**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>
</tbody>
</table>

**Note:** 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](#).

### 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>

**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 (e.g., 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</td>
<td>Conditional</td>
<td>Very low</td>
</tr>
<tr>
<td>follow-up with results comparable to Heller myotomy.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>POEM is an effective therapy for achalasia both in short-term and medium-term</td>
<td>Conditional</td>
<td>Low</td>
</tr>
<tr>
<td>follow-up with results comparable to pneumatic dilations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pretreatment information on GERD, nonsurgical options (pneumatic dilation), and</td>
<td>Good practice</td>
<td>NA</td>
</tr>
<tr>
<td>surgical options with lower GERD risk (Heller myotomy) should be provided to</td>
<td></td>
<td></td>
</tr>
<tr>
<td>patient.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>POEM is feasible and effective for symptom relief in patients previously treated</td>
<td>Conditional</td>
<td>Very low</td>
</tr>
<tr>
<td>with endoscopic therapies.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>POEM may be considered an option for treating recurrent symptoms after</td>
<td>Conditional</td>
<td>Low</td>
</tr>
<tr>
<td>laparoscopic Heller myotomy.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate training (in vivo/in vitro animal model) and proctorship should be</td>
<td>Good practice</td>
<td>NA</td>
</tr>
<tr>
<td>considered prior to a clinical program of POEM.</td>
<td></td>
<td></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.

**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>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</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>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 coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

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  - Qualified interpreters
  - Information written in other languages

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Toll free 855-332-4535, Fax 425-918-5592, TTY 800-537-7697 (TDD)

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.

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, 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).

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Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalini nga adda ket naglaon iti napateg nga impormasion maiapangep iti aplikasyonwo yonno coverage babaen iti Premera Blue Cross. Daytoy ket mabalini dagiti importante a pelta iti daytoy a pakdaar. Mabalini nga adda rumbeng nga aramideny nga addang sabbay dagiti particulak a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-ayyo yonno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagsasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

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본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 특이가 되는 날짜들이 있을 수 있습니다. 귀하는 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하는 이러한 정보와 도움을 귀하의 안전과 비용 부담없이 얻을 수 있는 권리가 있습니다。800-722-1471（TTY: 800-842-5357）로 전화하시는洽谈。

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Māori (Maori):

Punjabi (Punjabi):
ਹਾ ਸਕਦੀ ਹੋ ਵਾਲਣ ਲਈ ਇਹ ਰੱਖਿਆ ਜਾਂਦਾ ਹੈ। ਹਾ ਸਕਦੀ ਹੋ ਵਾਲਣ ਲਈ ਇਹ ਰੱਖਿਆ ਜਾਂਦਾ ਹੈ। ਹਾ ਸਕਦੀ ਹੋ ਵਾਲਣ ਲਈ ਇਹ ਰੱਖਿਆ ਜਾਂਦਾ ਹੈ। ਹਾ ਸਕਦੀ ਹੋ ਵਾਲਣ ਲਈ ਇਹ ਰੱਖਿਆ ਜਾਂਦਾ ਹੈ। ਹਾ ਸਕਦੀ ਹੋ ਵਾਲਣ ਲਈ ਇਹ ਰੱਖਿਆ ਜਾਂਦਾ ਹੈ। ਹਾ ਸਕਦੀ ਹੋ ਵਾਲਣ ਲਈ ਇਹ ਰੱਖਿਆ ਜਾਂਦਾ ਹੈ। ਹਾ ਸਕਦੀ ਹੋ ਵਾਲਣ ਲਈ ਇਹ ਰੱਖਿਆ ਜਾਂਦਾ ਹੈ। ਹਾ ਸਕਦੀ ਹੋ ਵਾਲਣ ਲਈ ਇਹ ਰੱਖਿਆ ਜਾਂਦਾ ਹੈ।

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Ang Panawana na ito ay naglalaman ng mahalagang impormasyon. Ang panawana na ito ay maaring naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang pahina dito sa panawana. Maaaring maging alamang na ka na mga h wbahag na habang sa ilang mga ilang panahon unang mapanatili ang iyong pagsakop sa kalusugan o tulong na tungo sa walang gastos. May karapatan ka na makakuha ng galing impormasyon at tungo sa iyong wika ng walang gastos. Turnaw sa 800-722-1471 (TTY: 800-842-5357).

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