Peroral Endoscopic Myotomy (POEM) for Treatment of Esophageal Achalasia

Policy

Peroral endoscopic myotomy (POEM) is considered investigational as a treatment for esophageal achalasia.

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.

Related Policies

2.01.38 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
7.01.137 Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD)
8.01.17 Hematopoietic Stem-Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome

Policy Guidelines

Coding

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Description

Esophageal achalasia is characterized by prolonged occlusion of the lower esophageal sphincter (LES) 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 LES. This procedure has the intent of reducing the total number of incisions needed and, thus, reducing the overall invasiveness of surgery.

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 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.

**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.\(^1\) Treatment options for achalasia have traditionally included pharmacotherapy such as injections with botulinum toxin, pneumatic dilation, and laparoscopic Heller myotomy.\(^1,2\) 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.\(^2\) One-year response rates of 86% and rates of major mucosal tears requiring subsequent intervention of 0.6% have been reported.\(^3\)

Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure developed in Japan by Dr. Haruhiro Inoue et al.\(^2,4\) 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 (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.\(^2,5\)

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).

**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.

**Scope**

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer 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.
**Benefit Application**

N/A

**Rationale**

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<td>Interventions of interest are:</td>
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<td>Relevant outcomes include:</td>
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<td>• Peroral endoscopic myotomy</td>
<td>• Esophageal dilatation</td>
<td>• Symptoms</td>
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<td>• Heller myotomy</td>
<td>• Functional outcomes</td>
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<td>• Botulinum toxin injection</td>
<td>• Health status measures</td>
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This policy was created in September 2013 and has been updated with a search of the MEDLINE database through October 10, 2016. Literature included in this review on the efficacy of peroral endoscopic myotomy (POEM) is comprised of 4 nonrandomized comparative studies and several case series studies. No randomized controlled trials (RCTs) comparing POEM with other treatment options have been found. Following is a summary of the nonrandomized studies and selected larger series (≥50 patients) on this procedure.

**Systematic Reviews**

Several systematic reviews have evaluated the outcomes of POEM. Three recent reviews have summarized outcomes of case series studies.(6-8) The systematic review by Akintoye et al (2016) evaluated outcomes for 2373 patients from 36 studies.(6) Clinical success rates were achieved in 98% of patients (95% confidence interval [CI], 97% to 100%) and mean Eckardt scores decreased from baseline at 1, 6, and 12 months. (The Eckardt score grades 4 major symptoms of achalasia [dysphagia, regurgitation, retrosternal pain, weight loss] each on a 0 [none] to 3 [severe] scale, for a maximum score of 12; total scores of ≥4 represent treatment failure.) The systematic review by Crespin et al (2016) evaluated outcomes for 1299 patients from 19 studies.(7) Improvements in Eckardt scores were statistically significant in all studies. The most frequently reported complications were mucosal perforation, pneumothorax, pneumoperitoneum, and subcutaneous emphysema. The systematic review by Patel et al (2016) evaluated outcomes for 1122 patients from 22 studies.(8) Eckardt scores dropped from 6.8 at baseline to 1.2 postoperatively. There were improvements in lower esophageal sphincter (LES) pressure and symptoms.

Two systematic reviews only selected studies comparing POEM to an alternative surgical treatment.(10,11) We only report results from the systematic review by Marano et al (2016) because it included the period of time covered in the other review and assessed more patients and studies.(10) It evaluated outcomes for 486 patients (196 receiving POEM, 290 receiving laparoscopic Heller myotomy [LHM]) from 11 studies. None were randomized. Reviewers rated all studies to have a moderate risk of bias. No information on differences in disease severity between treatment groups was provided. There were no significant differences in the reduction of Eckardt scores, postoperative pain scores, or requirements for analgesics between procedures. Hospital length of stay was shorter for POEM.

**Section Summary**

Conclusions on comparative efficacy cannot be determined from these systematic reviews, because reviews of case series do not assess comparator treatments. The systematic reviews evaluating comparative studies only included nonrandomized studies and does not appear to have taken into account differences in patient characteristics.

**Nonrandomized Comparative Studies**
In a nonrandomized trial with historical control, Hungness et al. (2013) reported on perioperative outcomes in patients with achalasia treated with POEM (n=18) or laparoscopic Heller myotomy (LHM) (n=55) at a single U.S. center. Operative times were shorter for POEM than for LHM (113 and 125 minutes, respectively, p<0.05). Additionally, estimated blood loss was less in patients treated with POEM (≤10 mL in all POEM cases vs 50 mL for LHM, p<0.001). Myotomy lengths, complication rates, and length of stay were similar between groups. Pain scores were similar post-anesthesia and post-operatively on the first day, but were higher at 2 hours for POEM patients (3.5 vs. 2.0, p=0.03). Narcotic use was similar between groups, although fewer patients treated with POEM received ketorolac, a nonsteroidal anti-inflammatory drug. POEM patients’ Eckardt scores decreased (median 1 post-operative vs. 7 preoperative, p<0.001), and 16 patients (89%) had treatment success (score≤3) at a median of 6 months follow-up.

In a retrospective study of a prospective database at Oregon Health & Sciences University (Portland, OR), Bhayani et al. (2014) compared outcomes in 37 patients who underwent POEM and 64 patients who underwent LHM for achalasia. Full-thickness esophageal injury occurred in 4 POEM patients, and 8 esophageal and 3 gastric perforations occurred in LHM patients. Mean (SD) hospitalization was 1.1 (0.6) days in the POEM group versus 2.2 (1.9) days in the LHM group (Mann-Whitney U test for all comparisons, p<0.001). Eckardt scores were statistically lower postoperatively in the POEM group compared with the LHM group (p<0.001), but at 6 months (64% of patients assessed), Eckardt scores did not differ statistically between groups (p=0.1). Postoperative decreases in lower esophageal sphincter (LES) pressures were similar between groups. At 6 months, resting LES pressure was higher in the POEM group compared with the LHM group (16 mm Hg vs. 7 mm Hg, p=0.006). (LES pressure >15 mm Hg predicts recurrent dysphagia.)

In a retrospective study of patients with type III achalasia, Kumbhari et al. (2015) compared outcomes of 49 patients who underwent POEM versus 25 patients who underwent LHM. Defining clinical response as a reduction in Eckardt score to 1 or less, clinical response was more frequent in the POEM group than the LHM group (98.0% vs. 80.8%, p<0.01). However, LHM patients had more severe disease by several different measures. On multivariable analysis, there was no statistically significant difference in the odds of failure between procedures, although the point estimate of the odds was in favor of POEM (odds ratio, 11.32; p=0.06). Procedure times were shorter with POEM. There was no difference in length of stay. The overall rate of adverse events was lower in the POEM group (27% vs. 6%, p=0.01).

Ujiki et al. (2013) compared outcomes of 18 patients undergoing POEM to 21 patients who underwent LHM. Postoperative Eckardt scores were similar (POEM 0.7 vs. LHM 1.0). Several outcomes related to recovery from surgery were in favor of POEM; postoperative pain, analgesic use, and return to activities of daily living.

Sanaka et al (2016) compared outcomes in their own institution for 36 patients undergoing POEM, 142 undergoing LHM, and 36 undergoing pneumatic dilation. At baseline, patients undergoing the 3 procedures had different characteristics. POEM patients were older, had higher body mass index, and had more prior treatments. After treatment, patients undergoing all 3 procedures had significant improvements as measured by high-resolution esophageal manometry and timed barium esophagram. Eckhardt symptom scores were only available for POEM patients. Long-term outcomes were not reported.

Wang et al (2016) retrospectively reviewed outcomes for POEM (n=21) and pneumatic dilation (n=10) in patients ages 65 years and older. All were treated successfully, with decreases in Eckardt scores. At a mean follow-up of 21.8 months for POEM and 35 months for pneumatic dilation patients, 1 POEM case failed and 2 pneumatic dilation procedures failed.

**Section Summary**

The nonrandomized studies comparing POEM to other procedures are retrospective and involved patients who may not be comparable. Although outcomes were generally similar between POEM and the comparator treatments (LHM, pneumatic dilation), potential confounding and selection bias make outcome comparisons uncertain. The comparative studies did not report long-term outcomes.

**Selected Case Series Studies**

Inoue et al. (2015) reported outcomes on 500 consecutive patients at a Japanese institution. Outcomes were available for variable proportion of patients at various time intervals after the procedure; 302 (60.4%) at 2 months, 102 (27.6% of 370) at 1 to 2 years, and 61 (58.1% of 105) at more than 3 years. The median Eckardt score at all
time points was 1. Lower esophageal sphincter pressure ranged from 13.4 to 11.7. Between 16.8% and 21.3% of subjects reported symptoms of GERD. The overall complication rate was 3.2%.

Ramchandani et al. reported outcomes on 200 consecutive patients at one institution in India. (19) Outcomes at 1 year were available for 102 patients. Clinical success as defined as an Eckardt score of 3 or less was achieved in 92% on a per-protocol analysis and 83% on intention-to-treat analysis which included additional patients with technical failure and patients lost to follow-up. The mean Eckardt score was 1.18 after POEM.

In a prospective case series, von Renteln et al. (2013) reported on 70 patients who underwent POEM at five centers in Europe and North America. (20) Mean follow-up period was 10 months (range, 3-12 months). Follow-up evaluation at 6 months and 1 year showed sustained treatment success of 89% and 82%, respectively. Mean pretreatment Eckardt score was 6.9 compared with 1.3 at 6 months and 1.7 at 1 year (p<0.001 for both comparisons with pretreatment score). In Multivariate analysis, neither age, previous treatment (Botox/dilation), myotomy length, pre-procedure LES pressure, pretreatment Eckardt score, sex, procedure duration, nor full-thickness dissection during POEM were significant predictors of treatment failure at 1 year. At 3 months after POEM, esophagitis was observed in 42% of cases. However, severity of esophagitis was minor (grade A or B), and all patients could be managed adequately with proton pump inhibitor (PPI) therapy. At 3 months, 22% of patients required occasional and 12% required daily PPI therapy. The 1-year follow-up evaluation showed overall rates of gastroesophageal reflux disease of 37%, and PPI use of 29%. Other complication rates of POEM ranged from 1% to 4%.

Teitelbaum et al. (2014) also evaluated 1-year outcomes after POEM. (21) Forty-one patients who were treated at Northwestern University (Evanston, IL) and were more than 1 year post-POEM were included. Most patients (37 [90%]) had no previous endoscopic treatment (botulinum toxin injection or pneumatic dilation). Ninety-two percent of 39 patients available for symptom assessment had treatment success (Eckardt score <4). In 21 patients evaluated, mean (SD) LES pressure was 11(4) mm Hg.

Ling et al. (2014) reported quality-of-life outcomes in 2 (probably overlapping) patient cohorts who underwent POEM for achalasia at a single center in China. Quality of life was assessed at pretreatment and at 1-year follow-up using the 36-Item Short-Form Health Survey; Physical Component Summary (PCS) and Mental Component Summary (MCS) raw scores were transformed to a 0 (poor health) to 100 (good health) scale. In a group of 21 patients who had failed previous pneumatic dilation, mean (SD) PCS improved from 30(13) to 65(10), and mean MCS improved from 43(10) to 67(11) (Student t test, p<0.001 for both comparisons). (22) Incidence of intraoperative subcutaneous emphysema and pneumothorax was 14% and 5%, respectively; postoperative esophagitis developed in 19%. In 87 previously untreated patients, mean (SD) PCS improved from 33(11) to 69(18) (Student t test, p<0.001), and mean (SD) MCS improved from 44(13) to 67(15) (Student t test, p=0.003). (23) Incidence of intraoperative subcutaneous emphysema and pneumothorax was 12% and 1%, respectively; postoperative esophagitis developed in 6%.

The study by Ren et al. (2012) highlighted POEM-specific complications. (24) In their series of 119 cases, 23% of patients developed subcutaneous emphysema intraoperatively and an additional 56%, postoperatively. Three of these patients required treatment with subcutaneous needle decompression. Additionally, 3% patients developed a pneumothorax intraoperatively and another 25% postoperatively. Postoperatively, the incidence of thoracic effusion was 49%, and of mild inflammation or segmental atelectasis of the lungs was 50%. All complications were resolved with conservative treatment.

At least two small case series have evaluated the efficacy and feasibility of POEM for patients with failed Heller myotomy/achalasia recurrence; success rates have been reported in over 90% of cases up to 10 months after rescue POEM. (25,26) Studies also have compared different POEM techniques; comparable outcomes have been reported between patients undergoing full-thickness versus circular myotomy. (20) An international survey of 16 centers (seven in North America, five in Asia, four in Europe, some of which were high-volume centers [≥30 POEMS per center]) reported 841 POEM procedures performed as of July 2012. (27)

Section Summary
Case series have shown improvement in symptoms of achalasia after POEM. Such studies do not permit comparison to other established treatments.
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

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<td>NCT01601678</td>
<td>Endoscopic Versus Laparoscopic Myotomy for Treatment of Idiopathic Achalasia: A Randomized Controlled Trial</td>
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<td>Dec 2019</td>
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<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>
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<td>Achalasia: a Prospective Randomized Controlled Trial</td>
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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.”(28)

American College of Gastroenterology
In 2013, the American College of Gastroenterology issued a clinical guideline on the diagnosis and management of achalasia.(29) 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.

U.S. Preventive Services Task Force Recommendations
Not applicable.
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.

References


Appendix

N/A

History

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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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Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніться у службу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефона 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):