

## Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

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<b>Approved By:</b>	Highmark Health Options – Market Leadership
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<b>Products:</b>	Medicaid
<b>Application:</b>	All participating hospitals and providers
<b>Page Number(s):</b>	1 of 5

### Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

### POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary transesophageal endoscopic therapies for gastroesophageal reflux disease.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

### DEFINITIONS

**Highmark Health Options (HHO)** – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children's Program (DHCP) and Diamond State Health Plan Plus LTSS (DSHP Plus LTSS) members.

### PROCEDURES

A prior authorization is required.

A variety of transesophageal endoscopic therapies have been developed for the treatment of gastroesophageal reflux disease (GERD). These include suture plication of the proximal gastric folds, injection of bulking agents or implantation of a bioprosthesis into the lower esophageal sphincter implantation of titanium beads with magnetic cores and radiofrequency energy.

The Stretta procedure uses radiofrequency energy to treat GERD and involves insertion of a flexible balloon-tipped catheter with needle electrodes for energy delivery via the esophagus. Precisely controlled radiofrequency energy is delivered to create lesions in the smooth muscle of the gastroesophageal junction.

The following transendoscopic therapies for the treatment of GERD are considered experimental/investigational and therefore noncovered. The long-term efficacy of these procedures has not yet been established.

- Endoscopic/endoluminal gastroplasty, gastroplication with suturing of the esophagogastric junction (e.g., EndoCinch and Muse); and
- Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., polymethylmethacrylate beads, zirconium oxide spheres, Enteryx, Durasphere<sup>®</sup>, Gatekeeper Reflux Repair System).

Transesophageal endoscopic radiofrequency therapy (Stretta), or transoral incisionless fundoplication (TIF) (e.g., StomaphyX, EsophyX) may be considered medically necessary for a select population of individuals, who are greater than or equal to age 18 with refractory GERD, who meet ALL the following criteria:

- Daily heartburn or regurgitation for greater than six (6) months; and
- Unsuccessful or partial response to anti-secretory pharmacologic therapy, have poor proton pump inhibitor (PPI) tolerance, or high concern for long term PPI use; and
- No specific motility disorder; and
- Evidence of reflux disease; and
  - Either have a 24-hour pH study demonstrating pathologic acid reflux (total acid exposure time greater than four (4%) percent), or a DeMeester composite score greater than 14.7; or
  - Have non-erosive reflux disease; or
  - Have grade I and II esophagitis by Savary-Miller criteria or have grades of esophagitis healed by drug therapy.

**CONTRAINDICATIONS**

- Greater than two (2) cm hiatal hernia (unless simultaneous or prior repair of hiatal hernia is performed); or
- Significant dysphagia; or
- Incomplete lower esophageal sphincter relaxation.

Transesophageal endoscopic radiofrequency therapy or transoral incisionless fundoplication not meeting the criteria as indicated in this policy is considered experimental/investigation because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

**SAVARY-MILLER CLASSIFICATION OF REFLUX ESOPHAGITIS**

Grade	Description
Grade 1	Single erosion above gastro-esophageal mucosal junction.
Grade 2	Multiple, noncircumferential erosions above gastro-esophageal mucosal junction.
Grade 3	Circumferential erosion above mucosal junction.
Grade 4	Chronic change with esophageal ulceration and associated stricture.
Grade 5	Barrett's esophagus with histologically confirmed intestinal differentiation within columnar epithelium.

**POST-PAYMENT AUDIT STATEMENT**

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

**PLACE OF SERVICE: INPATIENT/OUTPATIENT**

Experimental/investigational (E/I) services are not covered regardless of place of service.

Transesophageal endoscopic therapies for GERD are typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

**CODING REQUIREMENTS**
**COVERED CODES**

CPT code	Description
43192	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance.
43201	Esophagoscopy, rigid or flexible; with directed submucosal injection(s), any substance.
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed .
43212	Esophagoscopy, flexible, transoral; with placement of endoscopic stent (includes pre-and post-dilation and guide wire passage, when performed.
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance.
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injections of diagnostic or therapeutic substance(s) (e.g., anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis).
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.
43266	Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post- dilation and guide wire passage, when performed).

**COVERED DIAGNOSIS CODES FOR PROCEDURE CODES 43257 AND 43210**

Codes						
K21.00	K21.01	K21.9	K22.89			

**REIMBURSEMENT**

Participating facilities will be reimbursed per their Highmark Health Options contract.

## Reference

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**POLICY UPDATE HISTORY**

10/27/2021	Approved in Medical Policy Committee
11/2021	Approved in QI/UM
10/26/2022	Annual review; approved in Medical Policy Committee
11/2022	Approved in QI/UM