MEDICAL POLICY – 2.01.91
Peroral Endoscopic Myotomy (POEM) for Treatment of Esophageal Achalasia

BCBSA Ref. Policy: 2.01.91
Effective Date: Feb. 1, 2017
Last Revised: Nov. 10, 2017
Replaces: N/A

RELATED MEDICAL POLICIES:
- 2.01.38 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
- 7.01.137 Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease
- 8.01.17 Hematopoietic Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Esophageal achalasia is a rare problem with the esophagus. It affects the ability to pass food through the swallowing tube (the esophagus) and into the stomach. The muscles of the esophagus don’t move food down and the ring of muscles at the end of the esophagus don’t relax to easily allow food into the stomach. This makes swallowing very difficult. A new surgery, POEM (peroral endoscopic myotomy), is being tried. A viewing scope with a special cutting blade is passed through the mouth and into the esophagus. Part of the muscle layer of the lower part of the esophagus, the sphincter, and the upper part of the stomach is removed. POEM is investigational. More and larger studies are needed to compare POEM with standard surgery to treat esophageal achalasia.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Service</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peroral endoscopic myotomy</td>
<td>Peroral endoscopic myotomy (POEM) is considered investigational as a treatment for esophageal achalasia.</td>
</tr>
<tr>
<td></td>
<td><strong>Note:</strong> This policy addresses POEM. A similar acronym, POEMS syndrome, describes a different condition and is addressed in a separate medical policy. Please see Related Policies.</td>
</tr>
</tbody>
</table>

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>43499</td>
<td>Unlisted procedure, esophagus</td>
</tr>
</tbody>
</table>

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Related Information

N/A

Evidence Review

Background

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. Estimated U.S. prevalence of achalasia is 10 cases per 100,000, and estimated incidence is 0.6 cases per 100,000 per year. Treatment options for achalasia have traditionally included pharmacotherapy such as injections with botulinum toxin, pneumatic dilation, and laparoscopic Heller myotomy. Although the last two are considered the mainstay of treatment because of higher success rates and relative long-term efficacy compared with pharmacotherapy and botulinum toxin injections, both are associated with a perforation risk of about 1%. Laparoscopic Heller myotomy is the most invasive of the procedures, requiring laparoscopy and surgical dissection of the esophagogastric junction. One-year response rates of 86% and rates of major mucosal tears requiring subsequent intervention of 0.6% have been reported.

Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure developed in Japan by Dr. Haruhiro Inoue et al. POEM is performed with the patient under general anesthesia. After tunneling an endoscope down the esophagus toward the esophageal gastric junction, a surgeon performs the myotomy by cutting only the inner, circular lower esophageal sphincter (LES) muscles through a submucosal tunnel created in the proximal esophageal mucosa. POEM differs from laparoscopic surgery, which involves complete division of both circular and longitudinal LES muscle layers. Cutting the dysfunctional muscle fibers that prevent the LES from opening allows food to enter the stomach more easily.

Please note that the acronym POEM in this policy refers to peroral endoscopic myotomy. POEMS syndrome, which uses a similar acronym, is discussed in a separate medical policy (see Related Policies).

Summary of Evidence

For individuals who have achalasia who receive peroral endoscopic myotomy (POEM), the evidence includes systematic reviews, nonrandomized comparative studies, and case series. Relevant outcomes are symptoms, functional outcomes, health status measures, resource utilization, and treatment-related morbidity. The comparative studies reported primarily similar outcomes with POEM and with Heller myotomy for symptom relief, as assessed by the Eckardt score. Some studies showed shorter length of stay and less postoperative pain with POEM. However, potential imbalances in patient characteristics in these nonrandomized studies may 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, 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 esophagitis requiring
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.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td><strong>Ongoing</strong></td>
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<td></td>
<td></td>
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<tr>
<td>NCT02138643</td>
<td>Laparoscopy Heller Myotomy With Fundoplication Associated Versus Peroral Endoscopic Myotomy (POEM)</td>
<td>30</td>
<td>Feb 2017</td>
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<tr>
<td>NCT01601678</td>
<td>Endoscopic Versus Laparoscopic Myotomy for Treatment of Idiopathic Achalasia: A Randomized, Controlled Trial</td>
<td>220</td>
<td>Dec 2019</td>
</tr>
<tr>
<td>NCT01793922</td>
<td>A Prospective Randomized Multi-center Study Comparing Endoscopic Pneumodilation and Per Oral Endoscopic Myotomy (POEM) as Treatment of Idiopathic Achalasia</td>
<td>150</td>
<td>Jan 2023</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT01742494</td>
<td>Comparison Study of Conventional POEM and Hybrid POEM for Esophageal Achalasia</td>
<td>100</td>
<td>Dec 2012</td>
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<tr>
<td>NCT01750385</td>
<td>Bacteremia and Procalcitonin Levels in Peroral Endoscopic Myotomy for Achalasia</td>
<td>60</td>
<td>Aug 2013</td>
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<tr>
<td>NCT01768091</td>
<td>Peroral Endoscopic Myotomy Versus Pneumatic Dilation for Esophageal Achalasia: a Prospective Randomized Controlled Trial</td>
<td>200</td>
<td>Dec 2013</td>
</tr>
</tbody>
</table>

NCT: national clinical trial
Practice Guidelines and Position Statements

**Society of American Gastrointestinal and Endoscopic Surgeons**

In 2011, the Society of American Gastrointestinal and Endoscopic Surgeons issued an evidence-based, consensus guideline on the surgical management of esophageal achalasia. The guideline stated that the POEM technique “is in its infancy and further experience is needed before providing recommendations.”

**American College of Gastroenterology**

In 2013, the American College of Gastroenterology issued a clinical guideline on the diagnosis and management of achalasia. POEM was discussed as an emerging therapy, and stated to have promise as an alternative to the laparoscopic approach. The guideline further states that randomized prospective comparison trials are needed, and the procedure should be performed in the context of clinical trials.

**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.

**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.

**References**


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/11/13</td>
<td>New Policy. Policy created with literature search through August 1, 2013; considered investigational.</td>
</tr>
<tr>
<td>11/20/14</td>
<td>Annual Review. Policy updated with literature review through August 18, 2014; references 3, 6-7, 9-12, and 18 added; no change to policy statement. ICD-9 and ICD-10 diagnosis codes removed; these do not relate to adjudication of this policy.</td>
</tr>
<tr>
<td>02/01/17</td>
<td>Annual Review, approved January 10, 2017. Policy updated with literature review through October 10, 2016; references 6-8, 10-11, and 15-16 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>11/10/17</td>
<td>Policy moved to new format, no changes to policy statement.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.
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  - Information written in other languages

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  Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)


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Daytroy a Pakdaak ket naglaon iti Napagte nga Impormasion. Daytroy a pakdaak mabalin nga adda ket naglaon iti napagte nga impormasion maipanggep iti aplikasyon woy yoy coverage babaen iti Premera Blue Cross. Daytroy ket mabalin dagiti importante a petsa iti daytroy a pakdaak. Mabalin nga adda rumbeng nga aramideny nga adda sakkay dagiti partikular a naituding nga adda alaw tapno mapagtailadney a coverage ti saluy-ayno woy tulong kadagit gastos. Adda karbenganyo a mangala iti daytroy nga impormasion ken tulong iti bukdyo a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

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Por favor, lea con atención y conserve los documentos importantes.

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