ may be an option for mild GERD in select patients, but additional long-term data and randomized controlled trials are needed before broader clinical adoption. There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of GERDx ™ device for the treatment of GERD.

Polymer Injection/Implantation Techniques

These are referred to as bulking techniques as their proposed mechanism of action is to provide bulking support to the sphincter keeping stomach fluids and acids from backing up into the esophagus. It does not affect the stomach's ability to produce acid or other digestive fluids. The procedure is not reversible. There are several polymer injection techniques under investigation, including Enteryx™ injection therapy (Boston Scientific Corp., Natick, MA), in which inert polymer material is injected deep into the submucosal

zone beneath the LES to form a ring like “bulking” zone to augment sphincter pressure and decrease tLESRs; the Gatekeeper™ Reflux Repair System (Medtronic, Inc., Minneapolis, MN), which allows endoscopic introduction of an expandable hydrogen prosthesis into the submucosa of the LES zone; and the Plexiglas (polymethylmethacrylate [PMMA]) implantation procedure (Röhm GmbH & Co. KG, Darmstadt, Germany), in which PMMA microspheres are injected endoscopically by needle under high pressure into the submucosa of the proximal LES zone to provide “bulking” support to the sphincter. At this time, neither Gatekeeper nor PMMA are FDA approved.

On October 14, 2005 the FDA issued a preliminary public health notification recall of all Enteryx™ Procedure Kits and Single Pack Enteryx™ Injectors to health care practitioners stating serious adverse events, including death, occurred in patients treated with Enteryx™ for GERD (FDA, 2005).

The evidence does not permit conclusions on health outcomes or if endoscopic suturing or implantation of inert polymers are as beneficial as established alternatives. Case series data are inadequate to demonstrate improvement in health outcome. The procedures have not been compared to Nissen fundoplication in controlled trials, and the risks and benefits of the procedures compared to Nissen fundoplication are not established. There is no long-term outcome data to show the durability of these procedures.

Non-Invasive Post-Prandial Anti-Reflux Devices
RefluxStop® is an implantable device designed to treat GERD by restoring the lower esophageal sphincter (LES) to its natural anatomical position without encircling or compressing the esophagus. Unlike traditional anti-reflux surgeries that wrap or apply pressure around the food passage—which can lead to dysphagia, pain with swallowing, and impaired ability to belch or vomit—RefluxStop® avoids these issues by not constricting the esophageal lumen. Its mechanism of action focuses on reconstructing all three components of the anti-reflux barrier, supporting normal anatomy and enabling the body’s physiologic function to resolve reflux (Implantica, 2025).

A prospective, single-arm multicenter study evaluated the RefluxStop implant—designed to treat GERD by restoring lower esophageal sphincter and angle of His anatomy without compressing the esophagus—in 50 patients, with 44 patients having 4-year follow-up. The device demonstrated sustained benefit, with median GERD-HRQL scores reduced by 90% from baseline at 4 years and only two patients using daily PPIs despite normal pH studies. No device-related adverse events, migrations, explants, or esophageal dilations occurred throughout the study period. Between years 1–4, dysphagia was rare (1/47), and only two participants were dissatisfied with treatment, one due to underlying esophageal dysmotility rather than reflux. Overall findings show stable long-term safety and effectiveness with minimal adverse events, attributed to the device’s non-encircling design; however, limitations included the absence of a control group, small sample size, surgeon expertise, and limited generalizability to patients with complex anatomy or comorbidities. Ongoing evaluation is planned at 5-year follow-up (Harsányi et al., 2024).

The NoReflux device is a 1-way biodegradable valve that is attached to the gastro-esophageal junction using a CE-and FDA-approved glue. Upon attachment, NoReflux prevents reflux of gastric acid into the esophagus. Researchers are developing

advanced soft, magnetic valves—engineered as lattice structures and integrated into esophageal stents—to enable on-demand opening through externally applied magnetic fields, potentially offering a less invasive and customizable treatment option for GERD. These early-stage prototypes aim to improve control and sealing compared with existing devices but remain in development and validation phases (Zhu et al., 2025).

Lower Esophageal Sphincter (LES) Electrical Stimulation (i.e., EndoStim)
Lower esophageal sphincter (LES) electrical stimulation using the EndoStim system is an investigational implantable therapy designed to treat GERD by delivering low-energy electrical impulses to strengthen an incompetent LES and restore the antireflux barrier. The system includes an implantable pulse generator, bipolar lead with stitch electrodes placed laparoscopically into the LES muscle, and an external wireless controller. After implantation, stimulation typically begins within 12 hours and follows a standard protocol of 30-minute sessions administered 12 times per day, using 215 microsecond pulses at 20 Hz and 3–8 mA. Clinical trials to date show feasibility of implantation and functional LES stimulation, but the therapy remains in development for the U.S. market and is not currently FDA-approved (Hayes, Inc., 2025).

Anti-reflux mucosal intervention (ARMI) procedures (i.e., Antireflux Mucosectomy (ARMS) and Antireflux Mucosal Ablation (ARMA))
Antireflux mucosectomy (ARMS) and antireflux mucosal ablation (ARMA), collectively referred to as antireflux mucosal interventions (ARMI), are emerging endoscopic techniques designed to reshape and reinforce the gastroesophageal junction as a treatment for gastroesophageal reflux disease (GERD). ARMS achieves this by performing a limited mucosal resection in the gastric cardia, promoting scar formation that augments the antireflux barrier. ARMA uses targeted mucosal ablation to induce tissue contraction and stiffening with the same therapeutic intent. These minimally invasive approaches are being explored as alternatives for individuals who have persistent GERD symptoms despite optimized proton pump inhibitor (PPI) therapy or for those seeking less invasive options than traditional antireflux surgery.

Antireflux mucosal ablation (ARMA) and antireflux mucosectomy (ARMS) are minimally invasive endoscopic procedures evaluated for PPI-refractory gastroesophageal reflux disease (GERD). A meta-analysis demonstrated that ARMA produced a significant reduction in acid exposure time, with a pooled standardized mean difference (SMD) of –20.74 (95% CI: –25.51 to –15.97, $p < 0.0001$), while ARMS resulted in a significant improvement in DeMeester scores, with an SMD of –2.79 (95% CI: –4.33 to –1.26, $p < 0.0001$). Clinical success rates were 87% for ARMA and 78% for ARMS, defined as symptom improvement or reduced reliance on PPIs (*Al-Obaidi et al., 2025*). Despite encouraging outcomes, substantial heterogeneity across studies indicates a need for further research to clarify patient selection and long-term effectiveness.

A systematic review of 66 studies including 3767 patients compared outcomes between antireflux mucosectomy (ARMS) and radiofrequency ablation of the lower esophageal sphincter (Stretta) for GERD. Most patients underwent Stretta (81.6%, n=3074), with 18.4% (n=693) receiving ARMS. Patient satisfaction was 65% for ARMS and 77% for Stretta. Both procedures significantly reduced PPI use (ARMS 100% → 40.18%; Stretta 99.42% → 48.51%) and improved GERD-HRQL scores (ARMS 19.75 → 8.24; Stretta 21.02 → 10.45). DeMeester scores also improved similarly (ARMS 44.99 → 15.02; Stretta 52.29 → 28.99). However, ARMS showed higher overall morbidity (25% vs 17%, P=.001) and greater risks of stricture (OR 13.03), bleeding (OR 13.16), and perforation

(OR 13.03) compared with Stretta. Both treatments appear effective, but ARMS carries substantially higher procedural risks (Angeramo et al., 2025).
Currently, no U.S. or international gastroenterology society (ASGE, ACG, AGA) includes antireflux mucosectomy (ARMS) or antireflux mucosal ablation (ARMA) in their evidence-based clinical practice guidelines for GERD management. Available literature consists of observational studies and systematic reviews, but these procedures remain investigational and not guideline-endorsed.

Acupuncture
Huang et al. (2025) report that several non-pharmacological and combined therapies—such as acupuncture, breathing training, low-FODMAP diets, acupoint stimulation with traditional Chinese medicine, and combinations of these modalities with conventional Western medicine—are increasingly used in GERD management. However, their systematic review found that the strength and consistency of evidence supporting many of these non-pharmacological approaches remain limited and, in some cases, contradictory.

A 2025 systematic review and trial sequential meta-analysis of 12 studies evaluated the effectiveness of manual acupuncture for gastroesophageal reflux disease (GERD) (Yin et al., 2025). The analysis found that acupuncture was associated with reduced symptom scores (MD −3.43) and lower recurrence rates (RR 0.32); however, all efficacy and safety outcomes were rated as very low-certainty evidence using the GRADE framework. No significant difference in adverse events was observed compared with proton pump inhibitors (PPIs), but statistical power for safety outcomes was insufficient. Importantly, PPIs demonstrated significantly greater global symptom improvement (RR 1.22), supported by a long-established safety and effectiveness profile. Subgroup and sensitivity analyses did not change the overall conclusions. Based on the available evidence, manual acupuncture shows limited and low-certainty benefit and does not achieve the symptom improvement seen with PPI therapy. Current evidence does not support manual acupuncture as a primary treatment for GERD, and its role remains investigational for coverage purpose.

Barrett's Esophagus (BE)
Endoscopically based therapies for Barrett's esophagus (BE) are designed to destroy the damaged tissue in the esophagus associated with BE and thus reduce the risk of esophageal cancer in these individuals. There are currently two endoscopically based therapies for BE: (1) Photodynamic Therapy (PDT); (2) Thermal Ablation.

1. **Photodynamic Therapy (PDT):** PDT using porfimer sodium (Photofrin) is an FDA approved treatment for Barrett's esophagus with high grade dysplasia. Porfimer sodium is a light-sensitizing drug (a photosynthesizer) which is administered intravenously or by mouth. The drug concentrates in the Barrett's tissues. The esophageal tissue is then exposed to modified laser light. Photoactivation of the drug then destroys the cells in which is it has been absorbed.
2. **Thermal Ablation (TA):** The goal of this therapy is to ablate dysplastic tissue, reversing the histopathological changes characteristic of BE, and initiating squamous re-epithelialization of the esophagus. Using a controller to limit the amount of heat energy generated, a high-frequency electric current is passed through a heater element for less than a second to destroy the innermost layer of esophageal tissue. The HALO^{360} Coagulation System, which is also referred to as the BÂRRX device, is an example of this technology.

The Reflux Band Upper Esophageal Sphincter Assist Device
The Reflux Band (Restech), formerly known as the Reza Band UES Assist Deviceis a non-medication, non-surgical medical device that is externally worn and applies a slight, external pressure to the cricoid cartilage to generate added intraluminal UES pressure to stop reflux from rising above the UES. There is no evidence in the peer-reviewed medical literature to support its effectiveness (rdbiomed, 2020).

WATS-3D
WATS-3D biopsy (CDx Diagnostics Inc.) is performed during esophageal endoscopy using a stiff brush that is spun and moved up and down and across abnormal tissue to collect small strips and clumps of cells. Biopsy specimens are stained and analyzed at CDx Diagnostics in a process that includes computerized image analysis of all visible cells, which are displayed with highlighting of suspicious features. The WATS3D biopsy procedure, also referred to as WATS3D, is performed by a gastroenterologist in an outpatient setting during endoscopic examination of the esophagus and is intended as an adjunct to standard 4-quadrant focal biopsies for screening, diagnosis, or surveillance of patients with known or suspected esophageal precancer (e.g., Barrett’s esophagus) or cancer (Hayes, 2023).

The evidence for the use of WATS3D is limited to its utility in diagnostic yield, and it is unclear whether it results in improved patient outcomes. In a prospective, multicenter, randomized controlled trial; 160 patients with BE underwent either forceps biopsy sampling followed by WATS3D or WATS3D followed by biopsy sampling. The primary outcome was rate of detection of high-grade dysplasia/esophageal adenocarcinoma using WATS3D in conjunction with biopsy sampling compared with biopsy sampling alone. Results showed that the addition of WATS to biopsy sampling was feasible and yielded an additional 23 cases of HGD/esophageal adenocarcinoma (absolute increase, 14.4%) (Vennalaganti et al, 2018). In another multicenter prospective trial 4,203 patients underwent WATS3D adjunctively to targeted forceps biopsy and random four-quadrant forceps biopsy. In total, 594 patients were diagnosed with Barrett's esophagus (BE) by forceps biopsy alone, and 493 additional cases were detected by adding WATS, increasing the overall detection of BE by 83%. Low-grade dysplasia (LGD) was diagnosed in 26 patients by forceps biopsy alone, and 23 additional cases were detected by adding WATS3D, increasing the detection of LGD by 88.5% (Gross et al, 2017).

Smith et al. (2017) also investigated the benefit of WATS3D used adjunctively to the combination of random and targeted forceps biopsy in the detection of esophageal dysplasia and BE. Investigators alternated taking forceps biopsies (FB) and WATS3D samples first. Of 12,899 patients enrolled, FB identified 88 cases of esophageal dysplasia, and WATS detected an additional 213 cases missed by FB. These 213 cases represented an absolute increase of 1.65%, increasing the yield from 0.68% to 2.33%. Adding WATS3D to FB increased the overall detection of esophageal dysplasia by 242%. Fewer than 61 patients needed to be tested with WATS to identify an additional case of esophageal dysplasia. The combination of random and targeted FB identified 1,684 cases of BE, and WATS detected an additional 2,570 BE cases. The absolute incremental yield of adding WATS3D to FB is 19.9%, increasing the rate of detection from 13.1% to 33%. Adding WATS3D to FB increased the overall detection of BE by 153%.

In a multicenter randomized trial of 172 patients with Barrett’s esophagus and recent dysplasia, wide-area transepithelial sampling (WATS) was compared with four-quadrant

forceps biopsies (FB) for detection of high-grade dysplasia (HGD) and esophageal adenocarcinoma (EAC). HGD/EAC was identified by both methods in 21 patients, detected by WATS alone in 18, and by FB alone in 12, with no significant difference in detection rates between the two modalities as standalone techniques (P = 0.36). However, adding WATS to FB increased dysplasia detection by an absolute 10% (95% CI, 6–16%). Although WATS alone did not outperform FB, procedural times were shorter for WATS (4.9 minutes) compared with FB (6.6 minutes), and longest when combined (11.2 minutes). Several limitations may have influenced these findings, including the lack of a diagnostic gold standard for HGD/EAC and the fact that all WATS pathology was interpreted at a single central laboratory, raising uncertainty about whether a WATS-positive/FB-negative HGD diagnosis reflects equivalent progression risk. Additionally, follow-up data were unavailable because most patients had undergone ablation. While a separate study of 4,545 patients showed annual progression rates of 0.1% (NDBE), 1.89% (crypt dysplasia), and 3.47% (LGD) based on WATS diagnoses—similar to FB-based progression estimates—long-term outcomes for WATS-positive/FB-negative HGD remain uncertain and are being evaluated in a newly initiated study (Van Munster et al., 2023).

American College of Gastroenterology (ACG) stated, could not make a recommendation on the use of wide-area transepithelial sampling with computer-assisted 3-dimensional (WATS-3D) analysis in patients undergoing endoscopic surveillance of BE (Shaheen et al., 2022). American Gastroenterological Association (AGA) stated that WATS3D may be used as an adjunctive technique to sample the suspected or established Barrett's segment (in addition to the Seattle biopsy protocol), but further prospective studies directly comparing WATS-3D and Seattle protocol are needed to understand if WATS-3D sampling might be as or more effective (Muthusamy et al, 2022).

In their Clinical Practice Guidelines in Oncology for Esophageal and Esophagogastric Junction cancers, National Comprehensive Cancer Network stated that phase III randomized trials are needed to assess the utility and accuracy of WATS for detecting HGD/adenocarcinoma in patients with Barrett esophagus (NCCN, 2026).

In patients with known or suspected BE, American Society for Gastrointestinal Endoscopy (ASGE) suggests using WATS-3D in addition to Seattle protocol biopsy sampling compared with white-light endoscopy with Seattle protocol biopsy sampling a conditional recommendation based on low quality of evidence (ASGE, 2019).

Capsule Endoscopy of the Esophagus
Although sedated peroral endoscopy remains the reference standard for Barrett's esophagus (BE) screening, its invasiveness, cost, and limited suitability for population-level use contribute to underutilization (Shaheen et al., 2022). Non-endoscopic screening tools—such as the EndoSign Barrett's Esophagus Test (Cyted Health Inc.)—offer a less invasive alternative that may facilitate earlier detection, clinical intervention, and surveillance to prevent progression from BE to esophageal adenocarcinoma (EAC).

A 5-year evaluation of Barrett's esophagus surveillance compared outcomes before and after the introduction of capsule sponge testing. In the two years prior to adoption (2018–2019), 1,568 patients underwent endoscopic surveillance, while in the post-implementation period (2021–2022), 1,791 patients were surveyed, 920 with capsule sponge testing and 871 with traditional endoscopy. Of those screened using the

capsule sponge, 17.1% proceeded to endoscopy for further evaluation. The study found no significant differences in detection rates of high-grade dysplasia (HGD), intramucosal cancer (IMC), or invasive cancer between capsule sponge testing and endoscopic surveillance. However, endoscopic surveillance yielded more cases of indefinite for dysplasia and low-grade dysplasia (LGD). Overall, capsule sponge testing appeared non-inferior to traditional endoscopy for detecting advanced neoplasia, though longer follow-up is needed to ensure early dysplasia is adequately identified in patients managed through capsule sponge–based surveillance (Chien & Glen, 2025).

Confocal Laser Endomicroscopy
Confocal fluorescent endomicroscopy, or confocal laser endomicroscopy is based on tissue illumination with a low-power laser with subsequent detection of the fluorescence light reflected from the tissue through a pinhole (ASGE, 2014). Confocal refers to the alignment of both illumination and collections systems in the same focal plane. Confocal endomicroscopy based on tissue fluorence uses a local and/or intravenous contrast agent and generates a high-quality image that may be comparable with traditional histological examination. Cellvizio® (Mauna Kea Technologies ,Newtown, PA) is a probe-based Confocal Laser Endomicroscopy (pCLE) device that is compatible with flexible video-endoscopes. The goal is to increase diagnostic yield while minimizing procedure-related risks and the costs of tissue acquisition and analysis.

Standard endoscopic evaluation of patients with Barrett's Esophagus (BE) is performed using high-definition, white light endoscopy (HD-WLE). Current guidelines, the Seattle Protocol, dictate random, 4-quadrant biopsies every 1 to 2 centimeters (cm) of BE length in addition to biopsies of suspicious areas. However, surveillance for esophageal precancer presents some challenges and there are drawbacks to HD-WLE. For example, random, 4-quadrant biopsies prompted by HD-WLE can miss up to half of cancers, dysplastic changes associated with BE are patchy and difficult to identify, changes may be uninterpretable when inflammation or ulceration is present, and the technique is associated with sampling error and low interobserver agreement (Hayes, 2016).

CLE illuminates the target area with a blue laser light (488 nanometers [nm] wavelength) following the topical application or intravenous (IV) administration of a fluorescent agent. Probe-based CLE (pCLE) with the Cellvizio 100 Series System and Cellvizio 100 Series System with Confocal Miniprobes (Mauna Kea Technologies) is performed using a small probe, which is advanced through the accessory channel of a standard endoscope. The device uses fixed laser power and a depth of imaging ranging from 0 to 130 micrometers (µm) for the gastrointestinal tract and from 55 to 65 µm for the ultra-high-definition probe. Images are acquired by placing the imaging aperture directly in contact with the esophageal mucosa; the images are then displayed on a screen similar to standard endoscopy. The recordings are often obtained using a transparent cap at the distal end of the endoscope, which provides stabilization. When a site is identified for biopsy, mild pressure is applied to the tissue with the confocal probe or an argon plasma coagulator and the resulting reddish mucosa guides subsequent acquisition of biopsy samples for histopathological examination and diagnosis. pCLE is performed in an outpatient setting by a board-certified gastroenterologist experienced in endoscopy. Patients undergo conscious sedation for the procedure and receive IV fluorescein to enhance the CLE images. pCLE is performed as an adjunct to standard HD-WLE. The additional procedure time adds approximately 5 to 20 minutes per patient.

Limitations of CLE systems include a limited viewing area and depth of view. Another issue is the standardization of systems for classifying lesions viewed with CLE devices.

Gupta et al (2014) published a systematic review and meta-analysis of prospective studies comparing the accuracy of CLE plus targeted biopsy with standard 4-quadrant biopsy in patients with BE. In a meta-analysis of the diagnosis of HGD or esophageal adenocarcinoma, the pooled sensitivity was 68% (95% CI, 64% to 73%) and pooled specificity was 88% (95% CI, 87% to 89%). Leggett, et al. (2016) compared probe-based confocal endomicroscopy with volumetric endomicroscopy in ex vivo endoscopic mucosal resection specimens. The sensitivity, specificity, and diagnostic accuracy of probe-based confocal endomicroscopy for detection of BE dysplasia was 76% (95% confidence interval [CI], 59-88), 79% (95% CI, 53-92), and 77% (95% CI, 72-82), respectively. The use of volumetric laser endoscopy using a new algorithm showed a sensitivity of 86% (95% CI, 69-96), specificity of 88% (95% CI, 60-99), and diagnostic accuracy of 87% (95% CI, 86-88). Xiong et al (2016) published a meta-analysis of prospective studies evaluating the diagnostic accuracy of CLE in patients with BE, using histopathologic analysis as the criterion standard.(12) Studies were not required to compare CLE to standard 4-quadrant biopsy. Fourteen studies were included. In a pooled analysis seven studies (n=473 patients) reporting a per-patient analysis, the sensitivity of CLE for detecting neoplasia was 89% (95% CI, 82% to 94%) and the specificity was 83% (95% CI, 78% to 86%). The pooled positive and negative likelihood ratios were 6.53 (95% CI, 3.12 to 13.4) and 0.17 (95% CI, 0.11 to 0.29, respectively).

A systematic review of studies published from 2020 to 2024 evaluated advanced endoscopic imaging modalities—including chromoendoscopy, i-scan, FICE, NBI, and confocal laser endomicroscopy (CLE)—for early detection of gastrointestinal cancers (Mastoi et al., 2025). Across 23 included studies covering colorectal, gastric, and esophageal cancers, several modalities demonstrated higher diagnostic accuracy than standard white-light endoscopy (WLE). NBI showed superior accuracy for colorectal and gastric lesions, FICE performed well for gastric lesion detection, and CLE had high sensitivity for submucosal abnormalities. i-scan and chromoendoscopy also improved detection rates in multiple studies. Overall, these advanced techniques provide meaningful enhancements in early cancer detection, though broader adoption is limited by cost, training requirements, and the need for additional large-scale clinical evidence.

The American Society for Gastrointestinal Endoscopy guideline on screening and surveillance for Barrett's esophagus advises against the routine use of confocal laser endomicroscopy, recommending instead continued reliance on high-quality white-light endoscopy with Seattle protocol biopsy sampling (*ASGE Standards of Practice Committee, 2019*).

TissueCypher Barrett's Esophagus Assay

TissueCypher Barrett's Esophagus Assay is an artificial intelligence (AI) driven test that uses biomarkers, spatial biology, and an AI-driven risk classifier to identify a patient's five-year risk of progression to high-grade dysplasia (HGD) or esophageal adenocarcinoma (EAC) in patients with BE. The test characterizes molecular changes in BE tissue that precede dysplasia to identify candidates for eradication therapy for high-risk patients or reduced surveillance for low-risk patients (Davison et al., 2020; Castle Biosciences Inc., 2023a; Castle Biosciences Inc., 2023b). The test is intended for patients with a pathology diagnosis of nondysplastic BE (NDBE), indefinite for dysplasia (IND), or low-grade dysplasia (LGD) (Castle Biosciences Inc., 2023a). The test assesses

15 characteristics from 9 protein-based biomarkers and morphology in an esophagus tissue sample collected during an upper gastrointestinal endoscopy. The TissueCypher Image Analysis Platform is used to assess serial multichannel fluorescence of whole slide digital images. Algorithms combine characteristics of the biomarkers (e.g., fluorescence intensity) along with cell and tissue morphologic features (e.g., cell, nuclei, cytoplasm, plasma membrane) to assess the spatial relationship of biomarkers to each other and the tissue (Davison et al., 2020; Castle Biosciences Inc., 2023a; Castle Biosciences Inc., 2023e). The test calculates a risk score and reports a low, intermediate, or high risk of progression to HGD/EAC (Davison et al., 2020).

There is no consensus among medical societies that supports TissueCypher. The ACG could not make a recommendation on the use of TissueCypher due to low sensitivity and specificity (Shaheen, 2022), while in their Clinical Practice Update on New Technology and Innovation for Surveillance and Screening in Barrett's Esophagus the AGA states that the assay may be of benefit for patients with nondysplastic BE (Muthusamy, 2022).

The 2024 American Gastroenterological Association (AGA) guideline on endoscopic eradication therapy for Barrett's esophagus notes that certain tissue-based biomarkers—particularly aberrant p53 staining and the TissueCypher risk-stratification assay—may help identify patients at higher risk for progression to esophageal cancer. However, the guideline emphasizes that the routine use of these biomarkers in patients with nondysplastic BE (NDBE) remains uncertain. Decisions regarding their clinical application are deferred to the forthcoming AGA guideline on BE surveillance, indicating that the evidence is evolving and that no current recommendation is made for their standard incorporation into practice.

The 2025 AGA Clinical Practice Guideline on Surveillance of Barrett's Esophagus concluded: "In patients diagnosed with nondysplastic Barrett's esophagus (NDBE), Barrett's esophagus (BE) with indefinite for dysplasia (IND) or BE with low-grade dysplasia (LGD), the AGA makes no recommendation for or against the routine use of TissueCypher testing as an adjunct test to histopathology" (Wani et al., 2025).

Substantial uncertainty exists due to questions around test performance for identifying candidates for reduced surveillance; evidence also suggests that the test may not reliably identify patients at low risk of progression who would be candidates for reduced surveillance (Critchley-Thorne et al., 2016; Critchley-Thorne et al., 2017; Davison et al., 2020; Frei et al., 2020). There is a lack of evidence demonstrating improved clinical outcomes with testing.

Khoshiwal et al (2023) compared the risk stratification performance of the TissueCypher Barrett's Esophagus Test verus benchmarks of generalist and expert pathology. A total of 154 patients with BE (122 men), mean age 60.9 ± 9.8 years were studied. Twenty-four patients progressed to HGD/EAC within 5 years (median time of 1.7 years) and 130 did not progress to HGD/EAC within 5 years (median 7.8 years follow-up). The TSP-9 test demonstrated higher sensitivity (71% vs mean 63%, range 33%-88% across 30 pathologists), than the pathology review in detecting patients who progressed (P = .01186). However, currently no study has evaluated whether TissueCypher testing impacted patient clinical outcomes.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
National Comprehensive Cancer Network (NCCN)	esophageal.pdf (2026)
American College of Gastroenterology. (ACG)	Official journal of the American College of Gastroenterology | ACG (2022)
American Gastroenterological Association (AGA)	AGA Clinical Practice Update on the Personalized Approach to the Evaluation and Management of GERD: Expert Review - Clinical Gastroenterology and Hepatology (2022) AGA Clinical Practice Guideline on Surveillance of Barrett's Esophagus (2025) AGA Clinical Practice Guideline on Endoscopic Eradication Therapy of Barrett's Esophagus and Related Neoplasia (2024)
American Society for Gastrointestinal Endoscopy (ASGE)	American Society for Gastrointestinal Endoscopy guideline on the diagnosis and management of GERD: methodology and review of evidence (2025) https://www.asge.org/docs/default-source/guidelines/asge-guideline-on-screening-and-surveillance-of-barrett-s-esophagus-2019-september-gie.pdf
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), European Association for Endoscopic Surgery (EAES), Society for Surgery of the Alimentary Tract (SSAT), Society of Thoracic Surgeons (STS), American Society for Gastrointestinal Endoscopy (ASGE), and American Society for Metabolic and Bariatric Surgery (ASMBS)	Multi-Society Consensus Conference and Guideline on the Treatment of Gastroesophageal Reflux Disease (GERD) - A SAGES Publication (2023)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date

Stretta System (Mederi Therapeutics)	K991529	08/02/1999
LINX Reflux Management System	P100049	03/22/2012
Bard EndoCinch Suturing System (BESS)	K003956 K994290	01/05/2001 03/20/2000
Endoscopic Plication System; NDO EPS System; Plicator (Ndo Surgical, Inc.)	K023234 K072125	04/17/2003 10/18/2007
Angelchik Anti-Reflux Prosthesis	P790006	07/02/1984
SRS Endoscopic Stapling System (Medigus Ultrasonic Surgical Endostaple (MUSE), Medigus Ltd)	K120299 K132151	05/18/2012 03/19/2014
GERDx-System	K233240	06/21/2024
Durasphere	P980053A	09/13/1999
Reza Band Upper Esophageal Sphincter Assist Device (Somna Therapeutics, LLC)	K173934	04/13/2018
EsophyX2 System with SerosaFuse Fastener EsophyX System with SerosaFuse Fastener and accessories (EndoGastric Solutions (EGS)	K092400 K071651	11/06/2009 9/14/2007
StomaphyX StomaphyX system with SerosaFuse Fastener	K062875 K073644 K091832	03/09/2007 06/27/2008 07/22/2009
Gatekeeper Reflux Repair System	Not FDA-approved (withdrawn; investigational only)	
Plexiglas polymethylmethacrylate (PMMA) microspheres	Not FDA-approved for GERD; only preclinical material, not a device	
Cellvizio 100 series system with confocal Miniprobes (Mauna Kea Technologies)	K220477	04/11/2022
The HALO^{360} Coagulation System (Barrx Medical Inc)	K051168	06/29/2005

VI. CODING

See also Priority Health Billing Policy No. 143 Endoscopic Treatment of GERD

Transoral Incisionless Fundoplication (TIF) for GERD:

ICD-10 Codes that may support medical necessity

K20.8x	Other esophagitis
K20.9x	Esophagitis, unspecified
K21.0x	Gastro-esophageal reflux disease with esophagitis
K21.9	Gastro-esophageal reflux disease without esophagitis

CPT/HCPCS Codes

The following procedures are covered only for the gastroesophageal reflux disease (GERD) dx above:

43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed (*when billed for EsophyX System)*
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 *(when billed for Stretta System)*

The following procedures are not medically necessary for the GERD diagnoses above:

43211	Esophagoscopy, flexible, transoral; with endoscopic mucosal resection
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)

Endoscopic Mucosal Resection, Thermal Ablation Treatment or Photodynamic Therapy for Barrett's Esophagus:

ICD-10 Codes that may support medical necessity

K22.710	Barrett's esophagus with low grade dysplasia
K22.711	Barrett's esophagus with high grade dysplasia
K22.719	Barrett's esophagus with dysplasia, unspecified

CPT/HCPCS Codes

43211	Esophagoscopy, flexible, transoral; with endoscopic mucosal resection
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)

96570 Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); first 30 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of lung and gastrointestinal tract)

96571 Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); each additional 15 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of lung and gastrointestinal tract)

J9600 Injection, porfimer sodium, 75 mg

Magnetic sphincter augmentation (MSA) - LINX device:

ICD-10 Codes that may support medical necessity

K20.8x Other esophagitis
K20.9x Esophagitis, unspecified
K21.0x Gastro-esophageal reflux disease with esophagitis
K21.9 Gastro-esophageal reflux disease without esophagitis

CPT/HCPCS Codes

43284 Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed. Prior authorization required.

43285 Removal of esophageal sphincter augmentation device. No prior authorization.

Diagnostic Services

91010 Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report;

91013 Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report; with stimulation or perfusion (eg, stimulant, acid or alkali perfusion) (List separately in addition to code for primary procedure)

91020 Gastric motility (manometric) studies

91022 Duodenal motility (manometric) study

91030 Esophagus, acid perfusion (Bernstein) test for esophagitis

91034 Esophagus, gastroesophageal reflux test; with nasal catheter pH electrode(s) placement, recording, analysis and interpretation

91035 Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation

91037 Esophageal function test, gastroesophageal reflux test with nasal catheter intraluminal impedance electrode(s) placement, recording, analysis and interpretation;

91038 Esophageal function test, gastroesophageal reflux test with nasal catheter intraluminal impedance electrode(s) placement, recording, analysis and interpretation; prolonged (greater than 1 hour, up to 24 hours)

91040 Esophageal balloon distension study, diagnostic, with provocation when performed

TissueCypher:

0108U Gastroenterology (Barrett's esophagus), whole slide-digital imaging, including morphometric analysis, computer-assisted quantitative immunolabeling of 9 protein biomarkers (p16, AMACR, p53, CD68, COX-2, CD45RO, HIF1a, HER-2, K20) and morphology, formalin-fixed paraffin-embedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer (covered for Medicare only)

Prior Authorization Required:

0114U Gastroenterology (Barrett's esophagus), VIM and CCNA1 methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus

0398U Gastroenterology (Barrett esophagus), P16, RUNX3, HPP1, and FBN1 DNA methylation analysis using PCR, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score for progression to high-grade dysplasia or cancer

0506U Gastroenterology (Barrett's esophagus), esophageal cells, DNA methylation analysis by next-generation sequencing of at least 89 differentially methylated genomic regions, algorithm reported as likelihood for Barrett's esophagus

The following procedures are not covered:

43201 Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance (*when billed for Gatekeeper™ System, Enteryx™, PMMA beads, Duraspheres or other GERD /BE treatment not listed as covered)*

43206 Esophagoscopy, flexible, transoral; with optical endomicroscopy

43210 Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed *(when billed for EndoCinch™, Endoscopic Plication ™System*

43229 Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed) *(when billed for cryo or laser ablation techniques)*

43236 Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance (*when billed for Gatekeeper™ System, Enteryx™, PMMA beads, Duraspheres or other GERD or BE treatment not listed as covered)*

43252 Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy

43254 Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection

WATS-3D

WATS-3D Biopsy (CDx Diagnostics Inc.):

88104 Cytopathology, fluids, washings or brushings, except cervical or vaginal; smears with interpretation

88305 Level IV - Surgical pathology, gross and microscopic examination Abortion - spontaneous/missed Artery, biopsy Bone marrow, biopsy Bone exostosis Brain/meninges, other than for tumor resection Breast, biopsy, not requiring microscopic evaluation of surgical margins Breast, reduction mammoplasty Bronchus, biopsy Cell block, any source Cervix, biopsy Colon, biopsy Duodenum, biopsy Endocervix, curettings/biopsy Endometrium,

curettings/biopsy Esophagus, biopsy Extremity, amputation, traumatic Fallopian tube, biopsy Fallopian tube, ectopic pregnancy Femoral head, fracture Fingers/toes, amputation, non-traumatic Gingiva/oral mucosa, biopsy Heart valve Joint, resection Kidney, biopsy Larynx, biopsy Leiomyoma(s), uterine myomectomy - without uterus Lip, biopsy/wedge resection Lung, transbronchial biopsy Lymph node, biopsy Muscle, biopsy Nasal mucosa, biopsy Nasopharynx/oropharynx, biopsy Nerve, biopsy Odontogenic/dental cyst Omentum, biopsy Ovary with or without tube, non-neoplastic Ovary, biopsy/wedge resection Parathyroid gland Peritoneum, biopsy Pituitary tumor Placenta, other than third trimester Pleura/pericardium - biopsy/tissue Polyp, cervical/endometrial Polyp, colorectal Polyp, stomach/small intestine Prostate, needle biopsy Prostate, TUR Salivary gland, biopsy Sinus, paranasal biopsy Skin, other than cyst/tag/debridement/plastic repair Small intestine, biopsy Soft tissue, other than tumor/mass/lipoma/debridement Spleen Stomach, biopsy Synovium Testis, other than tumor/biopsy/castration Thyroglossal duct/brachial cleft cyst Tongue, biopsy Tonsil, biopsy Trachea, biopsy Ureter, biopsy Urethra, biopsy Urinary bladder, biopsy Uterus, with or without tubes and ovaries, for prolapse Vagina, biopsy Vulva/labia, biopsy

88312 Special stain including interpretation and report; Group I for microorganisms (eg, acid fast, methenamine silver)

88361 Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; using computer-assisted technology

WATS-3D is not medically necessary for the following Barrett's Esophagus diagnosis codes:

ICD-10 Codes

K22.710 Barrett's esophagus with low grade dysplasia
K22.711 Barrett's esophagus with high grade dysplasia
K22.719 Barrett's esophagus with dysplasia, unspecified

Unlisted Codes: Explanatory notes must accompany claims billed with unlisted codes. Not medically necessary if billed for GERD or BE for treatments listed in this policy as not medically necessary or not listed as covered.

E1399 Durable medical equipment, miscellaneous
L8499 Unlisted procedure for miscellaneous prosthetic services
43289 Unlisted laparoscopy procedure, esophagus
43499 Unlisted procedure, esophagus
43999 Unlisted procedure, stomach

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

To access Evicore guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

GERD

General

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SUMMARY OF CHANGES

Additions

- Added reference in Section II (Medicare section) to explicitly note that some advanced diagnostic laboratory tests may meet criteria for designation as Advanced Diagnostic Laboratory Tests under the Medicare Clinical Laboratory Fee Schedule (CLFS).

Past committee review dates: 02/2004, 01/2005, 12/2005, 2/2006,12/2006, 12/2007, 02/2008, 02/2009, 02/2010, 04/2010, 04/2011, 04/2012, 04/2012, 04/2013, 05/2014, 05/2015, 05/2016, 11/2016, 11/2017, 11/2018, 05/2019, 05/2020, 05/2021, 05/2022, 05/2023, 02/2024, 02/2025, 02/2026,05/2026

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