Minimally Invasive Procedures for Gastric and Esophageal Diseases

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Last Committee Approval Date: May 8, 2024
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Instructions for Use

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Related Commercial Policy

- Minimally Invasive Procedures for Gastric and Esophageal Diseases

Coverage Rationale

Overview

The following are unproven and not medically necessary for treating Gastroesophageal Reflux Disease (GERD) due to insufficient evidence of efficacy:

- Endoscopic therapies.
- Injection or implantation techniques.
- LINX Reflux Management System.

The per oral endoscopic myotomy (POEM) procedure is proven and medically necessary for Achalasia or Diffuse Esophageal Spasm. Per oral endoscopic myotomy (POEM) is unproven and not medically necessary for all other indications (e.g., Zenker's diverticula) due to insufficient evidence.

Gastric peroral endoscopic myotomy (G-POEM) is unproven and not medically necessary for the treatment of Gastroparesis.

Transoral incisionless fundoplication (TIF) is a transesophageal endoscopic procedure for the treatment of GERD that is covered. Current published peer reviewed literature supports the safety and efficacy of the EsophyX® device used in this procedure.

Endoscopic Procedures for Treatment of Gastroesophageal Reflux Disease (GERD) (Includes Stretta® Procedure, Bard EndoCinch™ Suturing System, and Plicator™ and Enteryx™ Systems)

Medicare does not have an NCD for endoscopic procedures for treatment of gastric reflux (GERD). Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Endoscopic Procedures for Treatment of Gastroesophageal Reflux Disease (GERD) (includes Stretta® Procedure, Bard EndoCinch™ Suturing System, Plicator™ and Enteryx™ Systems).

For states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled Minimally Invasive Procedures for Gastric and Esophageal Diseases.

LINX® Reflux Management System for the Treatment of Gastroesophageal Reflux Disease (GERD)

Medicare does not have an NCD for LINX® reflux management system for the treatment of GERD. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for LINX® Reflux Management System for the Treatment of Gastroesophageal Reflux Disease (GERD).

For states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled Minimally Invasive Procedures for Gastric and Esophageal Diseases.

Per Oral Endoscopic Myotomy (POEM)

Medicare does not have an NCD for per oral endoscopic myotomy. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Per Oral Endoscopic Myotomy (POEM).

For states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled Minimally Invasive Procedures for Gastric and Esophageal Diseases.

Gastric Per Oral Endoscopic Myotomy (G-POEM)

Medicare does not have an NCD for gastric per oral endoscopic myotomy. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Gastric Per Oral Endoscopic Myotomy (G-POEM).

For states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled Minimally Invasive Procedures for Gastric and Esophageal Diseases.

Transoral Incisionless Fundoplication (TIF)

Medicare does not have an NCD for Transoral incisionless fundoplication (TIF). Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Transoral Incisionless Fundoplication (TIF).

For states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled Minimally Invasive Procedures for Gastric and Esophageal Diseases.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service; however, language may be included in the listing below to indicate if a code is non-covered. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed
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
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed (Non-covered)
43289	Unlisted laparoscopy procedure, esophagus
43497	Lower esophageal myotomy, transoral (i.e., peroral endoscopic myotomy [POEM])
43499	Unlisted procedure, esophagus
43999	Unlisted procedure, stomach
49999	Unlisted procedure, abdomen, peritoneum and omentum

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Centers for Medicare and Medicaid Services (CMS) Related Documents

After checking the table below and searching the Medicare Coverage Database, if no NCD, LCD, or LCA is found, refer to the criteria as noted in the Coverage Rationale section above.

NCD	LCD	Article	Contractor Type	Contractor Name
Endoscopic Procedures for Treatment of Gastroesophageal Reflux Disease (GERD) (Includes Stretta® Procedure, Bard EndoCinch™ Suturing System, Plicator™ and Enteryx™ Systems)				
N/A	L34553 Stretta Procedure	A56703 Billing and Coding: Stretta Procedure	Part A MAC	Palmetto**
	L34659 Endoscopic Treatment of GERD	A56395 Billing and Coding: Endoscopic Treatment of GERD	Part A and B MAC	WPS*
	L35080 Select Minimally Invasive GERD Procedures	A56863 Billing and Coding: Select Minimally Invasive GERD Procedures	Part A and B MAC	NGS
	L34434 Upper Gastrointestinal Endoscopy and Visualization	A56389 Billing and Coding: Upper Gastrointestinal Endoscopy and Visualization	Part A and B MAC	Palmetto**
LINX® Reflux Management System for the Treatment of Gastroesophageal Reflux Disease (GERD)				
N/A	L35080 Select Minimally Invasive GERD Procedures	A56863 Billing and Coding: Select Minimally Invasive GERD Procedures	Part A and B MAC	NGS
Per Oral Endoscopic Myotomy (POEM)				
N/A	L38747 Peroral Endoscopic Myotomy (POEM)	A58287 Billing and Coding: Peroral Endoscopic Myotomy (POEM)	Part A and B MAC	Palmetto**
Gastric Per Oral Endoscopic Myotomy (G-POEM)				
N/A	L34434 Upper Gastrointestinal Endoscopy and Visualization	A56389 Billing and Coding: Upper Gastrointestinal Endoscopy and Visualization	Part A and B MAC	Palmetto**
	L34659 Endoscopic Treatment of GERD	A56395 Billing and Coding: Endoscopic Treatment of GERD	Part A and B MAC	WPS*
	L35080 Select Minimally Invasive GERD Procedures	A56863 Billing and Coding: Select Minimally Invasive GERD Procedures	Part A and B MAC	NGS
Transoral Incisionless Fundoplication (TIF)				
N/A	L34434 Upper Gastrointestinal Endoscopy and Visualization	A56389 Billing and Coding: Upper Gastrointestinal Endoscopy and Visualization	Part A and B MAC	Palmetto**
	L34659 Endoscopic Treatment of GERD	A56395 Billing and Coding: Endoscopic Treatment of GERD	Part A and B MAC	WPS*
	L35080 Select Minimally Invasive GERD Procedures	A56863 Billing and Coding: Select Minimally Invasive GERD Procedures	Part A and B MAC	NGS

Medicare Administrative Contractor (MAC) With Corresponding States/Territories	
MAC Name (Abbreviation)	**States/Territories**
CGS Administrators, LLC (CGS)	KY, OH
First Coast Service Options, Inc. (First Coast)	FL, PR, VI
National Government Services, Inc. (NGS)	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian Healthcare Solutions, LLC (Noridian)	AS, AK, AZ, CA, GU, HI, ID, MT, NV, ND, Northern Mariana Islands, OR, SD, UT, WA, WY
Novitas Solutions, Inc. (Novitas)	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX, VA**
Palmetto GBA (Palmetto)	AL, GA, NC, SC, TN, VA**, WV
Wisconsin Physicians Service Insurance Corporation (WPS)*	IA, IN, KS, MI, MO, NE
Notes	
*Wisconsin Physicians Service Insurance Corporation: Contract Number 05901 applies only to WPS Legacy Mutual of Omaha MAC A Providers. **For the state of Virginia: Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction.	

CMS Benefit Policy Manual

Chapter 4; § 180.3 Unlisted Service or Procedure

Clinical Evidence

Refer to the UnitedHealthcare Commercial Medical Policy titled Minimally Invasive Procedures for Gastric and Esophageal Diseases.

U.S. Food and Drug Administration (FDA)

LINX™ Reflux Management System for the Treatment of Gastroesophageal Reflux Disease (GERD)
U.S. Food and Drug Administration (FDA) EndoCinch™
U.S. Food and Drug Administration (FDA) Plicator™
U.S. Food and Drug Administration (FDA) Enteryx®
U.S. Food and Drug Administration (FDA) EsophyX®
U.S. Food and Drug Administration (FDA) SerosaFuse® Fasteners

References

UnitedHealthcare Commercial Medical Policy: Minimally Invasive Procedures for Gastric and Esophageal Diseases.

Policy History/Revision Information

Date	Summary of Changes
10/01/2024	**Centers for Medicare & Medicaid (CMS) Related Documents** • Added notation for the state of Virginia to indicate “Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction”
08/01/2024	**Applicable Codes** • Clarified introduction language
07/01/2024	**Title Change/Template Update** • Previously titled *Minimally Invasive Gastroesophageal Reflux Disease (GERD) Procedures* • Reformatted and reorganized policy; transferred content to new template • Changed policy type classification from “Policy Guideline” to “Medical Policy” • Added *Clinical Evidence, FDA,* and *References* sections • Updated *Instructions for Use*

Date	Summary of Changes

	Related Policies
	• Removed reference link to the UnitedHealthcare Medicare Advantage Coverage Summary titled *Gastroesophageal and Gastrointestinal (GI) Services and Procedures*
	Coverage Rationale
	Overview
	• Revised language to indicate:
	  ○ The following are unproven and not medically necessary for treating gastroesophageal reflux disease (GERD) due to insufficient evidence of efficacy:
	  ▪ Endoscopic therapies
	  ▪ Injection or implantation techniques
	  ▪ LINX Reflux Management System
	  ○ The per oral endoscopic myotomy (POEM) procedure is proven and medically necessary for achalasia or diffuse esophageal spasm
	  ○ Per oral endoscopic myotomy (POEM) is unproven and not medically necessary for all other indications (e.g., Zenker's diverticula) due to insufficient evidence
	  ○ Gastric peroral endoscopic myotomy (G-POEM) is unproven and not medically necessary for the treatment of gastroparesis
	Endoscopic Procedures for Treatment of Gastroesophageal Reflux Disease (GERD) (includes Stretta® Procedure, Bard EndoCinch™ Suturing System, and Plicator™ and Enteryx™ Systems)
	• Revised language to indicate:
	  ○ Medicare does not have a National Coverage Determination (NCD) for endoscopic procedures for treatment of gastric reflux (GERD)
	  ○ Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable; for specific LCDs/LCAs, refer to the table [in the *Centers for Medicare & Medicaid* (*CMS) Related Documents* section of the policy]
	  ○ For states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled *Minimally Invasive Procedures for Gastric and Esophageal Diseases*
	LINX® Reflux Management System for the Treatment of Gastroesophageal Reflux Disease (GERD)
	• Revised language to indicate:
	  ○ Medicare does not have a NCD for LINX® reflux management system for the treatment of GERD
	  ○ LCDs/LCAs exist and compliance with these policies is required where applicable; for specific LCDs/LCAs, refer to the table [in the *CMS Related Documents* section of the policy]
	  ○ For states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled *Minimally Invasive Procedures for Gastric and Esophageal Diseases*
	Per Oral Endoscopic Myotomy (POEM)
	• Added language to indicate:
	  ○ Medicare does not have a NCD for per oral endoscopic myotomy
	  ○ LCDs/LCAs exist and compliance with these policies is required where applicable; for specific LCDs/LCAs, refer to the table [in the *CMS Related Documents* section of the policy]
	  ○ For states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled *Minimally Invasive Procedures for Gastric and Esophageal Diseases*
	Gastric Per Oral Endoscopic Myotomy (G-POEM)
	• Added language to indicate:
	  ○ Medicare does not have a NCD for gastric per oral endoscopic myotomy
	  ○ LCDs/LCAs exist and compliance with these policies is required where applicable; for specific LCDs/LCAs, refer to the table [in the *CMS Related Documents* section of the policy]
	  ○ For states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled *Minimally Invasive Procedures for Gastric and Esophageal Diseases*
	Transoral Incisionless Fundoplication (TIF)
	• Revised language to indicate:
	  ○ Medicare does not have a NCD for transoral incisionless fundoplication (TIF)
	  ○ LCDs/LCAs exist and compliance with these policies is required where applicable; for specific LCDs/LCAs, refer to the table [in the *CMS Related Documents* section of the policy]

Date	Summary of Changes
	○ For states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled *Minimally Invasive Procedures for Gastric and Esophageal Diseases* **Applicable Codes** • Added CPT code 43497 **CMS Related Documents** • Updated list of documents available in the *Medicare Coverage Database* to reflect the most current information • Added list of applicable *Medicare Administrative Contractors (MACs) with Corresponding States/Territories* **Supporting Information** • Archived previous policy version MPG389.05

Instructions for Use

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

- Medical necessity coverage guidelines; including documentation requirements, and/or
- Medicare coding or billing requirements.

Medicare Advantage Policies are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates. This Policy is provided for informational purposes and does not constitute medical advice. It is intended to serve only as a general reference and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes this policy. For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.

Medicare Advantage Policies are developed as needed, are regularly reviewed, and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policies at any time by publishing a new version on this website. Medicare source materials used to develop these policies may include, but are not limited to, CMS statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. The information presented in this Policy is believed to be accurate and current as of the date of publication. Where there is a conflict between this document and Medicare source materials, the Medicare source materials apply. Medicare Advantage Policies are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing certain items or services referenced in this Medical Policy have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, in these circumstances, UnitedHealthcare applies internal coverage criteria as referenced in this Medical Policy. The internal coverage criteria in this Medical Policy was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

You are responsible for submission of accurate claims. Medicare Advantage Policies are intended to ensure that coverage decisions are made accurately. UnitedHealthcare Medicare Advantage Policies use Current Procedural

Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate's requirements need to be followed.