

**Subject:** Transoral Incisionless Fundoplication (TIF) for Treatment of GERD**Medical Policy #:** 20.12**Original Effective Date:** 04/25/2012**Status:** Reviewed**Last Annual Review Date:** 12/11/2024

## Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans, or the plan may have broader or more limited benefits than those listed in this Medical Policy.

## Description

A transoral incisionless fundoplication (TIF) procedure was developed using the **EsoPHYX** system to mimic anti-reflux surgery, as a minimally invasive alternative procedure with potentially fewer side effects for the treatment of GERD. The TIF procedure reconstructs the anti-reflux barrier and restores the competency of the gastroesophageal junction. The procedure is called a natural orifice surgery since the device is introduced into the body through the mouth, rather than through an abdominal incision.

## Coverage Determination

### Non-covered for Commercial and Medicaid.

PHP follows **MCG A-0205** Transoral (Endoluminal) Gastroplication or Suturing. Transoral incisionless fundoplication (TIF) for treatment of gastroesophageal reflux disease (GERD) is considered experimental and investigation based on insufficient evidence to support the effectiveness of TIF interventions, and the long-term outcomes **therefore is not a covered benefit for Commercial**. Due to contractual restrictions non-contracted providers may not access the MCG website but may obtain a copy of the criteria from the Prior Authorization staff.

### Covered for Medicare only.

**Prior authorization is not required.**

PHP follows (LCD), Endoscopic Treatment of GERD ([L34659](#)), and Policy Article ([A56395](#)), for **Medicare only** on the use of EsophyX™ for treatment of gastroesophageal reflux disease (GERD).

## Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	Description
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed. (For <b>EsoPHYX™</b> )

## Reviewed by / Approval Signatures

**Population Health & Clinical Quality Committee:** Clinton White, MD

**Medical Director:** Jim Romero, MD

**Date Approved:** 12-11-2024

## References

1. **CMS, Local Coverage Determination (LCD):** Endoscopic Treatment of GERD (L34659), Revision Date: 09-29-22, R#13 and related Policy Article (A56395), Revision history date: 09/29/2022, R5. [Cited 11-03-2023]
2. **MCG Health Ambulatory 27<sup>th</sup> Edition,** Transoral (Endoluminal) Gastroplication or Suturing, ACG: A-0205 (AC), Last Update: 09-21-2023. [Cited 11/06/2023]
3. **Aetna®,** Gastroesophageal Reflux Disease (GERD): Treatment Devices, policy number 0213, Last reviewed: 04/25/203, Next Review: 02/22/2024. [Cited 11/06/2023]
4. **United Healthcare,** Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD), Policy Number: Policy Number: 2023T0322GG Effective Date: Oct 1, 2023. [Cited 11/06/2023]
5. **Hayes,** EsophyX System With SerosaFuse Fastener (EndoGastric Solutions) For Endoluminal Repair For Gastroesophageal Reflux Disease (GERD), ARCHIVED Nov 15, 2015. [Cited 10/28/2022]
6. **Hayes,** EsophyX Device (Endogastric Solutions) Versus LINX Reflux Management System (Ethicon) (Product Comparison), Jun 25, 2021, ARCHIVED Jul 25, 2022 [Cited 11/07/2023]
7. **Hayes,** Stretta (Respiratory Technology Corp.) Radiofrequency Treatment for Gastroesophageal Reflux Disease, May 05, 2023. [Cited 11/06/2023]
8. **Hayes,** Health Technology Assessment, Transoral Incisionless Fundoplication 2.0 With EsophyX (EndoGastric Solutions Inc.) for Treatment of Gastroesophageal Reflux, May 09, 2023. [Cited 11/06/2023]
9. **Hayes,** Comparative Effectiveness Review Of Endoscopic Therapy For Gastroesophageal Reflux Disease, Annual review Jan 24, 2022, ARCHIVED Jan 06, 2023. [Cited 11/06/2023]

## Publication History

- 04-25-12 Original effective date
- 01-29-14 Presbyterian Policy Retired
- 01-29-14 Presbyterian now uses Aetna Criteria A-0213.
- 05-22-19 Annual review. Aetna still considers this experimental. No change.
- 11-18-20 Annual review. Reviewed by PHP Medical Policy Committee on 09/16/2020. Removed using Aetna for all LOB who considered TIF experimental. Commercial and Centennial will continue to be non-covered and will follow MCG A-0205. Coverage status changed to allow coverage of TIF treatment only to Medicare members using MCG- L34659R011 or LCD L34659/A56395. Also, MCG and other payers consider EsophyX as experimental & investigational. CPT code 43210 added which will not require PA but will set to not pay for Commercial and Centennial.
- 11-27-21 Annual review. Reviewed by PHP Medical Policy Committee on 10/29/2021. A minor change in LCD (L34659) criteria: The LCD (L34659) expanded coverage indication #3. Additional language was added to "hiatal hernia < or equal to 2 cm" to say, "including where the hernia has been reduced to 2 cm or less by a successful laparoscopic hernia reduction procedure prior to the TIF procedure." PHP will continue to follow LCD (L34659) and LCA (A56395) for Medicare members. No change for non-Medicare: Continue to follow MCG A-0205 as non-coverage for Commercial and Medicaid, since TIF using EsophyX™ for performing surgery is still considered investigational. Continue no PA requirement for code 43210. Previous configuration decision to not pay for commercial and Medicaid will continue.
- 11-16-22 Annual review. Reviewed by PHP Medical Policy Committee on 10/28/2022. No change. Continue to follow MCG (A-0205) as non-covered for commercial and Medicaid, since the use of EsophyX™ is considered investigational and experimental. Continue following LCD (L34659) and LCA (A56395) for Medicare only. The coverage determination guideline language removed from policy and reformatted to only include LCD/LCA weblinks and the description of services. Continue previous configuration to not pay for non-Medicare. Continue no PA requirement. Changed Centennial to Medicaid.
- 12-13-23 Annual review. Reviewed by PHP Medical Policy Committee on 11/08/2023. No change. Continue to follow MCG (A-0205) as non-covered for commercial and Medicaid, since the use of EsophyX™ is considered investigational and experimental. Continue following LCD (L34659) and LCA (A56395) for Medicare only. Continue previous configuration to not pay for non-Medicare. Continue no PA requirement.

*This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.*

*For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: [Click here for Medical Policies](#)*

**Web links:**

*At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.*

*When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.*