EsophyX® Z+ Reimbursement Guide

DISCLAIMER

The information contained in this reference is presented for information purposes only and does not constitute coding, billing, reimbursement or legal advice. Merit cannot guarantee that this document is complete or without errors, as coding, coverage, and payment are subject to change at any time. Coding listed in this guide represent no statement, promise, or guarantee that these codes will be appropriate or that reimbursement will be made. This coding and reimbursement guide cannot, under any circumstances, be interpreted as, or used in place of, clinical judgment. Any coding and reimbursement decisions and practices are the sole responsibility of the provider and/or designated party responsible for coding and reimbursement.

INDICATION

The EsophyX® Z+ Fastener Delivery Device with SerosaFuse® Fastener and accessories is indicated for use in transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia ≤ 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease. Patients with hiatal hernias larger than 2cm may be included, when a laparoscopic hiatal hernia repair reduces the hernia to 2cm or less.

WARNINGS AND PRECAUTIONS

Significant bleeding may occur in patients with hypertension and/or patients taking platelet function inhibitors or anti-coagulants. Vomiting and/or high physical activity post-TIF® procedure may cause fasteners to break or pull out of tissue. The device is intended to be used only with the 7.5mm SerosaFuse Fastener Cartridge. Ensure that the patient's esophagus is of sufficient dimension to accommodate the EsophyX Z+ device before beginning the procedure. The device is supplied sterile; handle in accordance with sterile device procedures. Do not use if package is damaged. Helical retractor and stylets are sharp. Handle with care. Do not use equipment or items which are not functioning properly. Repeated attempts to use any device component that fails to properly function could damage product and may cause patient injury. Should a malfunction occur, safely remove device under direct visualization. Do not use equipment that is not CE-marked or has not been cleared by the U.S. FDA. Verify the endoscope intended for use is compatible with the device. Compatibility is verified by using the appropriate Endoscope Compatibility Tool prior to insertion (insert the endoscope intended for use through the larger hole present on the compatibility tool; the entire working length of the endoscope should fit comfortably through the larger hole; the endoscope should not be able to fit through the smaller hole present on the compatibility tool). The device contains ferromagnetic metallic components that should be kept away from live voltages and/or protective earth portions of devices as they could present a shock hazard to the patient. Do not use in a Magnetic Resonance environment. This device is MR unsafe. Remove endoscope from device and replace if experiencing a loss of visualization related to endoscopy equipment. The amount of tissue to be approximated and fastened should be carefully chosen to ensure appropriate and suitable plications are achieved. An attempt to approximate too little or too much tissue could result in bleeding, focal necrosis, or plication failure. Helical retractor must be locked and positioned at the black line during device insertion and removal. The tissue mold must be partially or fully closed to advance the helical retractor into the tissue mold from the fully retracted position. The retractor lock only prevents forward motion of the helical retractor. Do not retract the retractor control during device insertion or withdrawal. Visually confirm that helical retractor, stylets, and fastener pushers are retracted and safely stowed in the device prior to insertion and removal; failure to do so could result in device damage and injury to patient anatomy. Always deploy the helical retractor under direct visualization. The tissue mold must be fully opened and unlocked (tactile and audible feedback from the knob ceases) during device insertion and removal. The tissue mold must be fully closed and locked (tactile and audible feedback from the knob ceases) when delivering fasteners. The device is a single use product. Do not re-sterilize. Risk of reuse includes disease transmission from inability to clean all components of the device. To avoid potential biohazard handle and dispose of the device and all associated components after use in accordance with accepted medical practice and applicable local, state, and national / federal laws and regulations. Do not press any endoscope buttons during device removal and during endoscope removal from the device. This device is not intended for use except as indicated. Repetitive use may result in pathophysiological risks and injuries. Ensure the patient is adequately anesthetized and paralyzed prior to starting the TIF procedure. Report any serious incidents and/or product malfunctions to the product manufacturer and the authority which has jurisdiction in the locale.

CONTRAINDICATIONS

Patients with bleeding disorders, strictures, severe esophagitis, esophageal diverticulae, obstructions, paraesophageal hernia, limited neck mobility, osteophytes of the spine, esophageal varices, esophageal infections or fungal disease, esophageal stenosis and any kind of normal or abnormal esophageal anatomy which would not permit insertion of a device of this size, chronic cough, or BMI > 35.

PATIENT SELECTION

Individuals that have GERD with a hiatal hernia ≤ 5 cm and Hill grade II, III, or IV. A hiatal hernia ≤ 5 cm is defined as maximum axial height from end of the esophagus to the diaphragm by any study including upper endoscopy esophagram and/or at time of surgery. Careful deliberation should be given to patients who have had previous anti-reflux surgery or other gastric surgical procedures and the TIF procedure is performed only when the benefits outweigh the risks. When a hiatal hernia repair (HHR) is completed in the same anesthesia setting as a TIF procedure, careful deliberation should be conducted around the results of the HHR. Physicians should note that a combined Hiatal Hernia Repair and TIF 2.0® (cTIF®) procedure can extend anesthesia time over a TIF 2.0 alone procedure by approximately 30 minutes. The exact time is dependent on clinical factors associated with the patient's anatomy and repair technique chosen by the operating physician. The procedural plan should be discussed in detail with the anesthesiologist, surgeon, and gastroenterologist. The procedural time would be clinically comparable to that of laparoscopic fundoplication which has a well-established safety profile. All perioperative risks, both procedural and anesthesia related, should be taken into consideration for each patient and the benefits of performing a cTIF procedure should outweigh the risks.

ESOPHYX Z+ PROCEDURE OVERVIEW

Transoral Incisionless Fundoplication (TIF 2.0®):
Through an endoscopic (transoral) approach, the EsophyX® device is used to perform a series of plications that recreate the dynamics of the Angle of HIS and restore the gastroesophageal valve (GEV). By building the GEV around the EsophyX device, TIF 2.0 provides a reproducible and standardizable fundoplication. The result is a 270-degree omega-shaped valve that is 3-4 cm in length.

Consecutive Transoral Incisionless Fundoplication (cTIF®):
Consists of a Hiatal Hernia Repair (HHR) followed by a Transoral Incisionless Fundoplication (TIF) procedure under a single anesthesia setting.

ICD-10-CM DIAGNOSIS CODES

The ICD-10-CM diagnosis codes listed in this table are not intended to be an exhaustive list of all possible diagnosis codes. Please consult an ICD-10-CM manual for a complete list of diagnosis codes and verify appropriate ICD-10 diagnosis codes, including those for any underlying condition(s).

ICD-10-CM	Description
K21.0	Gastro-esophageal reflux disease with esophagitis
K21.9	Gastro-esophageal reflux disease without esophagitis
K30	Functional dyspepsia
R10.13	Dyspepsia NOS
K44.9	Diaphragmatic hernia without obstruction or gangrene
R12	Heartburn

Source: ICD-10-CM Expert for Physicians and Hospitals, 2025. AAPC. https://www.cdc.gov/nchs/icd/icd-10-cm/index.html

HOSPITAL OUTPATIENT CODING AND PAYMENT

Current Procedural Terminology (CPT) codes are used to describe medical services and procedures provided by physicians; they are also used to report procedures performed in the outpatient facility setting. Physicians and outpatient hospital providers should consider the available coding options and select the appropriate CPT code based on the procedure(s) performed.

CPT Code	Ambulatory Payment Classification (APC)	Description	2025 Medicare National Average Payment	Commercial Payors
43210	5362	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed	$10,411.22	Contractual
43281[1]	5362	Laparoscopic paraesophageal hernia repair, includes fundoplication, when performed	$10,411.22	Contractual
43282[1]	5362	Laparoscopic paraesophageal hernia repair with mesh, includes fundoplication, when performed	$10,411.22	Contractual
49659	5361	Unlisted laparoscopic procedure related to hernia repair, used when no specific code exists for the service provided	$5,834.36	Contractual
C1889[2]	HCPCS	Implantable/insertable device, not otherwise classified *Note: CMS requires C1889 to be reported for HOPD device costs when there is no specific C-code for a device intensive procedure*	Revenue Codes 272, 278	

Source: CMS-1809-FC CY 2025 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule.
1. See warnings, precautions and contraindications 2. CMS requires C1889 to be reported for HOPD device costs when there is no specific C-code for a device intensive procedure.

PROFESSIONAL CODING AND PAYMENT

Surgical Procedures	Work RVUs	CY2025 Non-Facility National Rate	CY 2025 Facility National Rate
43210 - EGD esophagogastric fundoplasty	**7.75**	**$413.06**	**$413.06**
Laparoscopic Procedures			
• 43280 - Laparoscopic fundoplasty	18.10	$1,050.94	$1,050.94
• 43281 - Laparoscopic paraesophageal hernia repair +/- fundoplication	26.60	$1,491.17	$1,491.17
• 43282 - Lap paraesophageal hernia repair w/mesh +/- fundoplication	30.10	$1,680.72	$1,680.72

Source: CY2025 Medicare Physician Fee Schedule, CMS 1807-F. The 2025 MPFS Final Rule Conversion Factor of $32.3465 was used to calculate national payment rates.

CO-SURGEON BILLING[1-3]

The modifier-62 applies when 2 surgeons are required to perform distinct procedures on the same patient during the same operative session.

Best Practice	Examples	
	GI	General Surgeon
Both providers should be using the same diagnosis code(s)	K21.0/K44.9	K44.9/K21.0
Both providers must append modifier 62 on each claim	43281-62	43281-62
Each provider should document medical necessity for 2 surgeons	A consecutive transoral incisionless fundoplication (cTIF) at XX requires 2 surgeons, each with unique skills necessary to maximize the benefits to the patient, minimize OR time and total time under anesthesia. Neither surgeon can complete the other's segment of the procedure.	
Each provider should document the distinct part of the procedure he/she performed including the time it took, and work involved.	Surgeon: *"After the ports were placed, I dissected to mobilize the gastrohepatic ligament using care to protect and preserve the hepatic branch of the vagus nerve."* Gastroenterologist: *"I deployed a total of XX fasteners, satisfactorily contributing to the fundoplasty."*	
Each provider should document the other co-surgeon by name	Surgeon: *"Co-surgeon, Dr. ____, performed the fundoplication portion of the procedure which he/she will dictate separately."* Gastroenterologist: *"Co-surgeon, Dr. ____, preceded my fundoplication procedure with a laparoscopic hiatal hernia repair to reduce the hiatal hernia to __ cm or less."*	

1. Medicare Claims Processing Manual Chapter 12 - Physicians/Nonphysician Practitioners40.8. - Claims for Co-Surgeons and Team Surgeons.
2. Commercial payer requirements may differ. Providers should verify Modifier -62 Co-Surgeon claim guidelines prior to performing the procedure.
3. For information on multiple procedure indicators visit Medicare Physician Fee Schedule Database (MPFSDB) Indicator List.

INPATIENT CODING AND PAYMENT

Possible ICD-10-PCS Procedure Code and MS-DRG Assignments

The MS-DRG assignment will be influenced by the primary and secondary diagnosis codes reported for the stay along with other procedures that may be performed. Medicare will adjust reimbursement according to case severity which for many MS-DRGs consist of a family of 3 codes pertaining to the level of complication or comorbidities seen during the inpatient stay. The secondary diagnosis codes are used to make the determination of severity.

ICD-10-PCS Procedure Code	Description		
0DV48DZ	Restriction of Esophagogastric Junction with Intraluminal Device, Via Natural or Artificial Opening Endoscopic		
Gastroenterology Procedures	**Description**	**FY2025 Medicare National Average**	**Commercial Payors**
MS-DRG 326	Stomach, Esophageal and Duodenal Procedures with MCC	$33,554.46	Contractual
MS-DRG 327	Stomach, Esophageal and Duodenal Procedures with CC	$16,041.27	Contractual
MS-DRG 328	Stomach, Esophageal and Duodenal Procedures w/o CC/MCC	$10,527.47	Contractual

Source: CMS- 1808-F; FY 2025 Hospital IPPS Final Rule.

AMBULATORY SURGICAL CENTER CODING AND PAYMENT

CPT Code	Description	Ambulatory Payment Classification (APC)	2025 Medicare National Average Payment[2]	Commercial Payors
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed	5362	$7,125.55	Contractual
43281	Laparoscopic paraesophageal hernia repair, includes fundoplasty, when performed	5362	n/a	Contractual
43282	Laparoscopic paraesophageal hernia repair, includes fundoplasty, when performed, with mesh	5362	n/a	Contractual
C1889 (HCPCS Code)	Implantable/insertable device, not otherwise classified			Revenue Codes 272, 278

Source: CMS-1809-FC; Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. CY2025 NFRM Addendum B.

MERIT REIMBURSEMENT SUPPORT SERVICES

The TIF Access Program
For Coding, Coverage and Payment Support

Hours: Monday to Friday 9am–6pm EST
Email: Tifaccess@pro-spectus.com
Phone: (833) 274-5070
Fax: (833) 411-1320

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