

LCD for Endoscopic Treatment of GERD (L26646)

Contractor Information

Contractor Name

Wisconsin Physicians Service Insurance Corporation

Contractor Number

05102, 05202, 05302, 05402

Contractor Type

MAC - Part B

LCD Information

LCD ID Number

L26646

LCD Title

Endoscopic Treatment of GERD

Contractor's Determination Number

GI-510

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.

Oversight Region

Region I
Region X

Original Determination Effective Date

For services performed on or after 02/01/2008

Original Determination Ending Date**Revision Effective Date**

For services performed on or after 08/01/2009

Revision Ending 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 (R) procedure, the Bard (R) EndoCinch (TM) Suturing System, Plicator (TM), Enteryx (R) 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 (R) 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 (TM) Suturing System and the Plicator (TM) 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.

Enteryx (R) an ethylenevinyl alcohol polymer, was approved by the FDA via premarketing application (PMA) approval in April 2003 for the treatment of GERD symptoms in "patients responding to and requiring daily pharmacological therapy with proton pump inhibitors."

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 (TM) or OPSS codes.

Coding Information

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.

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.

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

ICD-9 Codes that Support Medical Necessity

XX000	Not Applicable
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Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

General Information

Documentation Requirements

The medical record must be made available to Medicare upon request.

Appendices

Utilization Guidelines

Sources of Information and Basis for Decision

WPS has consolidated the existing LCDs for MAC Jurisdiction 5 according to the instructions provided by CMS so that they are the same throughout the jurisdiction. In the vast majority of cases, one least restrictive LCD was selected as the jurisdictional LCD. In some cases, appropriate revisions, such as combining sections of LCDs that only addressed a portion of a general topic into a single, more complete document, were made to improve the clinical appropriateness of the LCD while keeping with the least restrictive requirement.

In situations where one or more of the states in the jurisdiction does not have an LCD on a topic, then the existing LCDs were reviewed and, based on the merits of the LCD, a decision was made to make the LCD jurisdictional or to have no LCD on that topic with the approval of CMS.

Some revisions of the existing LCDs were necessary to remove references to the former contractor and to update the Sources of Information and Basis for Decision. CPT, HCPCS and ICD-9 codes will be updated as necessary.

According to the J5 MAC contract, the J5 consolidated LCDs are posted on the web site for the 45 day final notification period prior to the policy implementation date. The MAC contractor is not required to utilize the formal notice and comment revision process specified in Chapter 13 of the Program Integrity Manual (PIM) until the consolidation process is final. However, WPS welcomes provider input regarding the J5 consolidated LCDs. Based on the comments received, LCDs will be revised as necessary during the transition from the existing to new contractor.

This policy does not reflect the sole opinion of the contractor or contractor medical director. Although the final decision rests with the contractor, this policy was developed in consideration of the active LCDs maintained by the preceding Medicare contractors for Jurisdiction 5.

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 STRETTA 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

Start Date of Comment Period

End Date of Comment Period

Start Date of Notice Period

12/15/2007

Revision History Number

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Revision History Explanation

07/30/2009: Restored accidental removal of contract number 05392 (WPS Part B MAC Eastern Missouri), effective 03/01/08. Correctly removed contract number 05392 effective 8/1/2009, as it is being combined with contractor number 05302 (WPS Part B MAC Missouri - Entire State.)

06/30/2009 The contractor number 05392 will no longer be valid as of 8/1/2009 as it will be joining with the W MO number.

added Missouri Eastern

Reason for Change

Last Reviewed On Date

11/01/2007

Related Documents

This LCD has no Related Documents.

LCD Attachments

There are no attachments for this LCD.

All Versions

Updated on 07/30/2009 with effective dates 08/01/2009 - N/A

Updated on 07/30/2009 with effective dates 03/01/2008 - 07/31/2009

Updated on 07/17/2009 with effective dates 03/01/2008 - N/A

Updated on 05/23/2008 with effective dates 03/01/2008 - N/A

Updated on 03/28/2008 with effective dates 03/01/2008 - N/A

Updated on 03/07/2008 with effective dates 03/01/2008 - N/A

Updated on 12/07/2007 with effective dates 02/01/2008 - N/A