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.

Related Policies

- Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
- Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD)

Policy

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

Policy Guidelines

There are no specific CPT codes for this procedure. It would likely be reported with the unlisted procedure, esophagus code 43499.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.
Rationale

Background

Estimated U.S. prevalence of achalasia is 10 cases per 100,000, and estimated incidence is 0.6 cases per 100,000 per year. Treatment options for achalasia have traditionally 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 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. One-year response rates of 86% and rates of major mucosal tears requiring subsequent intervention of 0.6% have been reported.

Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure developed in Japan by Dr. Haruhiro Inoue et al. 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 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.

Please note that the acronym POEM in this policy refers to peroral endoscopic myotomy. POEMS syndrome, which uses a similar acronym, is discussed in Policy No. 8.01.17 (Hematopoietic Stem-Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome).

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.

Literature Search

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 postanesthesia and postoperatively 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 postoperative vs 7 preoperative, p<0.001), and 16 patients (89%) had treatment success (score ≤3) at a median of 6 months follow-up. 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 and above represent treatment failure.
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 vs 7 mm Hg, p=0.006).

In a prospective case series, von Renteln et al (2013) reported on 70 patients who underwent POEM at 5 centers in Europe and North America. Mean follow-up period was 10 months (range, 3-12). 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/dilatation), myotomy length, preprocedure 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. 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. (LES pressure >15 mm Hg predicts recurrent dysphagia.)

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). 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). Incidence of intraoperative subcutaneous emphysema and pneumothorax was 12% and 1% respectively; postoperative esophagitis developed in 6%.

The largest published POEM series to date, by Ren et al (2012), highlighted POEM-specific complications. 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 2 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. Studies also
have compared different POEM techniques; comparable outcomes have been
reported between patients undergoing full-thickness versus circular myotomy. An
international survey of 16 centers (7 in North America, 5 in Asia, 4 in Europe, some of
which were high-volume centers [≥30 POEMs per center]) reported 841 POEM
procedures performed as of July 2012.

**Ongoing and Unpublished Clinical Trials**

An online search of ClinicalTrials.gov with the search terms “achalasia” and “peroral”
and “myotomy” identified 22 active POEM studies. Six registered RCTs are listed in
Table 1; none is set in the United States.

**Table 1. Active POEM Randomized Controlled Trials Listed at ClinicalTrials.gov**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Title</th>
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<td>NCT01601678</td>
<td>Endoscopic Versus Laparoscopic Myotomy for Treatment of Idiopathic Achalasia: A Randomized,</td>
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<td>Controlled Trial</td>
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<td>NCT01750385</td>
<td>Bacteremia and Procalcitonin Levels in Peroral Endoscopic Myotomy for Achalasia</td>
<td>60</td>
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<tr>
<td>NCT01793922</td>
<td>POEM Trial: Multi-center Study Comparing Endoscopic Pneumodilation and Per Oral Endoscopic Myotomy (POEM)</td>
<td>150</td>
<td>Jan 2018</td>
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<tr>
<td>NCT02138643</td>
<td>Laparoscopy Heller Myotomy With Fundoplication Associated Versus Peroral Endoscopic Myotomy (POEM)</td>
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a Estimated.
b Expected.

**Summary of Evidence**

Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure for treatment of esophageal achalasia that uses the oral cavity as a natural orifice entry point for lower esophageal sphincter (LES) myotomy. The intent of this approach is to reduce
the total number of incisions needed and, thus, the overall invasiveness of surgery. The evidence base comprises case series, cohort studies, and 2 nonrandomized comparative studies. 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. In a nonrandomized historical control trial, investigators reported that POEM resulted in shorter operative times and less blood loss than laparoscopic Heller myotomy (LHM), although myotomy lengths, complication rates, length of stay, and narcotic use were similar between surgical groups. A retrospective review showed higher LES pressure at 6 months in patients who underwent POEM compared with those who underwent LHM.

Evidence shows that the POEM technique is evolving and does not yet have a strong evidence base. Uncontrolled case series demonstrated that it can improve symptoms in patients with achalasia, but that adverse effects commonly occur. No studies have determined efficacy and safety compared with a control group, and no comparative effectiveness studies have evaluated long-term outcomes with POEM versus alternative treatment. Therefore, the use of POEM for treatment of esophageal achalasia is considered investigational.

SUPPLEMENTAL INFORMATION

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.”18

U.S. Preventive Services Task Force Recommendations

Peroral endoscopic myotomy is not a preventive service.

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


**Documentation Required for Clinical Review**

- No records required
Medical Policy

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis, or device code(s) does not constitute or imply member coverage or provider reimbursement.

IE

The following services are considered investigational and therefore not covered for any indication.

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<th>Type</th>
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Policy History

This section provides a chronological history of the activities, updates, and changes that have occurred with this Medical Policy.

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<th>Effective Date</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>1/30/2015</td>
<td>BCBSA Medical policy adoption</td>
<td>Medical Policy Committee</td>
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</table>

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain
indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements**

This service (or procedure) is considered *medically necessary* in certain instances and *investigational* in others (refer to policy for details).

For instances when the indication is *medically necessary*, clinical evidence is required to determine medical necessity. For instances when the indication is *investigational*, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.