Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia

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 pediatric and adult 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>

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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**

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. Treatment options for achalasia have included pharmacotherapy (eg, injections with botulinum toxin), pneumatic dilation, and laparoscopic Heller myotomy. 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. One-year response rates of 86% and major mucosal tear rates requiring the subsequent intervention of 0.6% have been reported.

Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure developed in Japan. 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 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.

**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 adults who have achalasia who receive POEM, the evidence includes systematic reviews of observational studies, a randomized control trial, 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 for POEM and for laparoscopic Heller myotomy (LHM) in symptom relief, as assessed by the Eckardt score. Some studies have shown a 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, the 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.

For pediatric patients who have achalasia who receive POEM, the evidence includes several nonrandomized studies and a systematic review. The relevant outcomes are symptoms, functional outcomes, health status measures, resource utilization, and treatment-related morbidity. The studies reported treatment success for POEM based on decreases in Eckardt scores and lower esophageal sphincter (LES) pressure. No randomized clinical trials have been reported. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and 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>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>
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<td>--------------</td>
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</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</td>
<td>240</td>
<td>Dec 2020</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>

Unpublished

| NCT02138643  | Laparoscopy Heller Myotomy With Fundoplication Associated Versus Peroral Endoscopic Myotomy (POEM) | 30                  | Dec 2017        |

NCT: national clinical trial

Practice Guidelines and Position Statements

**American Gastroenterological Association Institute**

The American Gastroenterological Association Institute (2017) published a clinical practice update on the use of peroral endoscopic myotomy (POEM) for the treatment of achalasia. Based on the 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

The American Society of Gastrointestinal and Endoscopic Surgeons (2014) 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

The American College of Gastroenterology (2013) 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

The Society of American Gastrointestinal and Endoscopic Surgeons (2012) 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

The International Society for Diseases of the Esophagus (2018) 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>11/11/13</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>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>
<tr>
<td>02/01/20</td>
<td>Annual Review, approved January 9, 2020. Policy updated with literature review through September 2019; references added. Policy statement clarified; for pediatric and adult esophageal achalasia; intent unchanged.</td>
</tr>
</tbody>
</table>

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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)

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Tsab ntawv tshaj xo no muaj cov ntsiab lus tseem ceeb. Tej zaum tsab ntawv tshaj xo no muaj cov ntsiab lus tseem cebb bok mg daim ntawv thov kev pab los yoj koq chov kev pab cuam los ntsawm Premera Blue Cross. Tej zaum muaj cov nhb tseem ceeb cuam rsau haub daim ntawv no. Tej zaum mono kuj yuav tau uq qee yam uas peb kom mg uas tsip pub dhaus cov caj nyong uas teev tsig rau haub daim ntawv no mas kij taj yuav taus baas kev pab cuam kho moh los yoj kev pab them tej nqi kho moh ntawv. Koj muaj cai kom lawv muab cov ntsiab lus no uas tau muab sau uq koh hom lus pub dawb rau koh. Hu rau 800-722-1471 (TTY: 800-842-5357).

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Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalina nga adda ket naglaon iti napateg nga impormasion maijanggep iti aplikasyon woyy coverage babaen iti Premera Blue Cross. Daytoy ket mabalina dagiti importante a pelsa iti daytoy a pakdaar. Mabalina nga adda rumbeg nga aramidenyo nga addang sabbay dagiti partikular a naituding nga adda aldaw tapo mapatagalinayio dey coverage ti salun-atyo wenno tungol kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tungol iti bukodyo a pagasaso nga awan ti bayadangy. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):

Oromoo (Cushite):

Chinese (Chinese):