Clinical Policy Title: Peroral endoscopic myotomy (POEM)

Clinical Policy Number: 08.03.04

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

Policy contains:
- Achalasia/dysphagia.
- Esophageal motility disorders.
- Esophagomyotomy.
- Peroral endoscopic myotomy.

Related policies:
- CP# 00.02.02 Botulinum toxin products
- CP# 09.01.03 Dysphagia testing

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’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 Keystone First 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. Keystone First’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. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of peroral endoscopic myotomy (POEM) for achalasia to be investigational and, therefore, not medically necessary.

Limitations:

All other uses of POEM are not medically necessary.

Note: The following CPT/HCPCS code is not listed in the Pennsylvania Medicaid fee schedule:

43499 - Unlisted procedure, esophagus

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 (Friedel 2013, Franklin 2014).

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**

Keystone First 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 21, 2016. 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**

Keystone First identified two systematic reviews (Barbieri 2015, Wei 2015), one evidence report (Hayes 2015) and three evidence-based guidelines for this policy (Stafanidis 2012, Vaezi 2013, ASGE 2014). 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, the Society of American Gastrointestinal and Endoscopic Surgeons, and the American Society for Gastrointestinal Endoscopy (ASGE) highlight the need for RCTs comparing the long-term efficacy POEM to established alternatives for treatment of achalasia before widespread adoption (Stafanidis 2012, Vaezi 2013, ASGE 2014).

**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-naïve 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.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Marano (2016)</td>
<td><strong>Key points:</strong></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:**                                                                                                                                                                                                                     |
### Citation

**Laparoscopic esophagomyotomy for achalasia in children**
- 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)**

**POEM for achalasia**
- 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 to 64 years); body mass index available in four series (26, 25 to 27); surveillance period (six months, three to 12 months); mean POEM duration (156 minutes, 42 to 112 minutes); myotomy length (10 cm, 6 to 14 cm).
- Technical success 97% (95% CI 94 to 98); clinical success 93% (95% CI 90 to 95).
- Most common adverse event: esophagitis 13% (95% CI 10 to 17).
- Most common major adverse events that required medical or surgical interventions: hypertensive pneumomediastinum and intramediastinal bleeding treatable with decompression 14% (95% CI 11 to 17); post-POEM surgery needed in 0.2% (95% CI, 0 to 0.5).
- Conclusions: Highly feasible and safe in the short term. POEM should only be performed in centers able to treat POEM complications.

**Hayes (2015)**

**POEM for achalasia**
- Search and summary report (no systematic review) of 26 studies, individual cohorts and indirect comparisons to alternative treatments. No randomized studies.
- Considerable overlap of authors and, presumably, patient groups. Some involved mixed patient groups that included patients with achalasia and other esophageal motility disorders.
- Four studies compared POEM with LHM; four reported outcomes comparing different POEM techniques.

**Wei (2015)**

**POEM versus LHM**
- 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 to 2.56, P = .70), gastroesophageal reflux (OR 1.00, 95% C, 0.38 to 2.61, P = 1.00), and symptomatic improvements by Eckardt score (OR 0.24, 95% CI 0.04 to 1.55, P = .13).
- No significant differences in other outcomes, including pain score, operating time, and hospital stay.

### Glossary

**Achalasia** — A disorder of the swallowing muscles of the lower portion of the esophagus characterized by a progressive inability to swallow solids and liquids. Caused by the lower esophageal sphincter (near the cardia) failing to relax, resulting in functional obstruction of the esophagus and difficulty swallowing. Three subtypes shown on high-resolution manometry are:
- **Type I** shows absence of any motility and contraction within the body of the esophagus.
- **Type II** shows simultaneous contractions.
- **Type III** reveals a simultaneous high-pressure spasm.
**Chagas disease** — An inflammatory, infectious disease caused by a parasite found in the feces of the triatomine (reduviid) bug. Chagas disease is common in South America, Central America, and Mexico, but rare cases have been found in the southern United States.

**Dysphagia** — Difficulty swallowing.

**Eckardt score** — A summary symptom score used to grade symptoms (weight loss, dysphagia, retrosternal pain, and regurgitation), stages and efficacy of achalasia treatment (maximum score 12).

**Esophagomyotomy (Heller myotomy)** — A surgical procedure that cuts the smooth muscles of the lower esophageal sphincter, allowing food and liquids to pass to the stomach.

**Lower esophageal sphincter (LES)** — A band of involuntary muscles at the junction of the esophagus and stomach. When the LES is closed, it prevents acid and stomach contents from traveling backwards from the stomach. During swallowing, the sphincters relax so food can pass to the stomach.

**Manometry** — A thin, pressure-sensitive tube passed through the nose, down the esophagus and into the stomach, that measures the rhythmic muscle contractions of the esophagus when swallowing.

**Peristalsis** — Successive waves of involuntary contraction passing along the walls of the esophagus or intestine and that force the contents onward.

**Peroral endoscopic myotomy (POEM)** — A procedure that uses a high-definition upper endoscope to cut the smooth muscles of the lower esophageal sphincter, allowing food and liquids to pass to the stomach.

**Pneumatic dilation** — A nonsurgical endoscopic procedure that uses inflated balloons to enlarge the circumference of the esophagus. The goal is to rupture the circular muscle fibers of the lower esophageal sphincter while leaving the mucosa intact, allowing food and liquids to pass to the stomach.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**Clinical trials:**

Search ClinicalTrials.gov on September 21, 2016 using terms “achalasia” AND (myotomy or "peroral endoscopic myotomy" or “POEM”) | Open Studies | United States. Thirteen studies found, eight relevant.


**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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