FEP 2.01.91 Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia

**Effective Date:** April 1, 2019

**Related Policies:**
7.01.137 Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

### Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia

**Description**
Esophageal achalasia is characterized by reduced numbers of neurons in the esophageal myenteric plexuses and reduced peristaltic activity, making it difficult for patients to swallow food and possibly leading to complications such as regurgitation, coughing, choking, aspiration pneumonia, esophagitis, ulceration, and weight loss. Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure that uses the oral cavity as a natural orifice entry point to perform myotomy of the lower esophageal sphincter. This procedure is intended to reduce the total number of incisions needed and thus the overall invasiveness of surgery.

**OBJECTIVE**
The objective of this evidence review is to determine whether peroral endoscopic myotomy improves the net health outcome in patients with esophageal achalasia.

**POLICY STATEMENT**
Peroral endoscopic myotomy is considered *investigational* as a treatment for esophageal achalasia.

**BENEFIT APPLICATION**
Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**FDA REGULATORY STATUS**
POEM uses available laparoscopic instrumentation and, as a surgical procedure, is not subject to regulation by the U.S. Food and Drug Administration.

**RATIONALE**

**Summary of Evidence**
For individuals who have achalasia who receive POEM, the evidence includes systematic reviews of observational studies, nonrandomized comparative studies, and case series. Relevant outcomes are symptoms, functional outcomes, health status measures, resource utilization, and treatment-related...
morbidly. The comparative studies have primarily reported similar outcomes for POEM and for Heller myotomy in symptom relief, as assessed by the Eckardt score. Some studies have shown shorter length of stay and less postoperative pain with POEM. However, potential imbalances in patient characteristics in these nonrandomized studies might have biased the treatment comparisons. In the case series, treatment success at short follow-up periods was reported for a high proportion of patients treated with POEM. However, the incidence of adverse events was relatively high, with POEM-specific complications, including subcutaneous emphysema, pneumothorax, and thoracic effusion, reported across studies. Additionally, a substantial proportion of patients undergoing POEM developed gastroesophageal reflux disease and esophagitis and required treatment. Case series do not permit conclusions about the efficacy of POEM relative to established treatment, and long-term outcomes of the procedure are not well described in the literature. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Gastroenterological Association Institute
In 2017, the American Gastroenterological Association Institute published a clinical practice update on the use of peroral endoscopic myotomy (POEM) for the treatment of achalasia.[30]

Based on expert review, the Institute made the following recommendations:
- POEM should be performed by experienced physicians in high-volume centers (competence achieved after estimated 20 to 40 procedures)
- If expertise is available, POEM should be considered primary therapy for type III achalasia
- If expertise is available, POEM should be considered comparable to Heller myotomy for any achalasia syndromes
- Patients receiving POEM should be considered high risk to develop reflux esophagitis and be advised of management considerations (eg, proton pump inhibitor therapy and/or surveillance endoscopy) prior to undergoing POEM.

American Society of Gastrointestinal and Endoscopic Surgeons
In 2014, the American Society of Gastrointestinal and Endoscopic Surgeons issued evidence-based, consensus guidelines on the use of endoscopy in the evaluation and management of dysphagia, including esophageal achalasia.[31]

The Society recommended that:
“… Endoscopic and surgical treatment options for achalasia should be discussed with the patient. In patients who opt for endoscopic management and are good surgical candidates, pneumatic dilation with large-caliber balloon dilators for the endoscopic treatment of achalasia was recommended… Long-term data and randomized trials comparing peroral endoscopic myotomy to conventional modalities of management are necessary before it can be adopted into clinical practice, but the procedure is becoming more widely used in expert centers.”

American College of Gastroenterology
In 2013, the American College of Gastroenterology issued clinical guidelines on the diagnosis and management of achalasia.[32]

POEM was discussed as an emerging therapy and stated to have promise as an alternative to the laparoscopic approach. The guidelines further stated that randomized prospective comparison trials are needed, and the procedure should be performed in the context of clinical trials.
Society of American Gastrointestinal and Endoscopic Surgeons
In 2012, the Society of American Gastrointestinal and Endoscopic Surgeons issued evidence-based, consensus guidelines on the surgical management of esophageal achalasia. The guidelines stated that the POEM technique “is in its infancy and further experience is needed before providing recommendations.”[33]

International Society for Diseases of the Esophagus
In 2018, the International Society for Diseases of the Esophagus published guidelines on the diagnosis and management of achalasia.[34]

The Society convened 51 experts from 11 countries, including several from the United States, to systematically review evidence, assess recommendations using the GRADE system, and vote to integrate the recommendations into the guidelines (>80% approval required for inclusion). Table 1 summarizes POEM recommendations.

Table 1. Recommendations for the Treatment of Achalasia

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>LOR</th>
<th>GOR</th>
</tr>
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<tbody>
<tr>
<td>1   POEM is an effective therapy for achalasia both in short- and medium-term follow-up with results comparable to Heller myotomy.</td>
<td>Conditional</td>
<td>Very low</td>
</tr>
<tr>
<td>2   POEM is an effective therapy for achalasia both in short- and medium-term follow-up with results comparable to pneumatic dilations.</td>
<td>Conditional</td>
<td>Low</td>
</tr>
<tr>
<td>3   Pretreatment information on GERD, nonsurgical options (pneumatic dilation), and surgical options with lower GERD risk (Heller myotomy) should be provided to patient.</td>
<td>Good practice</td>
<td>NA</td>
</tr>
<tr>
<td>4   POEM is feasible and effective for symptom relief in patients previously treated with endoscopic therapies.</td>
<td>Conditional</td>
<td>Very low</td>
</tr>
<tr>
<td>5   POEM may be considered an option for treating recurrent symptoms after laparoscopic Heller myotomy.</td>
<td>Conditional</td>
<td>Low</td>
</tr>
<tr>
<td>6   Appropriate training (in vivo/in vitro animal model) and proctorship should be considered prior to a clinical program of POEM.</td>
<td>Good practice</td>
<td>NA</td>
</tr>
</tbody>
</table>

GERD: gastroesophageal reflux disease; GOR: grade of recommendation; LOR: level of recommendation; NA: not applicable; POEM: peroral endoscopic myotomy.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.
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REFERENCES


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POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>December 2013</td>
<td>New Policy</td>
<td>Policy updated with literature review; references 3, 6-7, 9-12, and 18 added. No change to policy statement.</td>
</tr>
<tr>
<td>June 2016</td>
<td>Update Policy</td>
<td>Policy updated with literature review through October 15, 2015; references 8-11 and 23 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>March 2017</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 6-8, 10-11, and 15-16 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>March 2019</td>
<td>Update Policy</td>
<td>Policy updated with literature review through September 4, 2018; reference 9, 19, 30, and 34 added. Policy statement unchanged.</td>
</tr>
</tbody>
</table>

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