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

BCBSA Ref. Policy: 2.01.91
Effective Date: Feb. 1, 2019
Last Revised: Jan. 4, 2019
Replaces: N/A

<table>
<thead>
<tr>
<th>RELATED MEDICAL POLICIES:</th>
<th>2.01.38</th>
<th>Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7.01.137</td>
<td>Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease</td>
</tr>
<tr>
<td></td>
<td>8.01.17</td>
<td>Hematopoietic Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome</td>
</tr>
</tbody>
</table>

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 (the swallowing tube). It affects the ability to pass food through 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>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peroral endoscopic myotomy</td>
<td>Peroral endoscopic myotomy is considered investigational as a treatment for esophageal achalasia.</td>
</tr>
<tr>
<td>Note:</td>
<td>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>Unlisted procedure, esophagus</td>
</tr>
</tbody>
</table>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

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.

**Background**

**Esophageal Achalasia**

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. The estimated U.S. prevalence of achalasia is 10 cases per 100,000, and the estimated incidence is 0.6 cases per 100,000 per year.¹

**Treatment**

Treatment options for achalasia have included pharmacotherapy such as injections with botulinum toxin, pneumatic dilation, and laparoscopic Heller myotomy.¹² Although the latter two are considered the standard treatments because of higher success rates and relatively long-term efficacy compared with pharmacotherapy, both are associated with a perforation risk of about 1%. Heller myotomy is the most invasive of the procedures, requiring laparoscopy and surgical dissection of the esophagogastric junction.² One-year response rates of 86% and major mucosal tear rates requiring subsequent intervention of 0.6% have been reported.³

Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure developed in Japan.²⁴ POEM is performed with the patient under general anesthesia.⁵ 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 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 lower esophageal sphincter muscle layers. Cutting the dysfunctional muscle fibers that prevent the lower esophageal sphincter from opening allows food to enter the stomach more easily.²⁵

**NOTE:** 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 with 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 morbidity. The comparative studies have primarily reported similar outcomes with 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, 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.

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>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02138643</td>
<td>Laparoscopy Heller Myotomy With Fundoplication Associated Versus Peroral Endoscopic Myotomy (POEM)</td>
<td>30</td>
<td>Dec 2017 (ongoing)</td>
</tr>
<tr>
<td>NCT03228758</td>
<td>Efficacy of Anterior Versus Posterior Myotomy Approach in Peroral Endoscopic Myotomy (POEM) for the Treatment of Achalasia – a Single Operator Analysis</td>
<td>290</td>
<td>Nov 2019</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>NCT01402518</td>
<td>Observational Study of the Peroral Endoscopic Myotomy (POEM) Procedure</td>
<td>100</td>
<td>Nov 2019</td>
</tr>
<tr>
<td>NCT01601678</td>
<td>Endoscopic Versus Laparoscopic Myotomy for Treatment of Idiopathic Achalasia: A Randomized, Controlled Trial</td>
<td>240</td>
<td>Dec 2019</td>
</tr>
<tr>
<td>NCT01832779</td>
<td>Prospective Evaluation of the Clinical Utility of Peroral Endoscopic Myotomy (POEM)</td>
<td>600</td>
<td>Dec 2022</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>
</tbody>
</table>

NCT: national clinical trial

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. 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 American 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. 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. 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.”

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. 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 2 summarizes POEM recommendations.

Table 2. Recommendations for the Treatment of Achalasia

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>LOR</th>
<th>GOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>POEM is an effective therapy for achalasia both in short-term and medium-term follow-up with results comparable to Heller myotomy.</td>
<td>Conditional</td>
<td>Very low</td>
</tr>
<tr>
<td>POEM is an effective therapy for achalasia both in short-term and medium-term follow-up with results comparable to pneumatic dilations.</td>
<td>Conditional</td>
<td>Low</td>
</tr>
<tr>
<td>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>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>POEM may be considered an option for treating recurrent symptoms after laparoscopic Heller myotomy.</td>
<td>Conditional</td>
<td>Low</td>
</tr>
<tr>
<td>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

Medicare National Coverage

There is no national coverage determination.

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.


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<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>12/01/16</td>
<td>Annual Review, approved November 8, 2016. Policy reviewed with literature search through September 2016; No change to policy statement</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 whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination Is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):

Chinese (Chinese):
本通知有重要的讯息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保護的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Cushite (Oromo):
Oromoo (Cushite):

Italian (Italian):
Premera Blue Cross (TTY: 800-842-5357).

Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas claras en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costos adicionales. Líme al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog): Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay maaaring naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring magauna pa sa hango ng mga kahulugan ng impormasyon ni le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua ai na olo'o iai iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o le'a iai ni feau e tatau ona e faia ao le'i aulia le a loa o