

Achalasia and Gastroesophageal Reflux Disease Treatments



INDEPENDENT CARE HEALTH PLAN

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Medicare Advanced Medical Coverage Policy

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The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to [CMS website](#) for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
LCD (and pertinent LCA)	Endoscopic Treatment of GERD	L34659 A56395	J5 – J8 Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, NE
LCD (and pertinent LCA)	Select Minimally Invasive GERD Procedures	L35080 A56863	J6 – JK National Government Services, Inc. (Part A/B MAC)	CT, IL, MN, NY, ME, MA, NH, RI, VT, WI
LCD (and pertinent LCA)	Stretta Procedure	L34540 A57039	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCD (and pertinent LCA)	Upper Gastrointestinal Endoscopy (Diagnostic and Therapeutic)	L35350 A57414	JH – JL Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, DC, DE, LA, OK, MD, MS NM, NJ, PA, TX
LCD (and pertinent LCA)	Upper Gastrointestinal Endoscopy and Visualization	L34434 A56389	JJ - Palmetto GBA (Part A/B MAC)	AL, GA, TN
LCD (and pertinent LCA)	Peroral Endoscopic Myotomy (POEM)	L38747 A58287	JJ – JM Palmetto GBA (Part A/B MAC)	AL, GA, NC, SC, TN, VA, WV
LCD (and pertinent LCA)	Stretta Procedure	L34553 A56703	JJ - Palmetto GBA (Part A/B MAC)	AL, GA, TN, SC, VA, WV, NC
LCD (and pertinent LCA)	Diagnostic and Therapeutic Esophagogastroduodenoscopy	L33583 A57063	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI

Description

Achalasia is a rare smooth muscle disorder of the esophagus that is characterized by insufficient lower esophageal sphincter (LES) relaxation and loss of esophageal peristalsis. Symptoms include but may not be limited to: burning sensation in the chest (heartburn), chest pain, cough, regurgitation of undigested food and slowly progressive dysphagia. Treatment is aimed at decreasing the resting pressure in the lower esophageal sphincter (LES), the ring of muscle between the esophagus and stomach, to a level at which the sphincter no longer impedes the passage of ingested material.⁵⁸

Procedure for the treatment of achalasia include, but may not be limited to:

- Myotomy – A procedure that used small incisions to cut the muscles of the lower esophageal sphincter (LES) to allow food and liquids to pass into the stomach.
- Peroral endoscopic myotomy (POEM) uses endoscopy via the esophagus, which is utilized to create a submucosal tunnel in the lower part of the esophagus to reach the bundle of muscles of the LES to perform myotomy.

Gastroesophageal reflux disease (GERD) is a digestive disorder that occurs when the stomach acids flow back up into the esophagus, which may cause indigestion, heartburn or esophagitis. Symptoms include, but may not be limited to belching, heartburn (usually after eating), chronic sore throat, difficulty when swallowing, dry cough, pain in the chest or regurgitation.

Procedures for the treatment of GERD include, but may not be limited to:

- Fundoplication – A technique that is designed to recreate lower esophageal sphincter pressure by wrapping the fundus of the stomach around the esophagus in the abdomen.
- Transoral incisionless esophagogastric fundoplication (TIF) (eg EsophyX) – A procedure which creates a valve, similar to that created in a traditional fundoplication procedure. The valve is created by folding the tissue and securing the valve with tissue fasteners through an endoscopic device without skin or muscle incisions.
- Transoral thermal (radiofrequency) therapy to the LES and/or gastric cardia (Stretta) – A procedure in which low-temperature radiofrequency energy is applied to the LES muscle causing thermal lesions, which intended to cause tissue shrinkage and tightening of the gastroesophageal junction.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above Medicare guidance for the treatment of **achalasia and GERD**.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

Achalasia

The following procedures for the **surgical treatments for achalasia** will be considered medically reasonable and necessary:

- Myotomy ([achalasia type I – III](#)); **OR**
- Pneumatic balloon dilation ([achalasia type I – III](#)); **OR**
- POEM ([achalasia type 1 - III](#));

AND when the following requirement has been met:

- Diagnosis confirmed by esophageal motility testing

GERD

The following **fundoplication procedures for treatment of chronic GERD** (persistent symptoms refractory to lifestyle changes and medical therapy) will be considered medically reasonable and necessary:

- Dor fundoplication; **OR**
- Nissen fundoplication; **OR**
- Toupet fundoplication; **OR**
- Transoral incisionless esophagogastric fundoplication (TIF) (eg EsophyX); **OR**
- Transoral thermal (eg, radiofrequency) therapy to LES and/or gastric cardia (eg, Stretta System)

AND when **ALL** the following requirements are met:

- Esophagogastroduodenoscopy (EGD) to rule out non-GERD etiology; **AND**
- Failure of standard dosing of proton pump inhibitor (PPI) treatment (eg, Dexilant [dexlansoprazole]) for 2 consecutive months or greater; **AND**

For TIF (Esophyx)

- When hiatal hernias are present they are not more than 2cm long; **AND**
- BMI is less than or equal to 35; **AND**
- Does not have achalasia or esophageal ulcers; **AND**
- Does not have Barrett's esophagus of 2cm or more; **AND**
- Has not previously had a TIF procedure that failed; **OR**

Transoral thermal (eg, radiofrequency) therapy to LES and/or gastric cardia (eg, Stretta System)

- When hiatal hernias are present, they are not more than 2cm long; **AND**
- Does not have dysphagia; **AND**
- Does not have Barrett's esophagus of 2cm or more; **AND**
- Does not have severe esophagitis; **AND**
- Does not have a history of autoimmune disease, collagen vascular disease, and/or coagulation disorders

Revision of a fundoplication will be considered medically reasonable and necessary when the following requirements are met:

- Dysphagia; **OR**

- Persistent or recurrent symptoms of reflux (eg, heartburn)

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

The following **surgical treatments of achalasia or GERD** will not be considered medically reasonable and necessary:

- Electrical stimulation of the lower esophageal sphincter (eg, EndoStim); **OR**
- Endoscopic plication or suturing (eg, Medigus ultrasonic surgical endostapler[MUSE]); **OR**
- Laparoscopic adjustable gastric banding (eg, LAP-BAND, Realize); **OR**
- Magnetic esophageal sphincter augmentation (MSA) (eg, LINX Reflux ManagementSystem); **OR**
- Roux-en-Y gastric bypass (RYGBP) (open or laparoscopic); **OR**
- Total esophagogastric disconnection (TED); **OR**

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

A review of the current medical literature demonstrates a lack of evidence or an unclear utility of the devices/procedures listed above. There is a lack of randomized trials comparing the various devices or procedures regarding benefits and long-term clinical outcomes. Efficacy for use is difficult to determine.

MSA

There is a paucity of long-term data on MSA outcomes with no randomized controlled trials comparing MSA over fundoplication.³⁰

RYGBP

There is considerable controversy regarding the role of RYGB as an antireflux procedure. There is a sizable variability in study results on the outcomes and rates of complications for fundoplication in obese

individuals. In regard to the role of RYGP, there is a lack of randomization comparing it directly with fundoplication. The procedure is technically difficult and one that produces major alterations in the anatomy, which can result in serious early and late complications.⁴

Endoscopic plication or suturing

There is a paucity of evidence to support the use of this procedure. A multicenter prospective study performed a six-month evaluation of 69 individuals. Improvement in GERD related quality of life (QOL) and reduction of PPI medications were evaluated. Even though results revealed a reduction in PPI use, it was concluded that additional studies are needed to establish the durability of the procedure.³⁴

TED

Most of the studies found only reviewed this procedure for neurologically impaired children.

Fundoplication procedure other than those listed above in the Coverage Determination section will not be considered medically reasonable and necessary:

- 90° anterior partial fundoplication (APF); **OR**
- Hill repair; **OR**
- Lind partial fundoplication³⁵

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

There were a small number of studies available regarding the comparisons of the 90° APF, Hill repair and the Lind partial fundoplication., The evidence comparing these procedures included only 1 RCT for each type of laparoscopic technique. There is insufficient data to draw conclusions in comparison to other fundoplication procedures.³⁵

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
32665	Thoracoscopy, surgical; with esophagomyotomy (Heller type)	
43195	Esophagoscopy, rigid, transoral; with balloon dilation (less than 30 mm diameter)	
43196	Esophagoscopy, rigid, transoral; with insertion of guide wire followed by dilation over guide wire	

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43205	Esophagoscopy, flexible, transoral; with band ligation of esophageal varices	
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)	
43213	Esophagoscopy, flexible, transoral; with dilation of esophagus, by balloon or dilator, retrograde (includes fluoroscopic guidance, when performed)	
43214	Esophagoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)	
43220	Esophagoscopy, flexible, transoral; with transendoscopic balloon dilation (less than 30 mm diameter)	
43226	Esophagoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) over guide wire	
43233	Esophagogastroduodenoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)	
43249	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic balloon dilation of esophagus (less than 30 mm diameter)	
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (eg, 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)	
43279	Laparoscopy, surgical, esophagomyotomy (Heller type), with fundoplasty, when performed	

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43280	Laparoscopy, surgical, esophagogastric fundoplasty (eg, Nissen, Toupet procedures)	
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed	
43285	Removal of esophageal sphincter augmentation device	
43325	Esophagogastric fundoplasty, with fundic patch (Thal-Nissen procedure)	
43327	Esophagogastric fundoplasty partial or complete; laparotomy	
43328	Esophagogastric fundoplasty partial or complete; thoracotomy	
43330	Esophagomyotomy (Heller type); abdominal approach	
43331	Esophagomyotomy (Heller type); thoracic approach	
43497	Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])	
43499	Unlisted procedure, esophagus	
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)	
43659	Unlisted laparoscopy procedure, stomach	
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)	
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy	
43999	Unlisted procedure, stomach	
49999	Unlisted procedure, abdomen, peritoneum and omentum	
CPT® Category III Code(s)	Description	Comments
No code(s) identified		
HCPCS Code(s)	Description	Comments
A9999	Miscellaneous DME supply or accessory, not otherwise specified	

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Appendix

Appendix A

Achalasia Types⁴⁵

Type I	Swallowing results in no significant change in esophageal pressurization. By Chicago Classification, Version 3 (CC-3) criteria, type I achalasia has 100 percent failed peristalsis as indicated by a distal contractile integral (DCI, an index of the strength of distal esophageal contraction) less than or equal to 100 mmHg.
Type II	Swallowing results in simultaneous pressurization that spans the entire length of the esophagus. According to CC-3, type II achalasia has 100 percent failed peristalsis and pan-esophageal pressurization seen in less than or equal to 20 percent of swallows.
Type III	Swallowing results in premature and often lumen-obliterating contractions or spasms. By CC-3 criteria, type III achalasia has no normal peristalsis and premature (spastic) contractions with distal latency less than 4.5 seconds and DCI greater than 450 mmHg·s·cm seen in greater than or equal to 20 percent of swallows.

Change Summary

- Click or tap to enter a date. New Policy.
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