

MEDICAL POLICY	Gastroesophageal Reflux Disease: Endoscopic Treatments (All Lines of Business Except Medicare)	
Effective Date: 2/1/2021  <div style="text-align: right;">2/1/2021</div>	Section: SUR	Policy No: 228
	Technology Assessment Committee Approved Date: 11/09; 2/11; 5/13; 4/14; 2/15; 2/16; 5/16 Medical Policy Committee Approved Date: 11/05; 11/07; 5/08; 7/17; 2/18; 6/18; 8/19; 11/19; 1/2021	
Medical Officer	Date	

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

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

POLICY CRITERIA

Note: This policy does not address the per-oral endoscopic myotomy (POEM) or magnetic esophageal ring (i.e., LINX® Reflux Management System) procedures.

- I. Transoral incisionless fundoplication (TIF)(i.e., EsophyX) is considered **not medically necessary and is not covered** for the treatment of gastroesophageal reflux disease.
- II. Other endoscopic treatments for gastroesophageal reflux disease are considered **investigational and are not covered**, including but not limited to the following (A.-E.):

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<ul style="list-style-type: none"> A. Transesophageal radiofrequency ablation of the gastroesophageal junction (e.g. Stretta®) B. Endoscopic suturing (e.g. EndoCinch™ Suturing System) C. Endoluminal gastroplasty D. Endoscopic implantation of a prosthesis or bulking agent (e.g. Gatekeeper™ Reflux Repair System, Durasphere™) <p>Link to Policy Summary</p>
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CPT CODES

All Lines of Business Except Medicare	
Prior Authorization Required	
43192	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance
Not Covered	
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
Unlisted Codes	
All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then prior-authorization is required.	
43499	Unlisted procedure, esophagus

DESCRIPTION

Gastroesophageal Reflux Disease (GERD)

According to Hayes, “GERD is the most common principal gastroenterology-related diagnosis, with 8.9 million cases diagnosed annually in the U.S., and it is the fifth most common hospital discharge diagnosis at 4.4 million.”¹ GERD involves the abnormal reflux of gastric contents into the esophagus. Chronic GERD can lead to mucosal damage. Causes of GERD include weakness or relaxation in the lower esophageal sphincter (LES), presence of a hiatal hernia (HH), and/or changes in gastroesophageal pressure. Initial therapy includes acid-suppressive medications and lifestyle modifications (e.g., elevated

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sleeping, reducing fat intake, weight loss). Pharmacogenic therapy includes proton pump inhibitors (PPIs) and histamine-2 receptor antagonists (H2Ras). “For patients who wish to discontinue use of these medications or for patients whose GERD is refractory to pharmacologic treatment, an open or laparoscopic Nissen fundoplication may be considered.”¹

Endoscopic Treatments for GERD

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

- (1) Radiofrequency energy (RFE) delivered to the GEJ (e.g., Stretta™)
 - RFE is applied to the lower esophageal sphincter (LES) muscle in order to “thicken the musculature and increase the size and amount of smooth muscle fibers for better barrier function and fewer transient LES relaxations.”¹
- (2) Endoscopic plication or suturing of the proximal stomach to the esophagus (e.g., EsophyX™)
 - Transoral incisionless fundoplication (TIF) is used to recreate a barrier against reflux by retracting the tissue at the LES and attaching implantable fasteners (EsophyX™) or staples (MUSE™).
- (3) Polymer injection or implantation of bulking agents into the gastric cardia or distal esophagus (e.g., Gatekeeper™ Reflux Repair System)
 - Bulking agents are implanted into the submucosa of the distal esophagus in order to restrict the dimensions of the esophagus; therefore, limiting the aperture through which gastroesophageal reflux must flow.²

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of endoscopic treatments for gastroesophageal reflux disease (GERD). Below is a summary of the available evidence identified through November 2020.

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

Systematic Reviews

- In 2016 (updated 2020), ECRI conducted an evidence review evaluating the safety and efficacy of the EsophyX for the treatment of gastroesophageal reflux disease.⁷ Searching the literature through October 2018, ECRI examined evidence from 2 systematic reviews with meta-analysis and one additional, small RCT. One systematic review with network meta-analysis (7 RCTs; n=1,128) reported that transoral incisionless fundoplication (TIF) (e.g. EsophyX) had the highest probability of

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increasing patients' health-related quality of life, but that laparoscopic Nissen fundoplication (LNF) patients had the highest probability of increasing patients' percent time at pH < 4 (0.99). A systematic review with meta-analysis (n=1,475; 32 RCTs and nonrandomized controlled trials) reported a TIF success rate of 99%, a hernia reduction rate of 91%, and 2% experiencing adverse events. The small, RCT not included for analysis in the above systematic reviews (n=63) reported significantly improved quality of life score (p < 0.001) at 5-year follow-up. Limitations across reviewed studies included high levels of heterogeneity across patient population size and follow-up; wide confidence intervals and values consistent with significant differences; and lack of long-term follow-up among most studies reviewed in the two systematic reviews. Investigators concluded that EsophyX is more effective than LNF and proton pump inhibitors pharmacotherapy, and that the overall evidence is "somewhat favorable" for EsophyX.

- In December 2017 (updated December 2019), Hayes published a comparative effectiveness review evaluating endoscopic therapies for gastroesophageal reflux disease (GERD), specifically Stretta™, EsophyX™, and MUSE™.¹ The literature review identified 19 eligible studies, including 12 evaluating radiofrequency therapy (Stretta), 5 studies evaluating transoral incisionless fundoplication (TIF)(i.e., EsophyX), and 2 studies evaluating endoscopic stapling with Medigus Ultrasonic Surgical Endostapler (MUSE). Sample sizes ranged from 27 to 217 patients and follow-up times varied from 6 months to 10 years. Outcome measures included GERD-health related quality of life (GERD-HRQL), PPI use, esophageal acid exposure (EAE), lower esophageal sphincter (LES) pressure, esophagitis, and complications.

Stretta

The percentage of patients who were able to discontinue PPIs ranged from 16.7% to 61.7% and 31% to 78% were able to lower their PPI dosage. When compared with laparoscopic fundoplication (LF), Stretta was favored in 2 studies and had a nonsignificant difference from sham in 2 studies. Stretta also showed significant improvement in GERD-HRQL scores in 61% to 72% of patients. There were conflicting results for heartburn improvement and regurgitation. Stretta had significant improvement from baseline for EAE; however, there were conflicting results when Stretta was compared to sham or other treatments. Complications were reported in up to 58% of patients, including abdominal pain, bloating, transient gastroparesis, esophagitis, dysphagia, nausea/vomiting, and swallowing pain.

EsophyX

For EsophyX, "the percentage of patients who discontinued PPI use was 66% to 90% at 6 months, 39% to 82% at 12 months, 70% to 76% at 24 months, and 71% at 36 months (4 studies/7 analyses)."¹ EsophyX showed improvement in GERD-HRQL scores in 55% to 73% of patients. In regards to heartburn, the results were conflicting. When evaluating regurgitation, "EsophyX was comparable with PPI therapy (0.5 versus 0.8; P=0.072), but was favored versus no treatment (0.5 versus 2.5; P<0.001)."¹ Results were also conflicting for the reflux testing outcomes—in two studies EsophyX was favored over sham, while one RCT found EsophyX to be

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comparable with sham for the percentage of patients achieving pH normalization. All studies reported complications ranging from 2% to 45%, including “operative pneumoperitoneum, postoperative failures (requiring revision or laparoscopic fundoplication), mild/transient sore throat, cough, belching, pain, nausea, vomiting, left shoulder pain, melena, hematemesis, constipation, asthma exacerbation, tinnitus, and de novo or worsening of dysphagia, bloating, flatulence, nausea, chest pain, esophagitis, and pneumonia.”¹

MUSE

In evaluating PPI usage, “there was a significant decrease in mean dose per day from baseline (1 noncomparative study) but there was no significant difference between MUSE and LF in the percentage of patients using PPIs (1 comparative study).”¹ MUSE showed improvement in GERD-HRQL scores in 64% to 73% of patients. No studies reported outcomes for heartburn or regurgitation. MUSE had significant improvements from baseline in pH levels; however, no comparisons to sham or other treatments were made. Of note, a total of 8 serious AEs were reported in the first 24 MUSE patients that required a protocol or device change. The most common AEs included chest pain, sore throat, atelectasis, shoulder pain, and increased belching.

The overall quality of evidence for endoscopic therapies for GERD was determined to be low; specifically, low quality for Stretta and EsophyX and very low for MUSE. Study limitations included, “lack of randomization and/or blinding, small sample size, generally short-term follow-up, lack of significance reporting for some measures, lack of and inconsistent comparators, loss to follow-up (especially for pH measures), 1 retrospective study, 1 study with a protocol change midway through, inconsistent use of outcome measures (objective and subjective), and potential lack of generalizability.”¹

Overall, Hayes gave the following ratings for the use of Stretta, EsophyX, or MUSE to treat GERD:

- Hayes Rating C (potential but unproven benefit)— “for the use of Stretta radiofrequency energy in adult patients with gastroesophageal reflux disease (GERD), no hiatal hernia (HH) or HH ≤ 2 centimeters (cm), who are good surgical candidates, and do not have American Society of Anesthesiologists (ASA) IV classification. This Rating reflects low-quality evidence suggesting improvement from baseline, but inconsistent and similar efficacy outcomes between Stretta and sham/proton pump inhibitor (PPI) therapy and inferior results compared with laparoscopic fundoplication on most efficacy outcomes. The Rating also reflects limited, if positive, evidence with respect to long-term outcomes.”¹
- Hayes Rating C (potential but unproven benefit)— “for use of EsophyX transoral incisionless fundoplication in adult patients with GERD, no HH or HH ≤ 2 cm, who require and respond to pharmacological therapy, and who do not have a condition that would interfere with device insertion. This Rating reflects low-quality evidence suggesting improvement from baseline, but inconsistent and similar efficacy outcomes

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between EsophyX and sham/PPI therapy. The Rating also reflects lack of evidence with respect to long-term outcomes.”¹

- Hayes rating D2 (insufficient evidence)—“for use of Medigus Ultrasonic Surgical Endostapler (MUSE) in adult patients with demonstrated GERD diagnosis who require and respond to pharmacological therapy. This Rating reflects the lack of evidence pertaining to efficacy and safety of this procedure in this patient population.”¹
- In 2019, the Oregon Health Evidence Review Commission (HERC) published a coverage guidance addressing new interventional procedures for the treatment of GERD.³ Investigators limited their evidence review to 2 systematic reviews, one of which is addressed in the Hayes review discussed below (Huang et al. (2017)),⁴ and one of which is discussed in the ECRI review discussed below (Richter et al. (2018)).⁵ On the basis of these studies, HERC concluded that transoral incisionless fundoplication (TIF) performed with the EsophyX device appears to improve GERD-related quality of life and reduces/eliminates the need for chronic PPI therapy, although the durability of this improvement beyond 3-years was uncertain. Evidence was judged insufficient to suggest that TIF reduces the rate of incident Barrett’s esophagus or complications of GERD. Investigators ultimately issued a “weak recommendation” for transoral incisionless fundoplication (TIF) on the basis of “low-certainty” evidence. A “weak recommendation” signifies that the therapy’s desirable effects “probably outweigh the undesirable effects...but [that] further research or additional information could lead to a different conclusion.” HERC also issued “strong recommendation” against repeat TIF for patients who have recurrent symptoms or fail the initial TIF procedure.
- In 2018, McCarty and colleagues conducted a systematic review and meta-analysis evaluating the safety and efficacy of TIF for the treatment of GERD.⁶ Independent investigators systematically searched the literature through March 2017, identified eligible studies, assessed study quality, extracted data and pooled results. Outcomes of interest included immediate technical success rate and serious adverse events. Symptomatic improvement was measured using GERD Health-related quality of life (HRQL), gastroesophageal reflux symptom score (GERSS), and Reflux Symptom Index (RSI). Objective success was determined by hiatal hernia reduction and pH monitoring. Mean follow-up time was 15.8 months.

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

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Randomized Controlled Trials (RCTs)

- In 2018, Trad and colleagues reported findings at 5-year follow-up for GERD patients who had been treated with transoral incisionless fundoplication (TIF).⁸ In total, data were reported for 44 of the initial 63 chronic GERD sufferers with symptoms refractory to proton pump inhibitor (PPI) therapy. At 5-year follow-up, troublesome regurgitation was eliminated in 80 percent of patients and GERD Health-related quality-of-life improved significantly. No serious adverse events reported. Limitations included the study’s small sample size, lack of comparator groups, and high attrition rate (30%). Moreover, 34% of patients assessed at 5-year follow-up continued to use daily PPI therapy, which undermines conclusions regarding the stand-alone efficacy of TIF.
- The evidence review identified four additional RCTs evaluating the Stretta or EsophyX endoscopic devices for treating GERD.⁹⁻¹³ All RCTs were included in the Hayes systematic review described above; therefore, they will not be summarized here.

CLINICAL PRACTICE GUIDELINES

American College of Gastroenterology (ACG)

The 2013 ACG evidence-based guidelines for the diagnosis and management of gastroesophageal reflux disease stated, “(t)he usage of current endoscopic therapy or transoral incisionless fundoplication cannot be recommended as an alternative to medical or traditional surgical therapy. (Strong recommendation, moderate level of evidence)”¹⁴

National Institute for Health and Care Excellence (NICE)

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

“The evidence on the safety of endoscopic radiofrequency ablation for gastro-oesophageal reflux disease (GORD) is adequate in the short and medium term but there is uncertainty about longer-term outcomes. With regard to efficacy, there is evidence of symptomatic relief but objective evidence on reduction of reflux is inconclusive. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.”¹⁵

The 2011 evidence-based NICE guideline for endoluminal gastroplication (e.g., EsophyX™) for gastroesophageal reflux disease stated the following:

“The evidence on endoluminal gastroplication for gastro-oesophageal reflux disease (GORD) raises no major safety concerns. Evidence from a number of randomized controlled trials (RCTs) shows a degree of efficacy in terms of reduced medication requirement in the short term, but changes in other efficacy outcomes are inconsistent and there is no good evidence of sustained

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improvement in oesophageal pH measurements. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.”¹⁶

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

“There is limited evidence of short-term efficacy on endoscopic augmentation of the lower oesophageal sphincter using hydrogel implants for the treatment of gastro-oesophageal reflux disease (GORD). This evidence also raises concerns about the procedure's safety. Therefore, this procedure should not be used without special arrangements for consent and for audit.”¹⁷

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

“Current evidence on the safety and efficacy of endoscopic injection of bulking agents for gastro-oesophageal reflux disease does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.”¹⁸

Society of American Gastrointestinal Endoscopic Surgeons (SAGES)

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

“Based on existing evidence, TIF can be performed with an acceptable safety risk in appropriately selected patients. The procedure leads to better control of GERD symptoms compared with PPI treatment in the short term (6 months), but appears to lose effectiveness during longer term follow-up and is associated with moderate patient satisfaction scores. Objective GERD measures improve similarly after TIF 2.0 compared with PPI. No comparative, controlled trials exist between TIF and surgical fundoplication, but preliminary evidence suggests that the latter can be used safely after TIF failure. (Level of evidence +++, strong recommendation)”¹⁹

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

“Based on existing evidence, Stretta significantly improves health related quality of life score, heartburn scores, the incidence of esophagitis, and esophageal acid exposure in patients with GERD, but does not increase lower esophageal sphincter basal pressure. In addition, it decreases the use of PPI by approximately 50%. The effectiveness of the procedure diminishes some over time, but persistent effects have been described up to 10 years after the procedure in appropriately selected patients with GERD. Stretta is more effective than PPI, but less so than

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fundoplication. Stretta is safe in adults and has a short learning curve. (Level of evidence +++, strong recommendation)¹⁹

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

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

American Society of General Surgeons (ASGS)

The ASGS released a positions statement on transoral fundoplication stating, “the ASGS supports the use of transoral fundoplication by trained General Surgeons for the treatment of symptomatic chronic gastroesophageal reflux disease (GERD) in patients who fail to achieve satisfactory response to a standard dose of Proton Pump Inhibitor (PPI) therapy or for those who wish to avoid the need for a lifetime of medication dependence.”²⁰ However, the validity of this recommendation is questionable as it is not based on a systematic review of the evidence.

American Gastroenterological Association (AGA)

In 2016, AGA released a technology coverage statement on minimally invasive surgical options for gastroesophageal reflux disease.²¹ The authors recommended transoral fundoplication in patients not responding to PPI therapy who have documented evidence of GERD or esophagitis. However, the reliability of this recommendation is limited as this is a position statement not based on a systematic review and appraisal of the available evidence.

POLICY SUMMARY

Evidence is insufficient to support the safety and efficacy of endoscopic treatments for GERD. Although available randomized controlled trials support the short-term clinical utility (within 2 years) of these treatments, longer-term (5 years or more) high quality randomized controlled trials are required to support medical necessity. To date, no evidence-based clinical practice guidelines have recommended the use of endoscopic therapies for GERD.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed

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annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

U.S. Food and Drug Administration (FDA)

Devices for the endoscopic treatment of gastroesophageal reflux disease have been approved by the FDA as class II devices under the 510(k) premarket notification process or as class III devices under the premarket approval (PMA) process. Additional information is available by searching the FDA 510(k) or PMA database for product code GEI.

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

Device Name and Manufacturer	Indications for Use
Stretta® by Mederi® ²²	Intended for general use in the electrosurgical coagulation of tissue and intended for use specifically in the treatment of Gastroesophageal Reflux Disease (GERD).
EsophyX™ by EndoGastric Solutions (EGS) ²³	The EndoGastric Solutions (EGS) EsophyX™ System with SerosaFuse™ Fastener is indicated for use in endoluminal, transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia < 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease.
EndoCinch™ Suturing System by Bard® ²⁴	For endoscopic placement of suture(s) in the soft tissue of the esophagus and stomach and for approximation of tissue for the treatment of symptomatic gastroesophageal reflux disease.
Medigus™ Ultrasonic Surgical Endostapler (MUSE™) System ²⁵	The Medigus Ultrasonic Surgical Endostapler (MUSE™) System is intended for endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach in order to create anterior partial fundoplication for treatment of symptomatic chronic Gastro Esophageal Reflux Disease in patients who require and respond to pharmacological therapy.

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Durasphere™ by Advanced UroScience, Inc.	<ul style="list-style-type: none"> • Durasphere is indicated for use in the treatment of adult women with stress urinary incontinence (SIU) due to intrinsic sphincter deficiency (ISD). • There is no FDA indication for the treatment of GERD.
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Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

MEDICAL POLICY CROSS REFERENCES

- Peroral Endoscopic Myotomy (POEM), SUR407
- Gastroesophageal Reflux Disease: Magnetic Esophageal Ring, SUR229

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