



## MEDICAL COVERAGE POLICY

**SERVICE:** Transoral Fundoplication

**Policy Number:** 227

**Effective Date:** 03/01/2020

**Last Review:** 01/23/2020

**Next Review Date:** 01/23/2021

### Important note:

Unless otherwise indicated, this policy will apply to all lines of business.

Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

**SERVICE:** Transoral Fundoplication, Transoral Incisionless Fundoplication

**PRIOR AUTHORIZATION:** Not required.

**POLICY:** Transoral fundoplication (EsophyX<sup>®</sup>) may be considered medically necessary **ONLY** for Medicare affiliated lines of business, when the following conditions are met:

- There has been symptomatic chronic gastroesophageal reflux (> 6 months of symptoms), **AND**
- Symptoms must be responsive to Proton Pump Inhibitors (PPIs) as judged by GERD HRQL (Health-related Quality of Life) scores of  $\leq 12$  while on PPIs and  $\geq 20$  when off for 14 days (also acceptable would be the difference of  $\geq 10$  of the scores between off and on therapy), and
- Hiatal hernia, if present, is  $\leq 2$  cm.

**For all other lines of business, transoral fundoplication is considered investigational, experimental and unproven because of a lack of quality medical literature demonstrating consistent long-term benefit.**

### OVERVIEW:

Gastroesophageal reflux disease (GERD) is most commonly treated by medical management. Many patients are treated with empirical therapy, without the use of endoscopy. However some patients require additional study and interventions.

American Society of General Surgeons issued a position paper which states the following: ASGS supports the use of transoral fundoplication by trained General Surgeons for the treatment of symptomatic chronic GERD in patients who fail to achieve satisfactory response to a standard dose of PPI therapy or for those who wish to avoid the need for a life time of medication dependence.

During transoral fundoplication, the surgeon creates an anterior partial fundoplication by attaching the fundus to the anterior and left lateral wall of the distal esophagus slightly above the esophagogastric junction through full thickness placation around the gastroesophageal junction.

### MANDATES:



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### SUPPORTING DATA:

#### CODES:

**Important note:**

*CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.*

CPT Codes:	43210 - Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty
CPT Not Covered:	
ICD10 codes:	K21.0, K21.9
ICD10 Not covered:	

**CMS:** LCD L34999 Transoral Incisionless Fundoplication was retired effective 10/25/2018

#### POLICY HISTORY:

Status	Date	Action
New	01/31/2017	New policy
Review	01/23/2018	No changes
Review	01/15/2019	No changes
Review	01/23/2020	No changes

#### REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Barnes WE, Hoddinott KM, Mundy S, et al. Transoral Incisionless Fundoplication Offers High Patient Satisfaction and Relief of Therapy-Resistant Typical and Atypical Symptoms of GERD in Community Practice. *Surgical Innov.* 2011; 18(2): 119-29.
2. Bell RC, Cadiere GB. Transoral rotational esophagogastric fundoplication: technical, anatomical, and safety consideration. *Surg Endosc.* 2011; 25(7): 2387-99.
3. Bell RC and Freeman KD. Clinical and pH-metric outcomes of transoral esophagogastric fundoplication for the treatment of gastroesophageal reflux disease. *Surg Endosc.* 2011; 25(6): 1975-84.
4. Cadiere GB, Buset M, Muls V, et al. Antireflux Transoral Incisionless Fundoplication using EsophyX: 12 month Results of a Prospective Multicenter Study. *World J Surg.* 2008; 32: 1676-1688.
5. Cadiere GB, Rajan A, Germany O, et al. Endoluminal fundoplication by a transoral device for the treatment of GERD: A feasibility study. *Surg Endosc.* 2008; 22: 333-342.
6. Cadiere GB, van Sante N, Graves JE, et al. Two-year results of a feasibility study on anti-reflux transoral incisionless fundoplication using EsophyX. *Surg Endosc.* 2009; 23: 957-964.
7. DeVault KR and Castell DO. Practice Guidelines: Updated Guidelines for the Diagnosis and Treatment of Gastroesophageal Reflux Disease. *American Journal of Gastroenterology.* 2005; 100: 190-200.
8. Hoppo T, Immauel A, Schuchert M, et al. Transoral Incisionless Fundoplication 2.0 Procedure Using EsophyXTM for Gastroesophageal Reflux Disease. *J Gastrointestinal Surge.* 2010; 14: 1895-1901.



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9. Ihde GM. Unpublished. Short Term Safety and Symptomatic Outcomes of Transoral Incisionless Fundoplication in Patients with Chronic GERD. Submitted to American Journal of Surgery, March 2011. No information of acceptance or publication at this time.
10. Jobe BA, O'Rourke RW, McMahon BP, et al. Transoral Endoscopic Fundoplication in the Treatment of Gastroesophageal Reflux Disease: the anatomic and physiologic basis for reconstruction of the esophagogastric junction using a novel device. *Annals of Surgery*. 2008; 248(1): 69-76.
11. Testoni PA, Corsetti M, DiPietro S, et al. Effectiveness of Transoral Incisionless Fundoplication on Symptoms, PPI Use, and pH Impedance Refluxes of GERD Patients. *World J Surg*. 2010; 34: 750-757.
12. Velanovich V. Endoscopic, endoluminal fundoplication for gastroesophageal reflux disease: Initial experience and lessons learned. *Surgery*. 2010; 148: 646-53.
13. Wittman BP, Conchillo JM, Rinsma NF, Betzel B, Peeters A, Koek GH, Stassen LP, Bouvy ND. Randomized controlled trial of transoral incisionless fundoplication vs. proton pump inhibitors for treatment of gastroesophageal reflux disease. *Am J Gastroenterol*. 2015 Apr;110(4):531-42.
14. Deepanshu Jain, Shashideep S. Transoral Incisionless Fundoplication for Refractory Gastroesophageal Reflux Disease: Where Do We Stand? *Clin Endosc* 2016;49:147-156