



## MEDICAL COVERAGE POLICY

### SERVICE: Transoral Fundoplication

Policy Number:	227
Effective Date:	06/01/2025
Last Review:	05/12/2025
Next Review:	05/12/2026

**Important note:** Unless otherwise indicated, medical policies will apply to all lines of business.

Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.

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

**PRIOR AUTHORIZATION:** Required for Commercial and Self-funded plans. Not required for Medicare and Medicaid.

**POLICY:** Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details.

**Note:** Unless otherwise indicated (see below), this policy will apply to all lines of business.

**For Medicare plans**, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). **Palmetto** [L34434 Upper Gastrointestinal Endoscopy and Visualization](#). If there are no applicable NCD or LCD criteria, use the criteria set forth below.

**Transoral fundoplication (EsophyX®) 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 Medicaid plans**, please confirm coverage as outlined in the [Texas Medicaid Provider Procedures Manual | TMHP](#) (TMPPM). If there are no applicable criteria to guide medical necessity decision making in the TMPPM, use the criteria set forth below.

**BSWHP considers transoral fundoplication investigational, experimental and unproven** because of a lack of quality medical literature demonstrating consistent long-term benefit.

## BACKGROUND:

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



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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 lifetime 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:** None

#### **CODES:**

##### **Important note:**

*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	K21.0x, K21.9
ICD10 Not covered	

#### **POLICY HISTORY:**

Status	Date	Action
New	01/31/2017	New policy
Reviewed	01/23/2018	No changes
Reviewed	01/15/2019	No changes
Reviewed	01/23/2020	No changes
Reviewed	01/28/2021	No changes
Reviewed	01/27/2022	No changes
Reviewed	01/26/2023	No changes
Reviewed	01/02/2024	Formatting changes, added hyperlinks to LCD and TMPPM, beginning and ending note sections updated to align with CMS requirements and business entity changes.
Reviewed	05/12/2025	Ending note sections updated to align with CMS requirements and business entity changes
Updated	08/11/2025	Removed "Medicare NCD or LCD specific InterQual criteria may be used when available."

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## **REFERENCES:**

The following scientific references were utilized in the formulation of this medical policy. BSWHP 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 BSWHP 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, Immanuel A, Schuchert M, et al. Transoral Incisionless Fundoplication 2.0 Procedure Using EsophyXTM for Gastroesophageal Reflux Disease. *J Gastrointestinal Surge.* 2010; 14: 1895-1901.
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. Effective 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



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#### Note:

*Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.*

*RightCare STAR Medicaid is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.*