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MEDICAL POLICY – 2.01.38

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

BCBSA Ref. Policy: 2.01.38

Effective Date:	Dec. 1, 2017
Last Revised:	Nov. 9, 2017
Replaces:	N/A

RELATED MEDICAL POLICIES:

2.01.91	Peroral Endoscopic Myotomy (POEM) for Treatment of Esophageal Achalasia
7.01.137	Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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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. GERD is usually treated with changes to lifestyle and diet. 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 effective.

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

Service	Investigational
Transoral incisionless fundoplication (TIF)	**Transoral incisionless fundoplication (TIF)(ie, Esophyx®) is considered investigational as a treatment of gastroesophageal reflux disease.**
Transesophageal radiofrequency	**Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (ie, Stretta® procedure) is considered investigational as a treatment of gastroesophageal reflux disease.**
Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent	**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.**

Coding

Code	Description
CPT	
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
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
43499	Unlisted procedure, esophagus

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).

Related Information

N/A

Evidence Review

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 (RF) energy, and injection/implantation of prosthetic devices or bulking agents.

The objective of this evidence review is to determine whether transoral incisionless fundoplication (TIF) using the EsophyX System, application of radiofrequency energy, or injection/implantation of prosthetic devices or bulking agents is an effective treatment for gastroesophageal reflux disease (GERD).

Background

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]

The pathophysiology of GERD involves excessive exposure of the esophagus to stomach acid, which occurs for 1 of 3 reasons. There can be an incompetent barrier between the esophagus and stomach, either due to dysfunction of the lower esophageal sphincter (LES) or incompetence of the diaphragm (eg, a hiatal hernia). Another mechanism is if some stomach acid has refluxed into the esophagus, the normal rhythmic movements within the esophagus that would move that acid back into the stomach are abnormally slow. A third mechanism is

abnormally slow clearance of acid out of the stomach. 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.

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.[37] Proton pump inhibitors (PPIs) have been shown to be the most effective medical treatment. In a Cochrane systematic review, PPIs demonstrated superiority to H2-receptor agonists and prokinetics in both network meta-analyses and direct comparisons.

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 LES pressure. If a hiatal hernia is present, the procedure also restores the position of the LES 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 (eg, dysphagia or gas-bloat syndrome [excessive gastrointestinal gas]). Also, sometimes the laparoscopic procedure needs to be converted to an open procedure.

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. Three types of procedures have been investigated.

1. Transesophageal endoscopic gastroplasty (gastroplication, TIF) is an outpatient procedure. During this procedure, a device is put into the esophagus by way of the mouth and suture(s), staples, or fasteners are placed in the lower esophageal sphincter. The sutures/staples/fasteners are designed to strengthen and lengthen the sphincter to decrease reflux.

2. Radiofrequency (RF) 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, RF 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, Shoreview, MN) 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.

FDA product code: DQX.

Endoscopic submucosal implantation of polymethylmethacrylate beads into the lower esophageal folds has also been investigated.

Summary of Evidence

For individuals who have GERD who receive TIF, the evidence includes 4 small randomized controlled trials (RCTs), registry data, and numerous case series. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The results from these trials are not conclusive. For example, in the largest trial, more patients who underwent TIF with the EsophyX® device achieved short-term symptom relief, and there was a greater decrease in esophageal pH for TIF than for continued proton pump inhibitor (PPI) therapy. However, the mean improvement in symptoms scores did not differ between groups. The benefit appears to decrease over time, and long-term follow-up is not available for most outcomes. In the other trials, there was improvement on some outcomes but little benefit on objective outcomes such as pH measurements. The improvement in subjective symptoms in the absence of an objective benefit suggests a strong placebo effect of surgery compared with continued PPI therapy. One small RCT compared TIF with laparoscopic Nissen fundoplication, and reported no difference in short-term outcomes. Small sample size, substantial loss to follow-up, and short follow-up make conclusions uncertain. In addition, some outcomes (eg, medication use) favored the Nissen group though differences were not statistically significant. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have 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, however, a meta-analysis of these same studies found no significant improvement in outcomes. Nonrandomized studies show maintenance of efficacy at 3 to 10 years, although symptom relief may be lower than after fundoplication, and reoperations greater. Larger RCTs with longer follow-up are needed to better define the risks and benefits of this procedure. 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 1 RCT and case series. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The RCT for 1 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–Health-Related Quality of Life 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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01118585[a]	Prospective Outcome Evaluation of Transoral Incisionless Fundoplication (TIF) for the Treatment of Gastroesophageal Reflux Disease (GERD): The TIF Registry Study	500	Dec 2017 active but not recruiting
NCT01110811[a]	A Randomized Controlled Trial Comparing Transoral	60	Mar 2017 active

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Incisionless Fundoplication (TIF) Using EsophyX With Sham Procedure for the Treatment of PPI Dependent GERD: the TIF vs. Sham Study		but not recruiting
NCT02211105[a]	Laparoscopic Nissen Fundoplication (LNF) Surgery Versus Transoral Incisionless Fundoplication (TIF): Anti-Reflux Treatment Registry	46	Dec 2018 terminated
NCT01682265	Stretta in Reflux Uncontrolled by Intake of Inhibitors of Protons Pump (IPP)-The SIRUP Trial-Multicentric, Randomized, Double Blind, Prospective Study	60	Dec 2018
NCT02366169[a]	A Worldwide Post-Market Surveillance Registry to Assess the Medigus Ultrasonic Surgical Endostapler (MUSE™) System for the Treatment of GERD	200	Dec 2019

NCT: national clinical trial

[a] 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 provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2011 Input

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

2015 Input

In response to requests for clinical input on transesophageal RF (Stretta®) as a treatment of 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 treatment of GERD with transesophageal RF to create submucosal thermal lesions of the gastroesophageal junction (ie, Stretta®). Potential conflicts of interest were noted by 2 reviewers.

Practice Guidelines and Position Statements

American Society for Gastrointestinal Endoscopy

In 2015, the American Society for Gastrointestinal Endoscopy (ASGE) published guidelines on endoscopic procedures for GERD.[36] ASGE gave a number of recommendations based on moderate or high-quality evidence for the endoscopic evaluation of GERD. ASGE suggested, based on low-quality evidence, that antireflux therapy be considered for selected patients with uncomplicated GERD.

American College of Gastroenterology

Updated guidelines released by the American College of Gastroenterology in 2013 state that the usage of current endoscopic therapy or transoral incisionless fundoplication cannot be recommended as an alternative to medical or traditional surgical therapy (Conditional recommendation, moderate level of evidence).[37]

Society of American Gastrointestinal and Endoscopic Surgeons

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) provided evidence-based guidelines on endoluminal treatments for GERD in 2013.[38] SAGES gave a weak recommendation based on low-quality evidence for the EsophyX procedure, stating that long-term data are not yet available and that further studies are required to define optimal techniques and most appropriate patient selection criteria, and to further evaluate device and technique safety. SAGES gave a strong recommendation based on high-quality evidence that Stretta is considered appropriate therapy for patients being treated for GERD who are 18 years of age or older, who have had symptoms of heartburn, regurgitation, or both for 6 months or

more, who have been partially or completely responsive to antisecretory pharmacologic therapy, and who have declined laparoscopic fundoplication. The recommendation was unchanged for Stretta in 2017.

The 2017 SAGES Clinical Spotlight Review: Endoluminal Treatments for Gastroesophageal Reflux Disease (GERD) recommendation:

> 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)

American Society of General Surgeons

The American Society of General Surgeons (ASGS) issued a position statement on transoral fundoplication in 2011 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."[39]

American Gastroenterological Association

The 2008 Medical Position Statement of the American Gastroenterological Association[40] makes no recommendation for or against "the use of currently commercially available endoluminal antireflux procedures in the management of patients with an esophageal syndrome" based on insufficient evidence (Grade Insufficient).

In 2016, the American Gastroenterological Association issued a report entitled Technology Coverage Statement on Minimally Invasive Surgical Options for Gastroesophageal Reflux Disease stating they convened a multidisciplinary workgroup to develop a framework for selected services and procedures related to the diagnosis of GERD since their medical position statement on the management of GERD has not been updated since 2008. It concluded:

The three-year plus 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 ≤ 35, hiatal hernia ≤ 2 cm, esophagitis LA grade A or B, Barrett's esophagus ≤ 2cm, 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. Transoral fundoplication should be covered and reimbursed for appropriate patients who meet the selection criteria as described.

All available randomized controlled trials compared TIF 2.0 with medical treatment (PPI), but no study has compared it with surgical fundoplication.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) of the National Health Service of Great Britain issued updated interventional procedure guidance in 2013 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 for clinical governance, consent and audit or research."[41] The reviewing committee 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 issued guidance in 2011 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. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research."[42]

The 2004 Guidance from NICE 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 for consent and for audit or research."[43]

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Regulatory Status

Esophyx® (EndoGastric Solutions, Redmond, WA) received 510(k) marketing clearance in 2007 for full-thickness plication. In 2016, Esophyx® Z Device with SerosaFus Fasteners was cleared for marketing (K160960) by the FDA through the 510(k) process 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 gastroesophageal reflux disease (GERD).[1] FDA code: ODE.

The Medigus SRS Endoscopic Stapling System (MUSE, Medigus Ltd) received marketing clearance 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.

The CSM Stretta® System received 510(k) marketing clearance from the FDA in 2000 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 (Greenwich, CT). FDA product code: GEI.

Durasphere® is a bulking agent approved for treatment of urinary and fecal incontinence. Use of this product for esophageal reflux would be considered off-label use. The website of Carbon Medical Technologies states that Durasphere GR is an investigational device in the United States "intended to treat problems associated with GERD."

References

1. FDA. 510(k) Summary: EsophyX. 2016; **https://www.accessdata.fda.gov/cdrh_docs/pdf16/K160960.pdf**. Accessed November 2017.
2. Blue Cross and Blue Shield Association Technology Evaluation Center. Transesophageal Endoscopic Treatments for Gastroesophageal Reflux Disease. TEC Assessment. 2003;Volume 18, Tab 20. PMID
3. Ip S, Bonis P, Tatsoni A, et al. Comparative Effectiveness of Management Strategies for Gastroesophageal Reflux Disease. Evidence Report/Technology Assessment No. 1. (Prepared by Tufts-New England Medical Center Evidence-based Practice Center). AHRQ Publication No. 06-EHC003-EF. Rockville, MD: Agency for Healthcare Research and Quality. 2005; Availab le at: **https://effectivehealthcare.ahrq.gov/topics/gerd-2005/research** Accessed November 2017.
4. Ip S, Chung M, Moorthy D, et al. Management strategies for gastroesophageal reflux disease: An update. Comparative effectiveness review No. 29 (Prepared by Tufts Medical Center Evidence-based Practice Center under Contract No. HHSA 290-2007-10055-I.) AHRQ Publication No. 11-EHC049-EF. Rockville, MD: Agency for Healthcare Research and Quality. 2011; Available at: **https://effectivehealthcare.ahrq.gov/topics/gerd/research/** Accessed November 2017.
5. Humphries LA, Hernandez JM, Clark W, et al. Causes of dissatisfaction after laparoscopic fundoplication: the impact of new symptoms, recurrent symptoms, and the patient experience. Surg Endosc. May 2013;27(5):1537-1545. PMID 23508812
6. Hummel K, Richards W. Endoscopic treatment of gastroesophageal reflux disease. Surg Clin North Am. Jun 2015;95(3):653-667. PMID 25965137
7. Blue Cross and Blue Shield Association. Transoral incisionless fundoplication for gastroesophageal reflux disease. Evidence Street Assessment. 2016;(in press).
8. Hunter JG, Kahrilas PJ, Bell RC, et al. Efficacy of transoral fundoplication vs omeprazole for treatment of regurgitation in a randomized controlled trial. Gastroenterology. Feb 2015;148(2):324-333 e325. PMID 25448925
9. Hakansson B, Montgomery M, Cadiere GB, et al. Randomised clinical trial: transoral incisionless fundoplication vs. sham intervention to control chronic GERD. Aliment Pharmacol Ther. Dec 2015;42(11-12):1261-1270. PMID 26463242
10. Witteman BP, Conchillo JM, Rinsma NF, et al. Randomized controlled trial of transoral incisionless fundoplication vs. proton pump inhibitors for treatment of gastroesophageal reflux disease. Am J Gastroenterol. Apr 2015;110(4):531-542. PMID 25823768
11. Trad KS, Barnes WE, Simoni G, et al. Transoral incisionless fundoplication effective in eliminating GERD symptoms in partial responders to proton pump inhibitor therapy at 6 months: the TEMPO Randomized Clinical Trial. Surg Innov. Feb 2015;22(1):26-40. PMID 24756976
12. Sharma P, Katz P. Endoscopic therapies for gastroesophageal reflux disease: back in the game? Gastroenterology. Feb 2015;148(2):280-282. PMID 25527969
13. Trad KS, Simoni G, Barnes WE, et al. Efficacy of transoral fundoplication for treatment of chronic gastroesophageal reflux disease incompletely controlled with high-dose proton-pump inhibitors therapy: a randomized, multicenter, open label, crossover study. BMC Gastroenterol. 2014;14:174. PMID 25284142
14. Svoboda P, Kantorova I, Kozumplik L, et al. Our experience with transoral incisionless plication of gastroesophageal reflux disease: NOTES procedure. Hepatogastroenterology. Jul-Aug 2011;58(109):1208-1213. PMID 21937380
15. Frazzoni M, Conigliaro R, Manta R, et al. Reflux parameters as modified by EsophyX or laparoscopic fundoplication in refractory GERD. Aliment Pharmacol Ther. Jul 2011;34(1):67-75. PMID 21539587
16. Toomey P, Teta A, Patel K, et al. Transoral incisionless fundoplication: is it as safe and efficacious as a Nissen or Toupet fundoplication? Am Surg. Sep 2014;80(9):860-867. PMID 25197871
17. Bell RC, Mavrelis PG, Barnes WE, et al. A prospective multicenter registry of patients with chronic gastroesophageal reflux disease receiving transoral incisionless fundoplication. J Am Coll Surg. Dec 2012;215(6):794-809. PMID 22939637
18. Wilson EB, Barnes WE, Mavrelis PG, et al. The effects of transoral incisionless fundoplication on chronic GERD patients: 12-month prospective multicenter experience. Surg Laparosc Endosc Percutan Tech. Feb 2014;24(1):36-46. PMID 24487156

19. Bell RC, Barnes WE, Carter BJ, et al. Transoral incisionless fundoplication: 2-year results from the prospective multicenter U.S. study. Am Surg. Nov 2014;80(11):1093-1105. PMID 25347499

20. Muls V, Eckardt AJ, Marchese M, et al. Three-year results of a multicenter prospective study of transoral incisionless fundoplication. Surg Innov. Aug 2013;20(4):321-330. PMID 22968006

21. Testoni PA, Testoni S, Mazzoleni G, et al. Long-term efficacy of transoral incisionless fundoplication with Esophyx (Tif 2.0) and factors affecting outcomes in GERD patients followed for up to 6 years: a prospective single-center study. Surg Endosc. Sep 2015;29(9):2770-2780. PMID 25480624

22. Furnee EJ, Broeders JA, Draaisma WA, et al. Laparoscopic Nissen fundoplication after failed EsophyX fundoplication. Br J Surg. Jul 2010;97(7):1051-1055. PMID 20632271

23. Bell RC, Kurian AA, Freeman KD. Laparoscopic anti-reflux revision surgery after transoral incisionless fundoplication is safe and effective. Surg Endosc. Jul 2015;29(7):1746-1752. PMID 25380707

24. Lipka S, Kumar A, Richter JE. No evidence for efficacy of radiofrequency ablation for treatment of gastroesophageal reflux disease: a systematic review and meta-analysis. Clin Gastroenterol Hepatol. Jun 2015;13(6):1058-1067 e1051. PMID 25459556

25. Arts J, Bisschops R, Blondeau K, et al. A double-blind sham-controlled study of the effect of radiofrequency energy on symptoms and distensibility of the gastro-esophageal junction in GERD. Am J Gastroenterol. Feb 2012;107(2):222-230. PMID 22108449

26. Aziz AM, El-Khayat HR, Sadek A, et al. A prospective randomized trial of sham, single-dose Stretta, and double-dose Stretta for the treatment of gastroesophageal reflux disease. Surg Endosc. Apr 2010;24(4):818-825. PMID 19730952

27. Corley DA, Katz P, Wo JM, et al. Improvement of gastroesophageal reflux symptoms after radiofrequency energy: a randomized, sham-controlled trial. Gastroenterology. Sep 2003;125(3):668-676. PMID 12949712

28. Coron E, Sebille V, Cadiot G, et al. Clinical trial: Radiofrequency energy delivery in proton pump inhibitor-dependent gastro-oesophageal reflux disease patients. Aliment Pharmacol Ther. Nov 1 2008;28(9):1147-1158. PMID 18616516

29. Perry KA, Banerjee A, Melvin WS. Radiofrequency energy delivery to the lower esophageal sphincter reduces esophageal acid exposure and improves GERD symptoms: a systematic review and meta-analysis. Surg Laparosc Endosc Percutan Tech. Aug 2012;22(4):283-288. PMID 22874675

30. Liang WT, Yan C, Wang ZG, et al. Early and midterm outcome after laparoscopic fundoplication and a minimally invasive endoscopic procedure in patients with gastroesophageal reflux disease: a prospective observational study. J Laparoendosc Adv Surg Tech A. Aug 2015;25(8):657-661. PMID 26258269

31. Noar M, Squires P, Noar E, et al. Long-term maintenance effect of radiofrequency energy delivery for refractory GERD: a decade later. Surg Endosc. Aug 2014;28(8):2323-2333. PMID 24562599

32. Liang WT, Wang ZG, Wang F, et al. Long-term outcomes of patients with refractory gastroesophageal reflux disease following a minimally invasive endoscopic procedure: a prospective observational study. BMC Gastroenterol. 2014;14:178. PMID 25304252

33. Ganz RA, Fallon E, Wittchow T, et al. A new injectable agent for the treatment of GERD: results of the Durasphere pilot trial. Gastrointest Endosc. Feb 2009;69(2):318-323. PMID 19185691

34. Fockens P, Cohen L, Edmundowicz SA, et al. Prospective randomized controlled trial of an injectable esophageal prosthesis versus a sham procedure for endoscopic treatment of gastroesophageal reflux disease. Surg Endosc. Jun 2010;24(6):1387-1397. PMID 20198491

35. Feretis C, Benakis P, Dimopoulos C, et al. Endoscopic implantation of Plexiglas (PMMA) microspheres for the treatment of GERD. Gastrointest Endosc. Apr 2001;53(4):423-426. PMID 11275880

36. American Society for Gastrointestinal Endoscopy. The role of endoscopy in the management of GERD. Gastrointest Endosc 2015; 81:1305–1310. **http://www.asge.org/clinicalpractice/clinical-practice.aspx?id=352**. Accessed November 2017.

37. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol 2013; 108:308–328. Corrigendum. Am J Gastroenterol 2013; 108(10):1672. **http://gi.org/guideline/diagnosis-and-managemen-of-gastroesophageal-reflux-disease/**. Accessed November 2017.

38. Society of American Gastrointestinal and Endoscopic Surgeons. Endoluminal treatments for gastroesophageal reflux disease (GERD). 2013; **http://www.sages.org/publications/guidelines/endoluminal-treatments-for-gastroesophageal-reflux-disease-gerd/**. Accessed November 2017.

39. Society of American Gastrointestinal and Endoscopic Surgeons. Endoluminal treatments for gastroesophageal reflux disease (GERD). 2017; **http://www.sages.org/publications/guidelines/endoluminal-treatments-for-gastroesophageal-reflux-disease-gerd/**. Accessed November 2017.

40. American Society of General Surgeons (ASGS). Position statement: Transoral fundoplication. 2011; **https://theasgs.org/wp-content/uploads/2016/05/Coverage-of-Transoral-Fundoplication.pdf**. Accessed November 2017.

41. American Gastroenterological Association. Medical position statement on the management of gastroesophageal reflux disease. **http://www.gastrojournal.org/article/S0016-5085(08)01606-5/abstract** Accessed November 2017.

42. American Gastroenterological Association Technology Coverage Statement on Minimally Invasive Surgical Options for Gastroesophageal Reflux Disease 2016 ;. **https://www.gastro.org/about/Technology_Coverage_Minimally_Invasive_GERD_Procedures.pdf**.. Accessed November 2017.

43. National Institute for Health and Care Excellence (NICE). Endoscopic radiofrequency ablation for gastro-oesophageal reflux disease [IPG461]. 2013; **https://www.nice.org.uk/guidance/ipg461**. Accessed November 2017.

44. National Institute for Health and Care Excellence (NICE). Transoral incisionless fundoplication (TIF) in children [IPG404]. 2011; **https://www.nice.org.uk/guidance/ipg404**. Accessed November 2017.

45. National Institute for Health and Care Excellence (NICE). Endoscopic injection of bulking agents for gastro-oesophageal reflux disease [IPG55]. 2004; **https://www.nice.org.uk/guidance/ipg55**. Accessed November 2017.

History

Date	Comments
01/18/01	Add to Medicine Section - New Policy
01/08/02	Replace Policy - Updated with new references; policy statement expanded.
11/12/02	Replace Policy - Policy updated using 2002 TEC Assessment; policy statement unchanged.
05/13/03	Replace Policy - CPT codes updated.
01/01/04	Replace Policy - CPT code updates only.
05/11/04	Replace Policy - Policy updated with reference to 2003 Assessment; policy statement amended to include ENTERYX procedure as investigational. New CPT code added. Title changed.
07/13/04	Replace Policy - Policy updated with literature search; references added; policy statement unchanged.

Date	Comments
02/08/05	Replace Policy - Policy updated with new CPT category I code for Stretta added and category III code deletion; policy statement unchanged.
03/22/06	Code update - HCPCs code removed only, no other changes.
05/09/06	Replace Policy - Policy updated with literature and research; references added; policy statement enhanced
06/16/06	Update Scope and Disclaimer - No other changes.
09/12/06	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.
10/9/07	Replace Policy - Policy updated with literature search through April 2007; policy statement unchanged. Another FDA-cleared device (StomaphyX) added to description. References added.
08/12/08	Replace Policy - Policy updated with literature search; no change to the policy statement. References and code added.
12/16/08	Code Update - 0133T deleted no other changes.
09/15/09	Replace Policy - Policy updated with literature search, no change to policy statement. References added.
01/12/10	Cross Reference Update - No other changes.
04/13/10	Minor update - No other changes.
10/12/10	Replace Policy - Policy updated with literature review, reference numbers 41-52 added. No change in policy statements.
10/11/11	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.
02/14/12	Replace Policy – Clinical input reviewed; reference 3 added and references reordered; policy statements unchanged.
08/27/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
10/18/12	Update Related Policies – Add 7.01.137.
01/29/13	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.
08/15/13	Update Related Policies. Remove deleted policy 2.01.520 and add 2.01.20.
01/21/14	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.

Date	Comments
08/18/14	Update Related Policies. Remove 2.01.20 and 2.01.81 as they were archived.
12/03/14	Update Related Policies. Add 2.01.91.
04/24/15	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.
12/16/15	Update Related Policies. Remove 2.01.58 as it is archived.
12/01/16	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.
01/01/17	Coding update. Added CPT code 43210, removed 43200, 43212, 43232, and 43266.
12/01/17	Annual Review, approved November 9, 2017. Policy updated with literature review through November 2017. Policy statement unchanged. Updated the Practice Guidelines and Position Statements section.

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). ©2017 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.

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Premera:

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Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
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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 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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).

አማሪኛ (Amharic):
ይህ ማስታወቂያ አስፈላጊ መረጃ ይዟል። ይህ ማስታወቂያ ስለ ማመልከቻዎ ወይም የ Premera Blue Cross ሽፋን አስፈላጊ መረጃ ሊኖረው ይችላል። በዚህ ማስታወቂያ ውስጥ ቁልፍ ቀኖች ሊኖሩ ይችላሉ። የጤናን ሽፋንዎን ለመጠበቅና በእከፋፈል እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና ያለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መብት አለዎት።በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

العربية (Arabic):
يحوي هذا الإشعار معلومات هامة. قد يحوي هذا الإشعار معلومات مهمة بخصوص طلبك أو التغطية التي تريد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تواريخ معينة للحفاظ على تغطيتك الصحية أو للمساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بلغتك دون تكبد أية تكلفة. اتصل بـ800-722-1471 (TTY: 800-842-5357)

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

Oromoo (Cushite):
Beeksisni kun odeeffannoo barbaachisaa qaba. Beeksisti kun sagantaa yookan karaa Premera Blue Cross tiin tajaajila keessan ilaalchisee odeeffannoo barbaachisaa qabaachuu danda'a. Guyyaawwan murteessaa ta'an beeksisa kana keessatti ilaalaa. Tarii kaffaltiidhaan deeggaramuuf yookan tajaajila fayyaa keessaniif guyyaa dhumaa irratti wanti raawwattan jiraachuu danda'a. Kaffaltii irraa bilisa haala ta'een afaan keessaniin odeeffannoo argachuu fi deeggarsa argachuuf mirga ni qabaattu. Lakkoofsa bilbilaa 800-722-1471 (TTY: 800-842-5357) tii bilbilaa.

Français (French):
Cet avis a d'importantes informations. Cet avis peut avoir d'importantes informations sur votre demande ou la couverture par l'intermédiaire de Premera Blue Cross. Le présent avis peut contenir des dates clés. Vous devrez peut-être prendre des mesures par certains délais pour maintenir votre couverture de santé ou d'aide avec les coûts. Vous avez le droit d'obtenir cette information et de l'aide dans votre langue à aucun coût. Appelez le 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan ladann. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kèk aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resevwa enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rele nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):
Diese Benachrichtigung enthält wichtige Informationen. Diese Benachrichtigung enthält unter Umständen wichtige Informationen bezüglich Ihres Antrags auf Krankenversicherungsschutz durch Premera Blue Cross. Suchen Sie nach eventuellen wichtigen Terminen in dieser Benachrichtigung. Sie könnten bis zu bestimmten Stichtagen handeln müssen, um Ihren Krankenversicherungsschutz oder Hilfe mit den Kosten zu behalten. Sie haben das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Rufen Sie an unter 800-722-1471 (TTY: 800-842-5357).

Hmoob (Hmong):
Tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb. Tej zaum tsab ntawv tshaj xo no muaj cov ntsiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam los ntawm Premera Blue Cross. Tej zaum muaj cov hnub tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuj yuav tau ua qee yam uas peb kom koj ua tsis pub dhau cov caij nyoog uas teev tseg rau hauv daim ntawv no mas koj thiaj yuav tau txais kev pab cuam kho mob los yog kev pab them tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntshiab lus no uas tau muab sau ua koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

Iloko (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti apliksayonyo wenno coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagsasao nga awan ti bayadanyo. Tumawag iti numero nga 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 esserci date chiave in questo avviso. Potrebbe essere necessario 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. Chiama 800-722-1471 (TTY: 800-842-5357).

日本語 (Japanese):
この通知には重要な情報が含まれています。この通知には、Premera Blue Cross の申請または補償範囲に関する重要な情報が含まれている場合があります。この通知に記載されている可能性がある重要な日付をご確認ください。健康保険や有料サポートを維持するには、特定の期日までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하는 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하는 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

ລາວ (Lao):
ແຈ້ງການນີ້ມີຂໍ້ມູນສຳຄັນ. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສຳຄັນກ່ຽວກັບຄຳຮ້ອງສະໝັກ ຫຼື ຄວາມຄຸ້ມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີສຳຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈຳເປັນຕ້ອງດຳເນີນການຕາມກຳນົດເວລາສະເພາະເພື່ອຮັກສາຄວາມຄຸ້ມຄອງປະກັນສຸຂະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເລື່ອງຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄວ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໂທຫາ 800-722-1471 (TTY: 800-842-5357).

ភាសាខ្មែរ (Khmer):
សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរ៉ាប់រងរបស់អ្នកតាមរយៈ Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ចេញសមត្ថភាព ដល់កំណត់ថ្ងៃជាក់ច្បាស់នានា ដើម្បីនឹងរក្សាទុកការជានាវ៉ាប់រងសុខភាពរបស់អ្នក ឬប្រាក់ជំនួយចេញផ្លែ។ អ្នកមានសិទ្ធិទទួលព័ត៌មាននេះ និងជំនួយនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

ਪੰਜਾਬੀ (Punjabi):
ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਜਿਸ ਜਵਚ ਖਾਸ ਤਾਰੀਖਾ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀ ਜਸਹਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ਼ ਤੋਂ ਪਹਿਲਾਂ ਕੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫ਼ਤ ਵਿੱਚ ਤੇ ਆਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

فارسی (Farsi):
این اعلامیه حاوی اطلاعات مهم میباشد .این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید .شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید .شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کاربران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

Polskie (Polish):
To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócic uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie 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 ou 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).

Română (Romanian):
Prezenta notificare conține informații importante. Această notificare poate conține informații importante privind cererea sau acoperirea asigurării dumneavoastre de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența privitoare la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

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 указаны 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).

Fa'asamoa (Samoan):
Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'amatalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 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 o 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).

Tagalog (Tagalog):
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay maaaring naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับการการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือนี้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

Український (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):
Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).