Achalasia and Gastroesophageal Reflux Disease Treatments

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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.
### 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

<table>
<thead>
<tr>
<th>Type</th>
<th>Title</th>
<th>ID Number</th>
<th>Jurisdiction Medicare Administrative Contractors (MACs)</th>
<th>Applicable States/Territories</th>
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<tr>
<td>LCD (and pertinent LCA)</td>
<td>Endoscopic Treatment of GERD</td>
<td>L34659 A56395</td>
<td>J5 – J8 Wisconsin Physicians Service Insurance Corporation</td>
<td>IA, IN, KS, MI, MO, NE</td>
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<td>LCD (and pertinent LCA)</td>
<td>Select Minimally Invasive GERD Procedures</td>
<td>L35080 A56863</td>
<td>J6 – JK National Government Services, Inc. (Part A/B MAC)</td>
<td>CT, IL, MN, NY, ME, MA, NH, RI, VT, WI</td>
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<td>LCD (and pertinent LCA)</td>
<td>Stretta Procedure</td>
<td>L34540 A57039</td>
<td>J15 - CGS Administrators, LLC (Part A/B MAC)</td>
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<td>LCD (and pertinent LCA)</td>
<td>Upper Gastrointestinal Endoscopy (Diagnostic and Therapeutic)</td>
<td>L35350 A57414</td>
<td>JH – JL Novitas Solutions, Inc. (Part A/B MAC)</td>
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<td>Peroral Endoscopic Myotomy (POEM)</td>
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<td>JN - First Coast Service Options, Inc. (Part A/B MAC)</td>
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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

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 Management System); OR
• Roux-en-Y gastric bypass (RYGBP) (open or laparoscopic); OR
• Total esophagogastrectomy (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.  

**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.  

**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 fundoplication

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.

**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.

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<th>Comments</th>
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<td>32665</td>
<td>Thoracotomy, surgical; with esophagomyotomy (Heller type)</td>
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<td>43195</td>
<td>Esophagoscopy, rigid, transoral; with balloon dilation (less than 30 mm diameter)</td>
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<tr>
<td>43196</td>
<td>Esophagoscopy, rigid, transoral; with insertion of guide wire followed by dilation over guide wire</td>
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<tr>
<td>Code</td>
<td>Description</td>
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<td>43205</td>
<td>Esophagoscopy, flexible, transoral; with band ligation of esophageal varices</td>
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<td>43210</td>
<td>Esophagastroduodenoscopy, flexible, transoral; with esophagogastrectomy, partial or complete, includes duodenoscopy when performed</td>
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<td>43212</td>
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<td>Esophagoscopy, flexible, transoral; with dilation of esophagus, by balloon or dilator, retrograde (includes fluoroscopic guidance, when performed)</td>
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<td>43226</td>
<td>Esophagoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) over guide wire</td>
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<td>43233</td>
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<td>43249</td>
<td>Esophagastroduodenoscopy, flexible, transoral; with transendoscopic balloon dilation of esophagus (less than 30 mm diameter)</td>
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<td>43253</td>
<td>Esophagastroduodenoscopy, 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)</td>
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<td>43257</td>
<td>Esophagastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease</td>
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<tr>
<td>43266</td>
<td>Esophagastroduodenoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)</td>
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<tr>
<td>43279</td>
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<td>CPT® Category III Code(s)</td>
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<td>43280</td>
<td>Laparoscopy, surgical, esophagogastric fundoplasty (eg, Nissen, Toupet procedures)</td>
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<td>43284</td>
<td>Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed</td>
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<td>43285</td>
<td>Removal of esophageal sphincter augmentation device</td>
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<td>Esophagogastric fundoplasty, with fundic patch (Thal-Nissen procedure)</td>
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<td>43327</td>
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<td>Esophagogastric fundoplasty partial or complete; thoracotomy</td>
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<td>Esophagomyotomy (Heller type); thoracic approach</td>
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<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)</td>
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References


### Appendix A

#### Achalasia Types

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<tr>
<th>Type</th>
<th>Description</th>
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<tbody>
<tr>
<td>Type I</td>
<td>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.</td>
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<tr>
<td>Type II</td>
<td>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.</td>
</tr>
<tr>
<td>Type III</td>
<td>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.</td>
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