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Preauthorization	No	Review Dates: 03/07, 05/08, 05/09, 03/10, 01/11, 01/12, 01/13, 01/14, 01/15, 01/16, 01/17, 01/18, 01/19, 01/20	

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With gastroesophageal reflux disease and hiatal hernia two cm or less that is not controlled by proton pump inhibitors 	Interventions of interest are: <ul style="list-style-type: none"> Transoral incisionless fundoplication (e.g., EsophyX) 	Comparators of interest are: <ul style="list-style-type: none"> Laparoscopic fundoplication 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Change in disease status Quality of life Medication use Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> With gastroesophageal reflux disease and hiatal hernia two cm or less that is controlled by proton pump inhibitors 	Interventions of interest are: <ul style="list-style-type: none"> Transoral incisionless fundoplication (e.g., EsophyX) 	Comparators of interest are: <ul style="list-style-type: none"> Proton pump inhibitor therapy 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Change in disease status Quality of life Medication use Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> With gastroesophageal reflux disease 	Interventions of interest are: <ul style="list-style-type: none"> Endoscopic radiofrequency energy (e.g., Stretta) 	Comparators of interest are: <ul style="list-style-type: none"> Proton pump inhibitor therapy Laparoscopic fundoplication 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Change in disease status Quality of life Medication use Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> With gastroesophageal reflux disease 	Interventions of interest are: <ul style="list-style-type: none"> Esophageal bulking agents 	Comparators of interest are: <ul style="list-style-type: none"> Proton pump inhibitor therapy Laparoscopic fundoplication 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Change in disease status Quality of life Medication use Treatment-related morbidity

DESCRIPTION

Transesophageal endoscopic therapies are being developed for the treatment of gastroesophageal reflux disease (GERD). A variety of procedures are being evaluated, including transesophageal (or transoral) incisionless

fundoplication (TIF), application of radiofrequency energy, and injection/implantation of prosthetic devices or bulking agents.

SUMMARY OF EVIDENCE

For individuals who have GERD and a hiatal hernia of 2 cm or less that is not controlled by proton pump inhibitors (PPIs) who receive TIF (e.g., EsophyX), the evidence includes two randomized controlled trials (RCTs) comparing TIF with PPI therapy, nonrandomized studies comparing TIF with fundoplication, and case series with longer term follow-up. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The highest quality RCT (RESPECT) was sham-controlled that compared TIF with PPI therapy while the other RCT (TEMPO) compared TIF with maximum PPI therapy. Both trials found a significant benefit of TIF on the primary outcome measure in about 65% of patients. The sham-controlled trial reported improvement in 45% of the sham-controlled group and no benefit on secondary subjective outcome measures. The nonblinded RCT found significant improvements in subjective measures but no difference in objective outcome measures compared with PPI therapy. Together, these trial results would suggest a strong placebo effect of the surgery and a modest benefit of TIF in patients whose symptoms were not controlled by PPIs. For these patients, the most appropriate comparator would be laparoscopic fundoplication. Studies comparing TIF with fundoplication have limitations that include earlier TIF procedures and unbalanced groups at baseline and are inadequate to determine relative efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have GERD and a hiatal hernia of 2 cm or less that is controlled by PPIs who receive TIF (e.g., EsophyX), the evidence includes two RCTs and observational studies with longer term follow-up. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. A sham-controlled trial found that the time to resume PPI therapy was longer following TIF and the remission rate was higher, indicating that TIF is more effective than no therapy. The nonblinded RCT found a benefit of TIF compared with continued PPI therapy for subjective measures, but not for the objective measures of pH normalization and esophagitis. These results raise questions about a possible placebo effect for the procedure. Also, observational studies have indicated a loss of treatment effectiveness over time. Adverse events associated with the procedure (e.g., perforation) may be severe. At present, the available evidence does not support the use of this intervention in patients whose symptoms are adequately controlled by medical therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have GERD who receive endoscopic radiofrequency energy (e.g., Stretta), the evidence includes four small RCTs, a nonrandomized comparative study, and observational studies with longer term follow-up. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The RCTs reported some improvements in symptoms and quality of life following treatment with radiofrequency energy compared with sham controls. However, objective measures of GERD and a meta-analysis of these studies found no significant improvements in outcomes, raising questions about the mechanism of the symptom relief. Symptom relief is reported to be lower than after fundoplication, and reoperations greater. Larger RCTs with longer follow-up, preferably compared with fundoplication, are needed to define the risks and benefits of this procedure better. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have GERD who receive esophageal bulking agents, the evidence includes an RCT and case series. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The RCT for a single product was terminated early due to lack of efficacy, while other products have only case series to support use. High-quality data from large RCTs are needed to compare bulking procedures with both sham controls and with the currently accepted treatments for GERD (i.e., drug therapy,

laparoscopic fundoplication). Well-designed trials should use standardized outcome measures to examine whether subjective improvement (e.g., discontinuation of medication therapy, Gastroesophageal Reflux Disease Health-Related Quality of Life scores) is supported by objective improvement (e.g., esophageal acid exposure). The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

Transoral incisionless fundoplication (i.e., Esophyx®) is considered **investigational** as a treatment of gastroesophageal reflux disease.

Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (i.e., the Stretta® procedure) is considered **investigational** as a treatment of gastroesophageal reflux disease.

Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., polymethylmethacrylate beads, zirconium oxide spheres) is considered **investigational** as a treatment of gastroesophageal reflux disease.

MEDICARE ADVANTAGE

For Medicare Advantage, Transoral incisionless fundoplication (TIF) may be considered **medically necessary** *except* under the following conditions:

1. any patient who has recurrent symptoms or other evidence of failure following a prior TIF.
2. any patient in which a staged procedure is being done, as described as a laparoscopic esophageal or para-esophageal diaphragmatic hernia/opening closure followed by a TIF endoscopically.
3. any patient who has a preoperative hiatal hernia greater than two cm (this is because the FDA label for this device is for GERD associated with hiatal hernia of equal or less than two cm).
4. any GERD patients with BMI >35, esophagitis LA grade >B, Barrett's esophagus > two cm, and presence of achalasia or esophageal ulcer or has not been on an appropriate trial of proton pump inhibitors.

BACKGROUND

GASTROESOPHAGEAL REFLUX DISEASE

Gastroesophageal reflux disease (GERD) is a common disorder characterized by heartburn and other symptoms related to reflux of stomach acid into the esophagus. Nearly all individuals experience such symptoms at some point in their lives; a smaller number have chronic symptoms and are at risk for complications of GERD. The prevalence of GERD has been estimated to be 10% to 20% in the Western world, with a lower prevalence in Asia.¹

Pathophysiology

The pathophysiology of GERD involves excessive exposure to stomach acid, which occurs for several reasons. There can be an incompetent barrier between the esophagus and stomach, either due to dysfunction of the lower esophageal sphincter or incompetence of the diaphragm. Another mechanism is abnormally slow clearance of stomach acid. In this situation, delayed clearance leads to an increased reservoir of stomach acid and a greater tendency to reflux.

In addition to troubling symptoms, some patients will have a more serious disease, which results in complications such as erosive esophagitis, dysphagia, Barrett esophagus, and esophageal carcinoma. Pulmonary complications may result from aspiration of stomach acid into the lungs and can include asthma, pulmonary fibrosis, and bronchitis, or symptoms of chronic hoarseness, cough, and sore throat.

Treatment

Guidelines on the management of GERD emphasize initial medical management. Weight loss, smoking cessation, head of the bed elevation, and elimination of food triggers are all recommended in recent practice guidelines.¹ Proton pump inhibitors have been shown to be the most effective medical treatment. In a Cochrane systematic review, van Pinxteren et al (2010) reported that proton pump inhibitors demonstrated superiority to H2-receptor agonists and prokinetics in both network meta-analyses and direct comparisons.²

Surgical Treatment

The most common surgical procedure used for GERD is laparoscopic Nissen fundoplication. Fundoplication involves wrapping a portion of the gastric fundus around the distal esophagus to increase lower esophageal sphincter pressure. If a hiatal hernia is present, the procedure also restores the position of the lower esophageal sphincter to the correct location. Laparoscopic fundoplication was introduced in 1991 and has been rapidly adopted because it avoids complications associated with an open procedure.

Although 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).

Other Treatment Options

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. This type of procedure may be considered natural orifice transluminal surgery. Three types of procedures have been investigated.

1. Transesophageal endoscopic gastroplasty (gastropliation, transoral incisionless fundoplication) can be performed as an outpatient procedure. During this procedure, the fundus of the stomach is folded and then held in place with staples or fasteners that are deployed by the device. The endoscopic procedure is designed to recreate a valve and barrier to reflux.
2. Radiofrequency energy has been used to produce submucosal thermal lesions at the gastroesophageal junction. (This technique has also been referred to as the Stretta procedure.) Specifically, radiofrequency energy is applied through four electrodes inserted into the esophageal wall at multiple sites both above and below the squamocolumnar junction. The mechanism of action of the thermal lesions is not precisely known but may be related to ablation of the nerve pathways responsible for sphincter relaxation or may induce a tissue-tightening effect related to heat-induced collagen contraction and fibrosis.
3. Submucosal injection or implantation of a prosthetic or bulking agent to enhance the volume of the lower esophageal sphincter has also been investigated.

One bulking agent, pyrolytic carbon-coated zirconium oxide spheres (Durasphere), is being evaluated. The Gatekeeper™ Reflux Repair System (Medtronic) uses a soft, pliable, expandable prosthesis made of a polyacrylonitrile-based hydrogel. The prosthesis is implanted into the esophageal submucosa, and with time, the prosthesis absorbs water and expands, creating bulk in the region of implantation. U.S. Food and Drug Administration (FDA) product code: DQX. Endoscopic submucosal implantation of polymethylmethacrylate beads into the lower esophageal folds has also been investigated.

The Agency for Healthcare Research and Quality published a systematic review of management strategies for GERD in 2005, which was updated by Ip et al (2011).^{3,4} The 2005 comparative effectiveness review evaluated studies on the EndoCinch Suturing System, Stretta, Enteryx, and the NDO Plicator.³ The 2011 update excluded Enteryx and the NDO Plicator, because they were no longer available in the United States, and added the EsophyX procedure (endoscopic fundoplication), which was commercialized after the 2005 review.⁴ The 2011 report concluded that, for the three available endoscopic procedures (EndoCinch, Stretta, EsophyX), effectiveness remained substantially uncertain for the long-term management of GERD. All procedures have been associated with complications, including dysphagia, infection/fever, and bloating, although bloating and dysphagia are also adverse events of laparoscopic fundoplication.⁵ A review of endoscopic treatment of GERD by Hummel and Richards (2015) noted that EndoCinch is no longer manufactured.⁶

REGULATORY STATUS

In 2007, EsophyX[®] (EndoGastric Solutions) was cleared for marketing by FDA through the 510(k) process for full-thickness plication. In 2016, EsophyX[®] Z Device with SerosaFuse Fasteners was cleared for marketing by FDA through the 510(k) process (K160960) for use in transoral tissue approximation, full-thickness plication, ligation in the gastrointestinal tract, narrowing the gastroesophageal junction, and reduction of hiatal hernias of 2 cm or less in patients with symptomatic chronic GERD.⁷ In June 2017, EsophyX2 HD and the third-generation EsophyX Z Devices with SerosaFuse fasteners and accessories were cleared for marketing by FDA through the 510(k) process (K171307) for expanded indications, including patients who require and respond to pharmacologic therapy and patients with hiatal hernias larger than 2 cm when a laparoscopic hiatal hernia repair reduces a hernia to 2 cm or less.⁸ FDA product code: ODE.

The Medigus SRS Endoscopic Stapling System (MUSE, Medigus) was cleared for marketing by FDA through the 510(k) process in 2012 (K120299) and 2014 (K132151). MUSE 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. FDA product code: ODE.

In 2000, the CSM Stretta[®] System was cleared for marketing by FDA through the 510(k) process for general use in the electrosurgical coagulation of tissue and was specifically intended for use in the treatment of GERD. Stretta[®] is currently manufactured by Mederi Therapeutics. FDA product code: GEI.

Durasphere[®] is a bulking agent approved for treatment of urinary and fecal incontinence (see the Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence Protocol). Use of this product for esophageal reflux would be considered off-label use. The website of Carbon Medical Technologies states that the Durasphere[®] GR product is “intended to treat problems associated with GERD” but is considered an investigational device in the United States.

RELATED PROTOCOLS

Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary

Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

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