Clinical Policy Title: Peroral endoscopic myotomy (POEM)

Clinical Policy Number: 08.03.04

Effective Date: January 1, 2016
Initial Review Date: September 16, 2015
Most Recent Review Date: September 16, 2015
Next Review Date: September 2016

Policy contains:
- Achalasia.
- Dysphagia.
- Esophageal motility disorder.
- Peroral endoscopic myotomy (POEM).

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

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

Coverage policy

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

Limitations:

None.

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 smooth muscle layer of the esophagus 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 five 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).

Achalasia is an incurable, chronic condition that requires life-long 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 (ACG, 2013). Established treatments for achalasia are open or laparoscopic esophagomyotomy (also known as Heller myotomy), with or without an antireflux procedure, and pneumatic dilation (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, such as calcium channel blockers and long-acting nitrates, are among the least effective. No intervention significantly affects esophageal peristalsis, and despite initial success of these therapeutic interventions the LES hypertonicity returns over time, requiring repeat interventions (ACG, 2013).

**Peroral endoscopic myotomy:**
Peroral endoscopic myotomy (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

Arbor Health Plan 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 August 14, 2015. 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

Arbor Health Plan 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 studies were published at the time of writing this policy. There is considerable overlap of investigators and, presumably, patient groups, reflecting 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 randomized controlled studies. Guidelines from the American College of Gastroenterology, the Society of American Gastrointestinal and Endoscopic Surgeons, and the American Society for Gastrointestinal Endoscopy highlight the need for randomized, controlled studies comparing the long-term efficacy POEM to established alternatives for treatment of achalasia before widespread adoption (Stafanidis, 2012; Vaezi, 2013; ASGE, 2014).

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content</th>
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<tbody>
<tr>
<td>Barbieri (2015)</td>
<td>Key points:</td>
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<td></td>
<td>• Systematic review of 16 non-randomized studies, case series or indirect comparisons with LHM (n = 551 patients) published from 2010 – 2013.</td>
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<td>• Mean ages from all studies (median 44 years; range: 32 – 64 years). Body mass index available only in four series (median 26; range, 25 – 27). Surveillance period (median 6 months; range, 3 – 12 months). Mean POEM duration (median 156 minutes; range, 42 – 112 minutes). Myotomy length (median 10 cm; range, 6 – 14 cm). Performed in dedicated settings.</td>
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<td>• Technical and clinical success reported in 97% (95% confidence interval [CI], 94 – 98) and 93% (95% CI, 90 – 95), respectively.</td>
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<td>• Most common adverse event: post-POEM esophagitis pooled rate was 13% (95% CI, 10 – 17).</td>
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<td>• Most common major adverse events that required medical or surgical interventions: hypertensive pneumomediastinum and intramediastinal bleeding treatable with decompression occurred in 14% (95% CI, 11 – 17); post-POEM surgery needed in 0.2% (95% CI, 0 – 0.5).</td>
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<td>• Conclusions: Highly feasible and safe in short term. POEM should only be performed in centers able to treat POEM complications, such as pneumothorax or pneumoperitoneum.</td>
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<tr>
<td>Hayes (2015)</td>
<td>Key points:</td>
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<td></td>
<td>• Search and summary report (no systematic review) of 26 studies, individual cohorts and indirect comparisons to alternative treatments. No randomized studies.</td>
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<td>• Report noted considerable overlap of authors and, presumably, patient groups. Some involved mixed patient groups that included patients with achalasia, along with patients with other types of esophageal motility disorders.</td>
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<td></td>
<td>• Four studies compared POEM with LHM; four reported outcomes comparing different POEM techniques.</td>
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<tr>
<td>Wei (2015)</td>
<td>Key points:</td>
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<td>• Systematic review and meta-analysis of four studies comparing POEM and LHM. All studies were conducted in the United States and published in 2013.</td>
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<td>• POEM was associated with comparable complications (odds ratio [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 recurrence by Eckardt score (OR = 0.24; 95% CI, 0.04 – 1.55; P = .13).</td>
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<td>• No significant difference between procedures in other outcomes, including pain score, operating time and hospital stay.</td>
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**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.

**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 that occur in 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.

**Pseudoachalasia** — A condition with signs and symptoms similar to primary achalasia, but caused by another disease such as a mass in the esophagus or a nerve disease affecting lower esophageal motility. It is also called secondary achalasia.
Related policies

Arbor Health Plan Utilization Management program description.

References

Professional society guidelines/other:


Peer-reviewed references:


Clinical trials:

Searched ClinicalTrials.gov on August 17, 2015, using terms “achalasia,” myotomy or "peroral endoscopic myotomy" or “POEM”. | Open Studies. . Twenty-five 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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