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></td>
<td>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.</td>
</tr>
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Coding

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

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Related Information

N/A

Evidence Review
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. 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 the surgery.

NOTE: The acronym POEM in this policy refers to peroral endoscopic myotomy. POEMS syndrome, which uses a similar acronym, is an entirely different condition and is discussed in a separate medical policy (see Related Policies).

Treatment

Treatment options for achalasia have included pharmacotherapy such as injections with botulinum toxin, pneumatic dilation, and laparoscopic Heller myotomy. Although the last 2 are considered the mainstay of treatment because of higher success rates and relatively 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 major mucosal tear rates requiring 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.
Summary of Evidence

For individuals who have achalasia who receive 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 have primarily reported similar outcomes with POEM and with Heller myotomy for 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 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 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>
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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>Dec 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>
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Practice Guidelines and Position Statements

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. Peroral endoscopic myotomy 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 peroral endoscopic myotomy technique “is in its infancy and further experience is needed before providing recommendations.”
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>
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<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>
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  • Qualified interpreters
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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)

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