Clinical Review Criteria
Per Oral Endoscopic Myotomy (POEM) for Esophageal Achalasia

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Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
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<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
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<td>National Coverage Determinations (NCD)</td>
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<td>Local Coverage Determinations (LCD)</td>
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<td>Local Coverage Article</td>
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For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Esophageal achalasia (EA) is an uncommon motility disorder involving the smooth muscle layer of the esophagus and the lower esophageal sphincter (LES) located at the junction of the esophagus and stomach. Most commonly affecting middle-aged and older adults, the disorder can occur at any age and is characterized by incomplete LES relaxation, increased LES tone and lack of peristalsis of the esophagus, ultimately preventing the passage of food into the stomach. Symptoms include difficulty swallowing, regurgitation, chest pain and heart burn, as well as unintentional weight loss. Extreme complications may include aspiration of solids and liquids and perforation of the esophagus (Mayberry, 2001).

Diagnosis of EA relies on esophageal manometry or radiographic imaging and treatment options aim to disrupt or weaken the LES although no treatment option effectively cures the condition. Conservative options, such as pharmaceutical therapies, have LES muscle relaxing effects which may help to relieve symptoms in early stages, however, long term drug therapy is inconvenient, ineffective, and associated with a variety of unpleasant side effects. Alternative treatment options require the mechanical weakening of the LES via procedures that tear or cut the muscle. Laparoscopic Heller myotomy (LHM) has long been regarded as the standard treatment option for patients who are good surgical candidates (Campos, Vittinghoff et al. 2009). The technique involves cutting the muscles at the end of the esophagus and at the top of the stomach allowing the valve between the esophagus and stomach to remain open. In total, the procedure requires five small incisions on the abdomen wall.

Advances in the surgical field have allowed surgeons to improve practice offering alternative entry routes. Per oral endoscopic myotomy (POEM), for example, is a less invasive alternative to LHM. First described in human subjects in 2008, the technique, nearly analogous to LHM, allows the surgeons to enter via a natural orifice thus eliminating the need for skin incision. Further to this, when compared to LHM, the POEM technique allows surgeons to isolate the inner circular muscles for myotomy and offers better access to the mediastinal esophagus without disrupting the crura of the diaphragm. The technique is reported to minimize pain and blood loss (Inoue, Minami et al. 2010; Costamagna, Marchese et al. 2012).
The United States Food and Drug Administration (FDA) ensures the safety and effectiveness of drugs and medical devices. As a surgical procedure for the treatment of achalasia, POEM does not fall under the authority of the FDA. The Medical Technology and Assessment Committee (MTAC) has not previously addressed POEM for the treatment of achalasia and is currently reviewing it due to provider request to support a coverage decision.

Medical Technology Assessment Committee (MTAC)

Per Oral Endoscopic Myotomy

12/15/2014: Bhayani and colleagues compared the experience of 101 patients from a single institution undergoing either LHM or POEM. Swallowing outcomes at one and six months were assessed via objective measures (manometry and pH levels). In addition, the investigators collected information regarding operative time, complications and postoperative gastro-esophageal reflux disease (GERD). Manometry indicated that there were decreases in pressure across both groups, however, the postmyotomy resting pressures were higher for the POEM group than for LHM (16 vs. 7 mm Hg, P=0.006). The same effect was not seen between groups for relaxation pressure (9 vs. 4). Both groups experienced relief of symptoms with the POEM group showing significantly lower Eckhardt scores when compared with the LHM group at one month (0.8 vs. 1.8, P<0.0001). At six months, however, the difference was no longer significant (1.7 vs. 1.2, P=0.1). Ultimately, the investigators conclude that POEM is comparable with LHM for safe and effective treatment of EA (Bhayani, Kurian et al. 2014). While POEM appears to be comparable to LHM, the technique is still evolving. At this particular point in time, the body of evidence only reports on the success of POEM in highly select populations with short-term follow-up. To add to this, the study is not randomized and relies on a small sample or subjects. Ultimately, the literature does not support the safety and effectiveness of POEM for the treatment of achalasia when compared to LHM.

Conclusions: There is insufficient evidence to support the effectiveness of POEM compared to LHM for the treatment of EA. There is insufficient evidence to support the safety of POEM compared with LHM for the treatment of EA.

Articles: The literature search revealed over 200 studies relating to the use of POEM for the treatment of achalasia. The literature was dominated by publications that introduce and describe the technique as well as studies from individual centers describing their experience with POEM with short-term follow-up. A search of the clinicaltrials.gov website revealed several ongoing studies with the aim to evaluate of the clinical utility and safety of POEM (NCT01832779). For the purposes of this review, one of the larger and more recent nonrandomized comparison studies was identified for critical appraisal. The following articles were selected for critical appraisal: Bhayani NH, Kurian AA, Dunst CM, et al. A comparative study on comprehensive, objective outcomes of laparoscopic Heller myotomy with per-oral endoscopic myotomy (POEM) for achalasia. Annals of Surgery. 2014; 259(6): 1098-1103. See Evidence Table 1.

The use of Per Oral Endoscopic Myotomy does not meet the Kaiser Permanente Medical Technology Assessment Criteria.