Clinical Policy Title: Peroral endoscopic myotomy

Clinical Policy Number: 08.03.04

Effective Date: January 1, 2016
Initial Review Date: October 16, 2015
Most Recent Review Date: October 19, 2017
Next Review Date: October 2018

Related policies:

- CP# 00.02.02 Botulinum toxin products
- CP# 09.01.03 Electrical stimulation for oropharyngeal dysphagia

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of peroral endoscopic myotomy (POEM) for achalasia to be investigational and, therefore, not medically necessary (Hayes, 2016; American Society for Gastrointestinal Endoscopy [ASGE], 2014; Vaezi, 2013; Stafanidis, 2012)

Limitations:

All other uses of POEM are not medically necessary.

Alternative covered services:

- Open or laparoscopic esophagomyotomy with or without fundoplication.
- Endoscopically guided pneumatic dilation (PD).
- Botulinum toxin injection.
Oral pharmacologics (e.g., calcium channel blockers, long acting nitrates, anticholinergics, β-adrenergic agonists, and theophylline).

**Background**

Achalasia is an esophageal motility disorder of the esophageal smooth muscle layer and the lower esophageal sphincter (LES). Incomplete LES relaxation, increased LES pressure, and aperistalsis of the distal one-third of the esophageal body characterize the disorder (Friedel, 2013). Achalasia is rare in the pediatric population and even less so in children younger than 5 years of age (Franklin, 2014). The majority of cases are idiopathic, but the disorder can be associated with malignancy (especially involving the gastro-esophageal junction) and as a part of the spectrum of Chagas disease. In rare cases, achalasia is transmitted genetically (Franklin, 2014; Friedel, 2013).

The cardinal presenting symptom is progressive dysphagia, usually for both solids and liquids. Vomiting, weight loss, chest pain, regurgitation, heartburn, and coughing related to aspiration may occur. Advanced cases can result in malnutrition. The diagnostic standard is esophageal manometry on which achalasia displays the following characteristics — incomplete relaxation of the LES in response to swallowing, high resting LES pressure, and absent esophageal peristalsis. Other tests include barium contrast radiography and endoscopic assessment of the gastroesophageal junction and gastric cardia, as recommended, to rule out pseudoachalasia and mechanical obstruction. High-resolution manometry provides greater topographical detail that allows gastroenterologists to classify diseases into clinically relevant subtypes and remove normal variants from pathologic classification (Friedel, 2013).

**Treatment:**

Achalasia is an incurable chronic condition that requires lifelong follow up. Treatment goals are to relieve symptoms, improve esophageal emptying, and prevent further esophageal dilation. Current treatment options aim to decrease the resting pressure in the LES (American College of Gastroenterologists [ACG], 2013).

Established treatments for achalasia are open or laparoscopic esophagomyotomy (also known as Heller myotomy), with or without an antireflux procedure, and PD. However, their effectiveness decreases over time, and each is associated with procedural risks. Esophagectomy is reserved for patients with end-stage achalasia, characterized by megaesophagus or sigmoid esophagus, and significant esophageal dilation and tortuosity. Botulinum toxin injection into the LES is restricted, generally, to patients for whom PD and esophagomyotomy are not considered appropriate because of inherent patient-related risks. Oral pharmacologic interventions (e.g., calcium channel blockers and long-acting nitrates) are among the least effective. No intervention significantly affects esophageal peristalsis, and despite initial success of these interventions, LES hypertonicity returns over time, requiring repeat interventions (ACG, 2013).

**POEM:**
POEM is a hybrid technique derived from natural orifice transluminal endoscopic surgery and advances in endoscopic submucosal dissection to perform a myotomy. Developed in Japan, it involves an esophageal mucosal incision, followed by creation of a submucosal tunnel crossing the esophagogastric junction and myotomy before closure of the mucosal incision. POEM presents a novel, minimally invasive, and potentially effective endoscopic treatment for achalasia (Friedel, 2013).

Searches

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on September 7, 2017. Search terms were: "peroral endoscopic myotomy" and "esophageal achalasia" (MeSH).

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Select Health of South Carolina identified two systematic reviews (Barbieri, 2015; Wei, 2015), one evidence report (Hayes, 2015) and three evidence-based guidelines for this policy (ASGE 2014; Vaezi, 2013; Stafanidis, 2012). The evidence consists of single-arm studies and four individual, indirect comparisons of POEM to laparoscopic Heller myotomy (LHM). No randomized controlled trials (RCTs) were published at the time of writing this policy. There is considerable overlap of investigators and, presumably, patient groups, which reflects clinical experience with POEM limited to relatively few centers around the world. Some studies included patients with other types of esophageal motility disorders, as well as variable prior treatment exposure.

The evidence is insufficient to support the use of POEM as a treatment for achalasia. The results suggest POEM is a feasible and safe procedure achieving equivalent short-term outcomes compared to LHM for
achalasia. However, the role of POEM as a first-line treatment or salvage therapy must still be defined, and long-term results are needed. Established alternatives such as LHM and PD are supported by substantially more clinical experience and stronger evidence from RCTs. Guidelines from the ACG (Vaezi, 2013), the Society of American Gastrointestinal and Endoscopic Surgeons (Stafanidis, 2012), and the ASGE (2014) highlight the need for RCTs comparing the long-term efficacy POEM to established alternatives for treatment of achalasia before widespread adoption.

Policy update:

In 2016, we identified one new systematic review and meta-analysis comparing LHM and POEM (Marano, 2016) and one narrative review of laparoscopic esophagomyotomy procedures for achalasia in children (Pandian, 2016). The new evidence suggests comparable short-term outcomes for POEM and LHM in adults with either treatment-naive or treatment-experienced achalasia. The evidence for laparoscopic esophagomyotomy procedures in children is scant, with the majority of evidence assessing the short-term safety and efficacy of LHM; the evidence for POEM in pediatric patients is limited to just 12 patients. Both reviews stress the need for long-term follow-up and the need for multi-site efficacy studies, particularly in children. These results do not change previous findings. Therefore, no policy changes are warranted at this time.

In 2017, we added an updated Hayes report (2016). These results do not change previous findings, and no policy changes are warranted at this time.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Hayes (2016)</td>
<td>Key points:</td>
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<tr>
<td>POEM for treatment of esophageal achalasia</td>
<td>Systematic review of two randomized comparative trials, one case-control study, one retrospective cohort, two prospective cohort studies with historical controls, four prospective cohort studies, and three pretest/posttest studies. Sample sizes 29 to 500 patients.</td>
</tr>
<tr>
<td></td>
<td>Overall quality: Low with high risk of bias, limited follow-up., primary outcomes were predominantly procedural rather than clinical, and inconsistent reporting of rate of gastroesophageal reflux.</td>
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<td></td>
<td>Low quality evidence suggests POEM improved symptom relief, reduced LES pressure, resulted in weight gain, and achieved treatment success.</td>
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<td>Comparative studies suggest POEM and LHM may achieve similar efficacy and harms.</td>
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<tr>
<td></td>
<td>Variations in POEM technique may significantly affect procedural outcomes, but efficacy and harms outcomes remain similar.</td>
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<tr>
<td></td>
<td>Insufficient evidence to determine comparative effectiveness of POEM and standard treatments. RCTs are needed.</td>
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<tr>
<td>Marano (2016)</td>
<td>Key points:</td>
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<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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| LHM versus POEM for achalasia | - Systematic review and meta-analysis of 11 retrospective case–control studies (486 total patients [196 in POEM group, 290 in LHM group]) of patients who were both treatment-naïve and treatment-experienced.  
- Overall quality: low with a moderate risk of bias mainly due to lack of randomization or blinding and high heterogeneity between studies. Maximum follow-up 12 months.  
- No significant differences in Eckardt score, operative time, postoperative pain scores, analgesic requirements and complications.  
- POEM had a lower length of hospital stay (mean difference -0.629, 95% confidence interval [CI] -1.256 to -0.002, P = 0.049).  
- Reduction in symptomatic gastroesophageal reflux rate favors LHM in the short-term (odds ratio [OR] 1.81, 95% CI 1.11 - 2.95, P = 0.017).  
- POEM represents a safe and efficacy procedure comparable to the safety profile of LHM for achalasia at a short-term follow-up. Long-term clinical trials are urgently needed. |
| Pandian (2016) | **Key points:**  
- Narrative review of several retrospective studies (248 total patients) of LHM and one case report and two case series (12 total patients) of POEM.  
- Very limited data suggests LHM is safe and effective in the short term when performed by an experienced surgeon. POEM is emerging.  
- Further studies with detailed safety and efficacy profile over the long-term are needed and are ongoing. |
| Barbieri (2015) | **Key points:**  
- Systematic review of 16 non-randomized studies, case series, and indirect comparisons with LHM (551 total patients) published from 2010 to 2013. Performed in dedicated settings.  
- Mean age (median, range) (44 years, 32 years – 64 years); body mass index available in four series (26 kg/m², 25 kg/m² – 27 kg/m²); surveillance period (six months, 3 months – 12 months); mean POEM duration (156 min, 42 min – 112 min); myotomy length (10 cm, 6 cm – 14 cm).  
- Technical success 97% (95% CI 94% – 98%); clinical success 93% (95% CI 90% – 95%).  
- Most common adverse event: esophagitis 13% (95% CI 10% – 17%).  
- Most common major adverse events that required medical or surgical interventions: hypertensive pneumomediastinum and intramediastinal bleeding treatable with decompression 14% (95% CI 11% – 17%); post-POEM surgery needed in 0.2% (95% CI, 0% – 0.5%).  
- Conclusions: Highly feasible and safe in the short term. POEM should only be performed in centers able to treat POEM complications. |
| Wei (2015) | **Key points:**  
- Systematic review and meta-analysis of four studies comparing POEM and LHM. All studies were conducted in the United States and published in 2013. |
POEM was associated with comparable complications (OR 1.17, 95% CI 0.53 – 2.56, P = .70), gastroesophageal reflux (OR 1.00, 95% CI 0.38 – 2.61, P = 1.00), and symptomatic improvements by Eckardt score (OR 0.24, 95% CI 0.04 – 1.55, P = .13).

No significant differences in other outcomes, including pain score, operating time, and hospital stay.

References

Professional society guidelines/other:


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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