

**Contractor Name**

Wisconsin Physicians Service (WPS)

**Contractor Number**

00951, 00952, 00953, 00954  
05101, 05201, 05301, 05401,  
05102, 05202, 05302,  
05402, 52280

**Contractor Type**

Carrier B  
Fiscal Intermediary A  
MAC A  
MAC B

**LCD Database ID Number****LCD Version Number****LCD Title**

Endoscopic Treatment of GERD

**Contractor's Determination Number**

GI-010

**AMA CPT/ ADA CDT Copyright Statement**

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**CMS National Coverage Policy**

Title XVIII of the Social Security Act, Section 1862(a)(1)(A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act, Section 1833(e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

**Primary Geographic Jurisdiction**

**Carrier B:** Wisconsin, Illinois, Michigan, Minnesota

**Fiscal Intermediary A:** Alaska, Alabama, Arizona, Arkansas, California - Entire State, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri - Entire State, Mississippi, Montana, North Carolina, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, Nevada, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota,

Tennessee, Texas, Utah, Virginia, Vermont, Washington, Wisconsin, West Virginia, Wyoming, American Samoa, Guam, Northern Mariana Islands, U.S. Virgin Islands

**MAC A/B:** Iowa, Missouri, Nebraska, Kansas  
**Secondary Geographic Jurisdiction**

**Oversight Region**

**Original Determination Effective Date**

**Revision Effective Date**

**Indications and Limitations of Coverage and/or Medical Necessity**

Benefits are not available for endoluminal treatment for Gastroesophageal Reflux Disease (GERD) using the Stretta® procedure, the Bard EndoCinch™ Suturing System, Plicator™, Enteryx®, EsophyX™ or similar treatments as these procedures are not considered reasonable and necessary for the diagnosis or treatment of an injury or disease.

Currently, these procedures are considered non-covered due to the fact that current peer-reviewed literature does not support the efficacy of the services. Claims will be denied as “not proven effective.”

The Stretta® procedure is an endoluminal treatment for GERD in which radiofrequency energy is delivered to smooth muscle of the lower esophageal sphincter (LES). A flexible catheter equipped with special needle electrodes for precise energy delivery is placed by mouth into the esophagus and carefully controlled radiofrequency energy is then delivered to the LES and gastric cardia, creating thermal lesions. The manufacturer maintains that the changes that occur immediately, and over time, result in a “tighter” LES and a less compliant gastric cardia. Additionally, the interruption of nerve pathways in the LES area is believed to reduce the incidence of inappropriate LES “relaxations,” leading to an improvement in GERD symptoms. Substantial peer-reviewed evidence to fully support these assumptions remains to be published.

The Bard EndoCinch™ Suturing System and the Plicator™ are intended for use in endoscopic placement of suture(s) in the soft tissue of the esophagus and stomach and for approximation of tissue for treatment of symptomatic gastroesophageal reflux disease.

EsophyX™ is a device for performing transoral incisionless fundoplication surgery for treating gastroesophageal reflux disease. This procedure reconstructs the valve at the top of the stomach that helps prevent acid reflux.

Enteryx® is an endoscopic, minimally-invasive procedure in which an ethylene vinyl alcohol polymer solution is injected into your lower esophageal sphincter muscle using a small needle. This product was recalled in September 2005 due to adverse patient events.

These procedures are promising for treatment of patients in whom proton pump inhibitor therapy fails. Clinical data from various studies are emerging. At this time, open-label studies or patient registries with short term follow-ups are the dominant source of data. The overwhelming preponderance of reviewers remain equivocal in their support and have called for randomized controlled trials with long-term follow-ups. In the absence of evidence from such studies, and in the absence of wide acceptance, endoscopic treatments for GERD are not proven effective. **Therefore, they are not reimbursable even though some of the treatments may have associated CPT™ or OPPS codes.**

### Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

12x	Hospital-inpatient or home health visits (Part B only)
13x	Hospital-outpatient (HHA-A also) (under OPSS 13X must be used for ASC claims submitted for OPSS payment -- eff. 7/00)
21x	SNF-inpatient, Part A
22x	SNF-inpatient or home health visits (Part B only)
23x	SNF-outpatient (HHA-A also)
71x	Clinic-rural health
72x	Clinic-hospital based or independent renal dialysis facility
73x	Clinic-independent provider based FQHC (eff 10/91)
85x	Special facility or ASC surgery-rural primary care hospital (eff 10/94)

### Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

035X	Computed tomographic (CT) scan-general classification
0519	Clinic-other
075X	Gastro-intestinal services-general classification
0960	Professional fees-general classification
0969	Professional fees-other
0982	Professional fees-outpatient services
0983	Professional fees-clinic
0987	Professional fees-hospital visit
0988	Professional fees-consultation

### CPT/HCPCS Codes

- 43257 Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease
- 43499 Unlisted procedure, esophagus
- 43999 Unlisted procedure, stomach
- 49999 Unlisted procedure , abdomen, peritoneum and omentum

### Does the CPT 30% Rule Apply

No

### ICD-9 Codes that Support Medical Necessity

Note: ICD-9 codes must be coded to the highest level of specificity.

NA

### **Diagnoses that Support Medical Necessity**

NA

### **ICD-9 Codes that DO NOT Support Medical Necessity**

### **Diagnoses that DO NOT Support Medical Necessity**

### **Documentation Requirements**

### **Utilization Guidelines**

#### **Sources of Information and Basis for Decision**

1. Triadafilopoulos G, DiBaise JK, Nostrant TT, Stollman NH, Anderson PK, Wolfe MM, Rothstein RI, WO JM, Corley DA, Patti MG, Antignano LV, Goff JS, Edmundowicz SA, Castell DO, Rabine JC, Kim MS, Utley DS. The STRETТА procedure for the treatment of GERD: 6 and 12-month follow-up of the U.S. open label trial. *Gastrointestinal Endoscopy* 2002 Feb; 55 (2): 149-156
2. Hogan, Walter J MD; ASGE leadership: Promoting or validating endoscopic technology?; *Gastrointestinal Endoscopy* Vol 60 No 2 August 2004
3. Blue Cross Blue Shield Association Technology Evaluation Center; Transesophageal Endoscopic Treatments for Gastroesophageal Disease Assessment Program; Vol 18 No 20 Feb 2004
4. Other Medicare Contractor Local Coverage Determinations and article on coverage
5. Kahrilas, Peter J MD; Technology Review: Radiofrequency therapy of the lower esophageal sphincter for treatment of GERD; *Gastrointestinal Endoscopy* Vol 57 No 6 May 2003
6. Hogan, Walter J MD, Shaker, Reza MD; A Critical review of endoscopic therapy for gastroesophageal reflux disease; *Am J Med* Vol 115 No 3 August 18, 2003
7. Metz, David C MD; Managing gastroesophageal reflux disease for the lifetime of the patient: Evaluating the long-term options; *Am J of Med Supplements* Vol 117 No 5A September 6, 2004
8. William O. Richards, M.D., F.A.C.S.; Gastroesophageal Reflux Disease and the Truth About Endoluminal Therapy
9. Go, Dundon, et. al.; Delivery of radiofrequency energy to the lower esophageal sphincter improves symptoms of gastroesophageal reflux; *Surgery*, Vol 136 No 4 October 2004
10. George Triadafilopoulos, M.D.; Stretta: An Effective, Minimally Invasive Treatment of Gastroesophageal Reflux Disease; *The Am J. of Med.* Vol 115, August 18, 2003
11. Wolfson & Richards; The Stretta Procedure for the Treatment of GERD: A Registry of 558 patients; *Journal of Laparoendoscopic & Advanced Surgical Techniques*, Vol 12 No 6 2002
12. Cohen et al; Enteryx Implantation for GERD: Expanded multicenter Trial Results and Interim Postapproval Follow-Up to 24 months; *Gastrointestinal Endoscopy*, Vol 61 no 6: May 2005

**Advisory Committee Meeting Notes**

Meeting Date:

Wisconsin 9/25/09  
Illinois 9/16/09  
Michigan 9/09/09  
Minnesota 09/24/09  
J5 MAC 10/08/09

**Open Meeting Date**

8/19/09

**Start Date of Comment Period**

10/08/2009

**End Date of Comment Period**

11/23/2009

**Start Date of Notice Period**

(Published)

**Revision History Number/Explanation**

**Last Reviewed On**

**Related Documents**

NA

**LCD Attachments**

NA

**Does this LCD contain a "Least Costly Alternative" Provision?**

No