Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD)

Policy Number: PG0166
Last Review: 09/20/2022

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional
X Facility

DESCRIPTION:

Gastroesophageal reflux disease (GERD) is defined as symptoms or mucosa damage resulting from the reflux of gastric content into the esophagus. GERD occurs as a result of the stomach contents leaking back into the esophagus due to the improper closing of the lower esophageal sphincter. Causes include a weakness in the lower esophageal sphincter (LES), presence of a hiatal hernia (HH), temporary LES relaxation, alterations in the gastroesophageal pressure gradient and esophageal factors such as poor clearance and changes in motility. Symptoms include heartburn, acid reflux, morning hoarseness, difficulty swallowing, dry cough, and pain in the chest. Mucosa damage can vary from none to mild esophagitis, to more severe esophagitis, and, less commonly, Barrett's esophagus and esophageal carcinoma. The goal of therapy is to control both the symptoms and mucosal damage.

Treatments for GERD are designed to improve the function of the lower esophageal sphincter (LES). Medical management of GERD includes lifestyle changes (e.g., elevating the head of the bed, decreasing fat intake, quitting smoking, diet); pharmaceuticals (e.g., antacids); Histamine 2 receptor antagonists (H2RAs) and Proton pump inhibitors (PPIs); minimally invasive and endoscopic procedures; and surgical treatment.

The majority of GERD patients have mucosal disease, and symptoms are controlled with medical therapy. Anti-reflux surgery may be an option for patients who have failed pharmacotherapy or for those who choose not to continue on medication therapy for the long term. The most common surgical procedure, open or laparoscopic, used for GERD is a Nissen fundoplication. Fundoplication involves wrapping a portion of the gastric fundus around the distal esophagus to increase LES pressure. If a hiatal hernia is present, the procedure also restores the position of the LES to the correct location. Although laparoscopic fundoplication results in a high proportion of patients reporting symptom relief, complications can occur, and sometimes require conversion to an open procedure. Patients who have relief of symptoms of GERD after fundoplication may have dysphagia or gas-bloat syndrome (excessive gastrointestinal gas).

Due in part to the high prevalence of GERD, there has been interest in creating a minimally invasive transesophageal therapeutic alternative to open or laparoscopic fundoplication or chronic medical therapy. A variety of endoscopic therapies for the treatment of GERD have been developed and proposed as alternatives to pharmacological therapy or anti-reflux surgery. Currently, there are three endoluminal approaches being investigated to treat GERD.

Radiofrequency Energy
Radiofrequency energy for the treatment of GERD requires a special single-use catheter and radiofrequency energy generator. Thermal energy is delivered to the lower esophageal sphincter (LES) using endoscopically placed needles. Thermal lesions are produced. The procedure is generally performed using standard conscious sedation but has required general anesthesia in some patients. The possible mechanisms of action that result from radiofrequency energy are scarring or neurolysis at, or near, the gastroesophageal junction. This procedure is commonly referred to as the Stretta procedure.

Endoscopic Plication or Suturing
In these types of procedures, sutures are placed in the lower esophageal sphincter. Specifically, a needle puncture device attached to the endoscope creates pleats through a series of sutures passed by a needle through adjoining proximal fundic folds at the gastroesophageal junction. The sutures are designed to strengthen and lengthen the sphincter in order to decrease reflux. Endoscopic plication or suturing devices, which includes, but may not be limited to, the following:

- Transoral Incisionless Fundoplication (TIF) (e.g., EsophyX) is an endoscopic procedure, which is used to supposedly construct a durable antireflux valve. Using SerosaFuse Fasteners, the LES is reportedly tightened, which reestablishes a barrier to reflux and restores the competency of the gastroesophageal junction. The TIF procedure clinical objectives are a) to mechanically repair a defective gastroesophageal valve and b) to reduce small hiatal hernias. The goal of therapy is to control both the symptoms and mucosal damage.
- The Muse System or Medigus Ultrasonic Surgery Endostapler is intended for endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach to create anterior partial fundoplication for treatment of symptomatic chronic GERD in patients who require and respond to pharmacologic therapy
- The EndoCinch or Bard Endoscopic Suturing System (BESS) is used for endoscopic placement of suture(s) in the soft tissue of the esophagus and stomach and for the approximation of tissue for the treatment of symptomatic GERD. The EndoCinch is no longer recommended for use and the manufacturer, Bard, has discontinued the EndoCinch Suturing System.
- The NDO Endoscopic Plication System, also known as the NDO Plicator System, places a full-thickness transmural plication near the gastroesophageal junction under direct endoscopic visualization.
- GERDx (G-SURG) is an endoscopic full-thickness plication device that uses hydraulic elements for controlling.

Injection/Implantation of Prosthetic Devices or Bulking Agents
Bulking agents are substances injected, implantation of a prosthetic, or bulking agent placed under endoscopic guidance into the esophageal wall at the level of the esophagastric junction to impede reflux. Implantable products/devices include, but may not be limited to, the following:

- Gatekeeper Reflux Repair System is a hydrogel prosthesis that is implanted endoscopically into the LES. The National Institute for Health and Clinical Excellence (NICE) guidance concluded that there is limited evidence of short-term efficacy on endoscopic augmentation of the LES using hydrogel implants for the treatment of GERD. 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." The Gatekeeper Reflux Repair System clinical program was suspended in late 2005 before FDA approval due to concerns over efficacy.
- Medigus Ultrasonic Surgery Endostapler (MUSE) utilizes a disposable flexible endoscope that is inserted through the mouth. The system combines a miniaturized video camera, a surgical stapler, and ultrasonic sights for alignment. It has been suggested that the use of this device can help restore a normal gastroesophageal valve through anterior fundoplication via endoluminally placed staples.
- Plexiglas polymethylmethacrylate microspheres (PMMA). The PMMA procedure involves injection of an inert polymer material into the submucosa of the proximal lower esophageal sphincter zone to provide bulking support to the sphincter and decrease transient relaxation of the lower esophageal sphincter.
- Magnetic Esophageal Sphincter Augmentation, the LINX Reflux Management System, is an implant that consists of a small flexible band of interlinked titanium beads with magnetic cores. The magnetic attraction is proposed to help the lower esophageal sphincter (LES) resist opening to gastric pressures, preventing reflux

from the stomach into the esophagus. It is proposed that swallowing food or liquids creates sufficient pressure to overcome the magnetic bond between the beads, allowing the beads to separate and temporarily increase the size of the ring. The target population is individuals who have GERD symptoms despite maximum medical therapy (e.g., proton pump inhibitors) but who do not want to risk the adverse effects of a surgical procedure like Nissen fundoplication. A surgeon uses a laparoscopic incision to implant the device around the patient's esophagus just above the stomach while the patient is under general anesthesia.

- Enteryx is a chemically inert, non-carcinogenic, hypoallergenic, non-antigenic, radiopaque compound that is available in a liquid organic state but becomes solid on hydration (or placement in tissue). It is injected into the LES under fluoroscopic and endoscopic guidance. Current evidence for the use of Enteryx is limited to pilot studies as well as small trials that lack appropriate control groups and long-term follow-up data. Thus, the clinical value of Enteryx is uncertain at this time
- One bulking agent, pyrolytic carbon-coated zirconium oxide spheres (Durasphere), is being evaluated in the treatment of mild-moderate GERD. Pyrolytic carbon-coated graphite beads suspended in a water-based carrier gel suitable for suspending the carbon-coated beads.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Paramount Commercial Insurance Plans

- **Effective 10/01/2022 Transoral incisionless fundoplication (TIF) (e.g., EsophyX™) (43210) for GERD is covered, without a prior authorization.**
- **All other endoscopic therapies are non-covered for the treatment of GERD**

Elite (Medicare Advantage) Plans

- **Transoral incisionless fundoplication (TIF) (e.g., EsophyX™) (43210) for GERD, Effective 10/01/2022 no prior authorization is required.**
- **All other endoscopic therapies for the treatment of GERD are non-covered.**

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Paramount Commercial Insurance Plans

Transoral incisionless fundoplication (TIF) (e.g., EsophyX®; MUSE) is considered MEDICALLY NECESSARY as a treatment of gastroesophageal reflux disease when the following criteria are met

- Symptomatic chronic gastroesophageal reflux (chronic being defined as > 6 months of symptoms), and
- Symptoms must not be completely responsive to Proton Pump Inhibitors (PPIs) as judged by GERD Health-Related Quality of Life (HRQL) scores of < or equal to 12 while on PPIs and > or equal to 20 when off for 14 days (also acceptable would be the difference of > or equal to 10 of the scores between off and on therapy), and
- Hiatal hernia < or equal to 2 cm, including where the hernia has been reduced to 2 cm or less by a successful laparoscopic hernia reduction procedure prior to the TIF procedure. (Based on (FDA) approval).

Limitations

Coverage is not extended:

- For those patients who may have recurrent symptoms or may fail this procedure. No literature has been submitted for repeat TIF use. These procedures (repeat TIF) would be considered investigational at this time.
- For those patients with a hiatal hernia greater than 2 cm, except where the hernia has been reduced to 2 cm or less by a successful laparoscopic hernia reduction procedure prior to the TIF procedure. (Based on (FDA) approval).
- GERD patients with BMI > 35, esophagitis LA grade >B, Barrett's esophagus > 2 cm, and presence of achalasia or esophageal ulcer or has not been on an appropriate trial of proton pump inhibitors.

All other endoscopic therapies for the treatment of GERD are non-covered, as they are unproven and not medically necessary for treating gastroesophageal reflux disease (GERD) due to insufficient evidence.

Endoscopic procedures that are considered experimental and investigational including but not limited to ALL of the following:

1. Radiofrequency energy
    - Stretta System (43257)
2. Endoscopic plication or suturing
    - Medigus Ultrasonic Surgery Endostapler (MUSE)
    - Bard Endoscopic Suturing System (BESS) – EndoCinch Therapy, Endoluminal Plication
    - Endoscopic Plication System
    - Full Thickness Plicator
    - Syntheon ARD Plicator
    - Apollo OverStitch endoscopic suturing system
    - StomaphyX
    - C-BLART (clip band ligation anti-reflux therapy)
3. Injection/Implantation of Prosthetic Devices or Bulking Agents
    - Duraphere (Pyrolytic carbon coated zirconium oxide spheres)/Gatekeeper Reflux Repair System (43292, 43201)
    - Plexiglas (polymethylmethacrylate [PMMA]) procedure (43292, 43201)
    - Enteryx (43292, 43201)
    - LINX Reflux Management System *(Laparoscopic or open surgical procedure)* (43284, 43285)
    - Plicator System
    - Angelchik Anti-Reflux Prosthesis

The safety and efficacy of endoscopic therapies for the treatment of GERD have not been established in the published medical literature. Current studies are generally of small to moderate size, lack adequate control or comparison groups, and provide only short-term follow-up. Well-designed clinical trials with long-term follow up are required to establish that endoscopic therapies benefit health outcomes in patients with GERD by eliminating symptoms, preventing recurrence of symptoms or progression of disease, healing esophagitis, and reducing the need for pharmacologic therapy.

Elite (Medicare Advantage) Plans

While there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of transoral incisionless fundoplication (TIF) (e.g., EsophyX™) (43210) for GERD, The Center for Medicare & Medicaid Services requires this procedure be reviewed for medical necessity. Therefore, it may be covered with a prior authorization for Elite/Paramount Medicare Plan members.

Transoral incisionless fundoplication (TIF) (e.g., EsophyX®; MUSE) is considered MEDICALLY NECESSARY as a treatment of gastroesophageal reflux disease when the following criteria are met

- Symptomatic chronic gastroesophageal reflux (chronic being defined as > 6 months of symptoms), and
- Symptoms must not be completely responsive to Proton Pump Inhibitors (PPIs) as judged by GERD Health-Related Quality of Life (HRQL) scores of < or equal to 12 while on PPIs and > or equal to 20 when off for 14 days (also acceptable would be the difference of > or equal to 10 of the scores between off and on therapy), and
- Hiatal hernia < or equal to 2 cm, including where the hernia has been reduced to 2 cm or less by a successful laparoscopic hernia reduction procedure prior to the TIF procedure. (Based on (FDA) approval).

Limitations

Coverage is not extended:

- For those patients who may have recurrent symptoms or may fail this procedure. No literature has been submitted for repeat TIF use. These procedures (repeat TIF) would be considered investigational at this

time.

- For those patients with a hiatal hernia greater than 2 cm, except where the hernia has been reduced to 2 cm or less by a successful laparoscopic hernia reduction procedure prior to the TIF procedure. (Based on (FDA) approval).
- GERD patients with BMI > 35, esophagitis LA grade >B, Barrett's esophagus > 2 cm, and presence of achalasia or esophageal ulcer or has not been on an appropriate trial of proton pump inhibitors.

All other endoscopic therapies for the treatment of GERD are non-covered.

Reference

The Los Angeles Classification of Oesophagitis:

- Grade A: One (or more) mucosal break no longer than 5 mm that does not extend between the tops
- of two mucosal folds
- Grade B: One (or more) mucosal break more than 5 mm long that does not extend between the tops
- of two mucosal folds
- Grade C: One (or more) mucosal break that is continuous between the tops of two or more mucosal
- folds, but which involve less than 75% of the circumference

Grade D: One (or more) mucosal break which involves at least 75% of the esophageal circumference

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
43201	Esophagoscopy, rigid or flexible; with directed submucosal injection(s), any substance (not covered for GERD procedure) (Bulking agent)
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed (covered if criteria is met) (Transoral incisionless fundoplication (TIF))
43236	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with directed submucosal injection(s), any substance (not covered for GERD procedure) (Bulking agent)
43257	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease (not covered for GERD procedure) (Stretta)
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed (not covered for GERD procedure) (LINX Reflux Management System)
43285	Removal of esophageal sphincter augmentation device
43289	Unlisted laparoscopy procedure, esophagus (not covered for GERD procedure)
43499	Unlisted procedure, esophagus (not covered for GERD procedure)
43659	Unlisted laparoscopy procedure, stomach (not covered for GERD procedure)
43999	Unlisted procedure, stomach (not covered for GERD procedure)
DIAGNOSIS CODES	
K21.00	Gastro-hyphenesophageal reflux disease with esophagitis, without bleeding
K21.01	Gastro-hyphenesophageal reflux disease with esophagitis, with bleeding
K21.9	Gastro-hyphenesophageal reflux disease without esophagitis

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 10/15/2008

Date	Explanation & Changes
08/15/09	• Reviewed
03/18/13	• Updated Advantage denial code

06/20/14	• Changed title of policy from Stretta Endoscopic Radiofrequency Ablation System to Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD) • Added codes 43499 & 43999 • Radiofrequency energy (Stretta® System) (43257) for GERD may be covered with a prior authorization for Advantage members • Policy reviewed by TAWG and updated to reflect most current clinical evidence.
08/22/14	• Added codes 43201, 43236, 43289, 43659, C9724, C9737 • Policy reviewed by TAWG and updated to reflect most current clinical evidence
10/22/15	• Added new effective 7/1/15 codes 0392T & 0393T as non-covered Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
10/28/16	• C9724 & C9737 deleted effective 12/31/15 & 06/30/15 • Added effective 1/1/16 new code 43210 • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
03/24/17	• Effective 12/31/16 deleted codes 0392T & 0393T that were non-covered for all product lines • Added effective 01/01/17 new codes 43284 & 43285 as covered with prior authorization for Advantage only per ODM guidelines • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
03/22/18	• Transoral incisionless fundoplication (TIF) (e.g., EsophyX™) (43210) for GERD is now covered with prior authorization for Elite per CMS guidelines. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
12/15/2020	• Medical policy placed on the new Paramount Medical Policy Format
09/20/2022	• Policy reviewed and updated to reflect most current clinical evidence • Removed deleted codes 0392T and 0393T • Added ICD-10 diagnosis codes of reference • Effective 10/1/2022, for the Commercial product lines, Paramount allows coverage for Transoral Incisionless Fundoplication (TIF) with EsophyX, without a prior authorization • Effective 10/1/2022, Paramount allows the Elite/ProMedica Medicare Plan coverage for Transoral Incisionless Fundoplication (TIF) with EsophyX without a prior authorization
02/09/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/04/2024	• Medical Policy placed on the new Paramount Medical Policy format

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/
Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review

Medical Policy History

Paramount Medicaid Advantage

- **Radiofrequency energy (Stretta System) (43257) & Transoral incisionless fundoplication (TIF) (e.g., EsophyX) (43210) and implantation of prosthetic devices (LINX) (43284, 43285) for GERD requires a prior authorization.**
- **Procedures 43201 and 43236, directed submucosal injection(s), for GERD require a prior authorization.**
- **All other endoscopic therapies for the treatment of GERD are non-covered.**

Paramount Medicaid Advantage

While there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of radiofrequency energy (Stretta System) (43257), transoral incisionless fundoplication (TIF) (e.g., EsophyX) (43210), implantation of prosthetic devices (LINX) (43284, 43285) and procedures 43201 and 43236 for directed submucosal injection(s), the Ohio Department of Medicaid requires these procedures be reviewed for medical necessity.

Therefore, they may be covered with a prior authorization for Advantage members when meeting ALL of the following criteria:

- Age ≥ 18;
- Confirmed GERD by endoscopy, ambulatory PH, or barium swallow testing;
- Greater than one year of GERD symptoms (i.e., heartburn, regurgitation, difficulty swallowing, chest pain) (reflux symptoms that occur 2 to 3 times per week);
- History of daily proton pump inhibitor's (PPI's) for >6 months;
- GERD patients with body mass index (BMI) ≤ 35;
- No Hiatal hernia >2 cm;
- No Esophagitis LA (Los Angeles classification system) grade C or D;
- No Barrett's esophagus >2 cm;
- Absence of achalasia and esophageal ulcer;
- No altered esophageal anatomy that would prevent insertion of a device, i.e., fixed esophageal stricture, narrowing, gastric outlet obstruction or stenosis;
- Absence of esophageal motility disorder;
- No portal hypertension and/or varices; and
- No previous history of failed antireflux surgery/procedure, i.e., cervical spine fusion, Zenker's diverticulum, esophageal epiphrenic diverticulum, achalasia, scleroderma or dermatomyositis, eosinophilic esophagitis, > 2 dilations for esophageal stricture, or cirrhosis.
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All other endoscopic therapies for the treatment of GERD are non-covered.