Introduction

GERD — gastroesophageal reflux disease — is a long-term medical condition. It’s a digestive problem that affects the ring of muscles between the esophagus (the tube that carries swallowed food to the stomach) and the stomach. When food is swallowed, the muscles at the end of the esophagus open so food can pass into the stomach. The muscles then close to prevent acid and stomach contents from backing up into the esophagus. In GERD, however, the ring of muscles is too weak, and acid can leak back up into the esophagus. GERD is usually treated with changes to lifestyle and diet, or medications, or in some cases a surgery called fundoplication. A number of other treatments have been studied. These include a procedure that is done through the mouth that wraps the upper part of the stomach around the esophagus, the use of radiofrequency energy to try to improve the barrier between the stomach and the esophagus, and the placement of implants or fillers in the esophagus. These procedures are investigational (unproven). More studies are needed to determine if they are as effective as other standard treatments.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transoral incisionless fundoplication (TIF)</td>
<td>Transoral incisionless fundoplication (TIF) (ie, Esophyx®) is considered investigational as a treatment of gastroesophageal reflux disease.</td>
</tr>
<tr>
<td>Transesophageal radiofrequency</td>
<td>Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (ie, Stretta® procedure) is considered investigational as a treatment of gastroesophageal reflux disease.</td>
</tr>
<tr>
<td>Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent</td>
<td>Endoscopic submucosal implantation of a prosthesis (ie, Gatekeeper™ Reflux Repair System) or injection of a bulking agent (eg, polymethylmethacrylate beads [PMMA], zirconium oxide spheres [ie, Durasphere®]) is considered investigational as a treatment of gastroesophageal reflux disease.</td>
</tr>
</tbody>
</table>

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>43201</td>
<td>Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance</td>
</tr>
<tr>
<td>43210</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; with esophagogastroduodenostomy, partial or complete, includes duodenoscopy when performed</td>
</tr>
<tr>
<td>43236</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance</td>
</tr>
<tr>
<td>43257</td>
<td>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</td>
</tr>
<tr>
<td>43499</td>
<td>Unlisted procedure, esophagus</td>
</tr>
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</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).
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.

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 of the esophagus 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 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, elevating the head of the bed, 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 (gastroplication, 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 4 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). The 2005 comparative effectiveness review evaluated studies on the EndoCinch Suturing System, Stretta, Enteryx, and the NDO Plicator. 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. The 2011 report concluded that, for the 3 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. A review of endoscopic treatment of GERD by Hummel and Richards (2015) noted that EndoCinch is no longer manufactured. 
Summary of Evidence

For individuals with GERD and hiatal hernia of 2 cm or less that is not controlled by PPIs who receive TIF (eg, Esophyx), the evidence includes 2 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 when 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 with GERD and a hiatal hernia of 2 cm or less that is controlled by PPIs who receive TIF (eg, Esophyx), the evidence includes 2 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 (eg, 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 with GERD who receive endoscopic radiofrequency energy (eg, Stretta), the evidence includes 4 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 report improvements in symptoms and quality of life following treatment with RF 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 with 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 (ie, drug therapy, laparoscopic fundoplication). Well-designed trials should use standardized outcome measures to examine whether subjective improvement (eg, discontinuation of medication therapy, GERD–HRQL scores) is supported by objective improvement (eg, esophageal acid exposure). The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td></td>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
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<tr>
<td>NCT01118585(^a)</td>
<td>Prospective Outcome Evaluation of Transoral Incisionless Fundoplication (TIF) for the Treatment of Gastroesophageal Reflux Disease (GERD): The TIF Registry Study</td>
<td>500</td>
<td>Dec 2017 (ongoing)</td>
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<tr>
<td>NCT01682265</td>
<td>Stretta in Reflux Uncontrolled by Intake of Inhibitors of Protons Pump (IPP)-The SIRUP Trial-Multicentric, Randomized, Double Blind, Prospective Study</td>
<td>60</td>
<td>May 2019</td>
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<tr>
<td>NCT02366169(^a)</td>
<td>A Worldwide Post-Market Surveillance Registry to Assess the</td>
<td>200</td>
<td>Dec 2019</td>
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<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
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<tr>
<td>Medigus Ultrasonic Surgical Endostapler (MUSE™) System for the Treatment of GERD</td>
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<td></td>
<td></td>
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<tr>
<td>Unpublished</td>
<td></td>
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<tr>
<td>NCT02211105</td>
<td>Laparoscopic Nissen Fundoplication (LNF) Surgery Versus Transoral Incisionless Fundoplication (TIF): Anti- Reflux Treatment Registry</td>
<td>46</td>
<td>Apr 2017 (terminated)</td>
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<tr>
<td>NCT01110811*</td>
<td>A Randomized Controlled Trial Comparing Transoral Incisionless Fundoplication (TIF) Using EsophyX With Sham Procedure for the Treatment of PPI Dependent GERD: the TIF vs. Sham Study</td>
<td>60</td>
<td>Mar 2017 (unknown)</td>
</tr>
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</table>

NCT: national clinical trial
* Denotes industry-sponsored or cosponsored trial

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2015 Input

In response to requests for clinical input on transesophageal radiofrequency (Stretta) as a treatment of gastroesophageal reflux disease (GERD), input was received from 1 physician specialty society (2 reviewers) and 3 academic medical centers while this policy was under review for 2015. Input was mixed on the treatment of GERD with transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (ie, Stretta). Potential conflicts of interest were noted by 2 reviewers.
2011 Input

In response to requests for clinical input on transoral incisionless fundoplication (TIF) using EsophyX®, input was received from 2 physician specialty societies and 4 academic medical centers while this policy was under review in 2011. Reviewers agreed that TIF differed sufficiently from laparoscopic Nissen fundoplication to warrant evaluation as a separate procedure. Reviewers considered TIF (ie, EsophyX®) to be investigational for the treatment of GERD.

Practice Guidelines and Position Statements

American Society for Gastrointestinal Endoscopy

The American Society for Gastrointestinal Endoscopy (2015) published guidelines on endoscopic procedures for GERD.37 In its review of the EsophyX and Stretta procedures, the Society noted some positive findings but discrepancies between subjective and objective outcome measures or a lack of objective outcome measures in reported trials, concluding that these techniques represent “potentially new therapeutic indications for GI endoscopy,” but that prospective trials using objective measures of GERD as the primary end point could be useful in defining the clinical role of these procedures.

American College of Gastroenterology

Updated guidelines released by the American College of Gastroenterology (2013) indicated the use of current endoscopic therapy or transoral incisionless fundoplication (TIF) could not be recommended as an alternative to medical or traditional surgical therapy (Conditional recommendation, moderate level of evidence).1 The guidelines also cited limited data on small numbers of subjects and short duration of follow-up.

Society of American Gastrointestinal and Endoscopic Surgeons

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES; 2017) updated its evidence-based guidelines on endoluminal treatments for GERD.38 SAGES gave a strong recommendation based on moderate quality evidence that TIF using EsophyX can be performed with an acceptable safety risk in selected patients. SAGES concluded that EsophyX results in better control of GERD symptoms than proton pump inhibitor (PPI) treatment in the short term.
(6 months), and leads to similar improvement in objective GERD measures compared with PPIs. TIF appears to lose effectiveness during longer term follow-up and is associated with moderate patient satisfaction scores. SAGES found no comparative, controlled trials between TIF and surgical fundoplication, but preliminary evidence suggested that the surgical fundoplication can be used safely after TIF failure.

SAGES gave a strong recommendation based on moderate quality evidence that Stretta is safe for adults and significantly improves health-related quality of life score, heartburn scores, the incidence of esophagitis, and esophageal acid exposure in patients with GERD. Stretta was found more effective than PPI, but less so than fundoplication.

**American Society of General Surgeons**

The American Society of General Surgeons (ASGS; 2011) issued a position statement on transoral fundoplication stating that “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.”

**American Gastroenterological Association**

The American Gastroenterological Association (2016) issued a technology coverage statement on minimally invasive surgical options for GERD. Based on a literature review of 4 randomized controlled trials, a multicenter registry, and case series with longer term follow-up, the Association stated:

...evidence is sufficient to demonstrate sustainable improvement in health outcomes, symptom relief, decrease in PPI utilization and improvement in esophageal pH with transoral fundoplication. The selection criteria for transoral fundoplication includes GERD patients with BMI [body mass index] ≤35, hiatal hernia ≤2 cm, esophagitis LA [Los Angeles classification] grade A or B, Barrett’s esophagus ≤2 cm, and absence of achalasia and esophageal ulcer. This option should be considered in patients not responding to PPI therapy (symptoms of regurgitation) who have documented objective evidence of GERD (pathologic acid exposure on pH testing (both off and on medication) or esophagitis.
National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE; 2013) updated its guidance on endoscopic radiofrequency treatment for GERD, concluding: “The evidence on the safety of endoscopic radiofrequency ablation for gastro-esophageal reflux disease 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…” NICE noted “concern on the part of some specialists about the possibility that symptoms may improve as a result of denervation caused by the procedure; if that were the case then failure to recognize and treat reflux might lead to complications in the long term.”

NICE (2011) issued guidance on endoluminal gastroplication for GERD, concluding that “The evidence on endoluminal gastroplication for gastroesophageal reflux disease raises no major safety concerns. Evidence from a number of RCTs [randomized controlled trials] 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 improvement in esophageal pH measurements.…”

NICE (2004) issued guidance on bulking agents for GERD found that “Current evidence on the safety and efficacy of endoscopic injection of bulking agents for gastro-esophageal reflux disease does not appear adequate for this procedure to be used without special arrangements…. NICE (2016) removed guidance on endoscopic bulking agents/hydrogel implants from guidelines on treatment for “dyspepsia and gastro-esophageal reflux” because the product had been withdrawn by the manufacturer.

Medicare National Coverage

There is no national coverage determination.

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 the 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 hernia of 2 cm or less in patients with
symptomatic chronic GERD. 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 in patients with hiatal hernias larger than 2 cm when a
laparoscopic hiatal hernia repair reduces a hernia to 2 cm or less. FDA 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 is 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
Related Policies). 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.

References

   Gastroenterol. Mar 2013;108(3):308-328; quiz 329. PMID 23419381
2. van Pinxteren B, Sigterman KE, Bonis P, et al. Short-term treatment with proton pump inhibitors, H2-receptor antagonists and
   prokinetics for gastro-oesophageal reflux disease-like symptoms and endoscopy negative reflux disease. Cochrane Database


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/18/01</td>
<td>Add to Medicine Section - New Policy</td>
</tr>
<tr>
<td>01/08/02</td>
<td>Replace Policy - Updated with new references; policy statement expanded.</td>
</tr>
<tr>
<td>11/12/02</td>
<td>Replace Policy - Policy updated using 2002 TEC Assessment; policy statement unchanged.</td>
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<tr>
<td>05/13/03</td>
<td>Replace Policy - CPT codes updated.</td>
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<tr>
<td>01/01/04</td>
<td>Replace Policy - CPT code updates only.</td>
</tr>
<tr>
<td>05/11/04</td>
<td>Replace Policy - Policy updated with reference to 2003 Assessment; policy statement amended to include ENTERYX procedure as investigational. New CPT code added. Title changed.</td>
</tr>
<tr>
<td>07/13/04</td>
<td>Replace Policy - Policy updated with literature search; references added; policy statement unchanged.</td>
</tr>
<tr>
<td>02/08/05</td>
<td>Replace Policy - Policy updated with new CPT category I code for Stretta added and category III code deletion; policy statement unchanged.</td>
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<tr>
<td>03/22/06</td>
<td>Code update - HCPCs code removed only, no other changes.</td>
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<tr>
<td>05/09/06</td>
<td>Replace Policy - Policy updated with literature and research; references added; policy statement enhanced</td>
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<tr>
<td>06/16/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
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<tr>
<td>09/12/06</td>
<td>Replace Policy - Policy updated with information on Plicator procedure, which was incorporated into the benefit statement as an additional investigational treatment; Rationale updated; references added; no actual change in policy statement.</td>
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<tr>
<td>10/9/07</td>
<td>Replace Policy - Policy updated with literature search through April 2007; policy statement unchanged. Another FDA-cleared device (StomaphyX) added to description. References added.</td>
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<td>08/12/08</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. References and code added.</td>
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<td>12/16/08</td>
<td>Code Update - 0133T deleted no other changes.</td>
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<tr>
<td>09/15/09</td>
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<td>01/12/10</td>
<td>Cross Reference Update - No other changes.</td>
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<td>04/13/10</td>
<td>Minor update - No other changes.</td>
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<tr>
<td>10/12/10</td>
<td>Replace Policy - Policy updated with literature review, reference numbers 41-52 added. No change in policy statements.</td>
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<td>10/11/11</td>
<td>Replace Policy – Policy updated with literature review through May 2011; Rationale section revised; policy statements on biocompatible polymer and PMMA beads combined as bulking agents; remains investigational.</td>
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<tr>
<td>02/14/12</td>
<td>Replace Policy – Clinical input reviewed; reference 3 added and references reordered; policy statements unchanged.</td>
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<tr>
<td>08/27/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
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<td>10/18/12</td>
<td>Update Related Policies – Add 7.01.137.</td>
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<tr>
<td>01/29/13</td>
<td>Replace policy. Policy updated with literature review through September 2012; references 15, 19, 26 and 29 added and references reordered; policy statements unchanged. Add Related Policy 2.01.58.</td>
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<tr>
<td>08/15/13</td>
<td>Update Related Policies. Remove deleted policy 2.01.520 and add 2.01.20.</td>
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<tr>
<td>01/21/14</td>
<td>Replace policy. Policy updated with literature review through October 16, 2013; references added and reordered; policy statements unchanged. CPT coding updated; 43212 added to the policy and descriptors updated on others. ICD-9 diagnosis and ICD-10-CM codes removed; policy not adjudicated by diagnoses.</td>
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<td>08/18/14</td>
<td>Update Related Policies. Remove 2.01.20 and 2.01.81 as they were archived.</td>
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<td>12/03/14</td>
<td>Update Related Policies. Add 2.01.91.</td>
</tr>
<tr>
<td>04/24/15</td>
<td>Annual Review. Policy updated with literature review through October 8, 2014; clinical input reviewed; Rationale revised; references 8, 11, and 17 added and some references removed; NDO Plicator, EndoCinch, and Enteryx removed from policy because they are no longer available in the US. Remove ICD-9 and ICD-10 procedure codes; these are not utilized in policy adjudication.</td>
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<tr>
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<td>Annual Review, approved November 8, 2016. Policy updated with literature review through August 2016. References 5-11, 14,17,19,21,28,30 added. No change to policy statements.</td>
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<td>01/01/17</td>
<td>Coding update. Added CPT code 43210, removed 43200, 43212, 43232, and 43266.</td>
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<td>October 2017</td>
<td>new references added. Policy statements unchanged.</td>
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<tr>
<td>02/01/19</td>
<td>Annual Review, approved January 4, 2019. Policy updated with literature review through September 2018; references 10-11, 15, 23, and 30 added; references 42-43 updated. Policy statements unchanged.</td>
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</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with:
- Civil Rights Coordinator - Complaints and Appeals
  PO Box 91102, Seattle, WA 98111
  Toll free 855-332-4535, Fax 425-918-5952. TTY 800-842-5357
  Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at: https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
- U.S. Department of Health and Human Services
  200 Independence Avenue SW, Room S9FF, HHH Building
  Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
  Complaint forms are available at:

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):

يُعَد هذا الإشعار ظهراً حافزًا. قد يحوي هذا الإشعار معلومات مهمة يخصك طبقًا أو مصادرًا في هذا الإشعار. قد تحتاج إلى اتخاذ إجراء في تواريخ محددة للحصول على المعلومات المذكورة.عيداً ناشئًا، حان الوقت أن تعد جزءاً من هذه المعلومات والمعلومات التي تخصك. تفضل بمجرد أن ترى عقدًا في 800-722-1471 (TTY: 800-842-5357)

中文 (Chinese):

本通知有重要的讯息。本通知可能有关於您透过Premera Blue Cross提交的申请或保险的重要讯息。本通知内可能有重要日期，您可能需要在截止日期之前採取行动，以保留您的健康保险或者费用補贴。您有權利免费以您的母语得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)

Italiano (Italian):

Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero essere necessari un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.

Chiamia 800-722-1471 (TTY: 800-842-5357)

037338 (07-2016)
Presenta la información en su idioma. Esta información puede contener información importante para la resolución de alguna cuestión o para mantener su cobertura de salud.

Premera Blue Cross tiene el derecho de obtener esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

ไทย (Thai):
ประกาศนี้มีข้อบ่งชี้สำคัญเกี่ยวกับการขอต่อสัญญาคุ้มครองของบริการสุขภาพของคุณผ่าน Premera Blue Cross และมีข้อกำหนดในการใช้ค่าธรรมเนียมชนิดต่างๆที่การประชุมสุดยอดของบริษัทคุ้มครองสุขภาพนั้นที่มีข้อกำหนดในสิทธิเสรีภาพไม่ได้รับการปฏิบัติ โปรดติดต่อ 800-722-1471 (TTY: 800-842-5357).

Român (Romanian):

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Polski (Polish):
To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie wyników lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utraty polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie prawo do bezpłatnej informacji we własnym języku. Zadzwoncie pod 800-722-1471 (TTY: 800-842-5357).

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde e ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):