

POLICY TITLE	PERORAL ENDOSCOPIC MYOTOMY (POEM) FOR TREATMENT OF ESOPHAGEAL ACHALASIA
POLICY NUMBER	MP-1.143

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I. POLICY

Peroral endoscopic myotomy is considered **investigational** as a treatment for esophageal achalasia as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:

MP-2.053 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

II. PRODUCT VARIATIONS

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[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids

[N] Indemnity

[N] PPO

[N] SpecialCare

[N] HMO

[N] POS

[N] SeniorBlue HMO

[N] FEP PPO

[N] SeniorBlue PPO

III. DESCRIPTION/BACKGROUND

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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

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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.

Achalasia has an estimated prevalence in the United States of 10 cases per 100,000, with an incidence of 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 to pharmacotherapy and botulinum toxin injections, they 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)

Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure developed by a Japanese surgeon, Dr. Haruhiro Inoue and colleagues. (2, 3) POEM is performed with the patient under general anesthesia. (4) 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, 4)

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 (FDA).

IV. RATIONALE

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This policy was created in September 2013 with a search of the MEDLINE database through August 1, 2013. The literature on the efficacy of POEM consists primarily of small, case series and one nonrandomized trial with historical controls. No randomized controlled trials comparing POEM with other treatment options. Following is a summary of the larger series (≥50 patients) on this procedure.

In a nonrandomized, historical control trial, Hungness and colleagues (2013) reported on perioperative outcomes in patients with achalasia treated with POEM (n=18) or laparoscopic Heller myotomy (LHM) (n=55) at a single US center. (4) Operative times were shorter for POEM than for LHM (113 and 125 minutes, respectively, p<0.05).

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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 upon post-anesthesia care and postoperatively on the first day, but were higher at two 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. POEM patients' Eckardt scores decreased (median 1 post-op vs. 7 pre-op, $p < 0.001$), and 16 (89%) patients had a treatment success (score ≤ 3) at a median of six-months follow-up. (4)

In a prospective case series, von Renteln and colleagues (2013) reported on outcomes of 70 patients who underwent POEM at five centers in Europe and North America. (5) The mean follow-up period was 10 months (range, 3–12 months). Follow-up evaluation at six months and one-year showed sustained treatment success of 89% and 82%, respectively. The mean Eckhardt score pretreatment was 6.9 compared with 1.3 at 6 months and 1.7 at one-year ($p < 0.001$ for both comparisons). Multivariate analysis showed that neither age, previous treatment (Botox/dilatation), length of the myotomy, pre-procedure LES pressure, initial Eckardt score, sex, procedure duration, nor full-thickness dissection during POEM were significant predictors of treatment failure at one year. At three months after POEM, esophagitis was observed in 42% of cases. However, the severity of esophagitis was only 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 one-year follow-up evaluation showed overall rates of gastroesophageal reflux disease (GERD) of 37%, and PPI use of 29%. Other complication rates of POEM ranged from 1%-4%. (5)

The largest published POEM series to date, by Ren and colleagues (2012), highlights some of these POEM-specific complications. (6) 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% of their 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. (6)

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. (7, 8) Studies have also been undertaken comparing different POEM techniques; comparable outcomes have been reported between patients undergoing full-thickness versus circular myotomy. (9) An international survey involving 16 centers reported 841 POEM procedures performed as of July 2012; these centers comprised of seven in North America, five in Asia, and four in Europe, including high-volume centers (≥ 30 POEMs per center). (10)

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Ongoing Clinical Trials

Sixteen active POEM studies were registered in the National Clinical Trials database (ClinicalTrials.gov) as of August 20, 2013, with five U.S. centers currently participating in or sponsoring trials. Three studies are randomized controlled trials:

Peroral Endoscopic Myotomy Versus Pneumatic Dilation for Esophageal Achalasia: a Prospective Randomized Controlled Trial (NCT01768091)

The purpose of this Chinese single-center study is to determine the efficacy and safety of POEM compared with pneumatic dilation in the treatment of esophageal achalasia. The primary outcome measure is therapeutic success (as measured as symptom control to an Eckardt score of 3 or less) at two years of follow-up. This study is currently recruiting participants (N=200) with an estimated completion date of December 2013.

Endoscopic Versus Laparoscopic Myotomy for Treatment of Idiopathic Achalasia: A Randomized, Controlled Trial (NCT01601678)

The purpose of this international study (conducted across 18 centers within Europe and North America) is to compare the feasibility, safety and efficacy of POEM with laparoscopic myotomy (Heller myotomy) in the treatment of achalasia up to five years of follow-up. The primary outcome measure is the non-inferiority of POEM compared to LHM based on LES pressure on manometry after POEM compared to LHM at three months after procedure. This study is currently recruiting participants (N=220) with an estimated completion date of December 2019.

A Prospective Randomized Multi-center Study Comparing Endoscopic Pneumodilation and Per Oral Endoscopic Myotomy (POEM) as Treatment of Idiopathic Achalasia (NCT01793922)

The purpose of this study (Belgium single-center) is to compare the efficacy of POEM to the efficacy of pneumodilation as the initial treatment of symptomatic idiopathic achalasia. It is hypothesized by the study investigators that POEM has a higher long-term efficacy than pneumodilation in treatment of therapy-naive patients with idiopathic achalasia. The primary outcome measure is therapeutic success (as measured from date of pneumatic dilation or POEM to date of relapse of symptoms) at two years of follow-up. This study is not yet open for recruitment (N=150) with an estimated completion date of January 2023.

Summary

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 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 consists of case series and one non-randomized comparative trial with historical controls. Two of the larger case series, enrolling a total of 189 patients with achalasia treated with POEM, and one nonrandomized, historical control trial of 18 patients treated with POEM and 55 patients

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treated with Heller myotomy were included. Treatment success at short follow-up periods was reported for a high percent of patients treated with POEM. However, there were relatively high rates of adverse effects, with, POEM-specific complications reported across studies including subcutaneous emphysema, pneumothorax, and thoracic effusion. In addition, a substantial proportion of patients undergoing POEM developed esophagitis requiring treatment. In the nonrandomized historical control trial, investigators reported that POEM resulted in shorter operative times and less blood loss than laparoscopic Heller myotomy, although myotomy lengths, complication rates, length of stay, and narcotic use were similar between surgical groups.

The evidence shows that POEM is a technique in evolution that does not have a strong evidence base at this time. Uncontrolled case series demonstrate that it can improve symptoms in patients with achalasia, but that side effects can occur commonly. There are no controlled studies to determine the efficacy and safety above a control group, and there are no comparative effectiveness studies to evaluate long-term outcomes of POEM compared to alternative treatment, Therefore, the use of POEM for treatment of esophageal achalasia is considered investigational.

Practice Guidelines and Position Statements

None

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER

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with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational when used to report: PERORAL ENDOSCOPIC MYOTOMY (POEM)

CPT Codes®								
43499								

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IX. REFERENCES

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8. Zhou PH, Li QL, Yao LQ et al. *Peroral endoscopic remyotomy for failed Heller myotomy: a prospective single-center study.* *Endoscopy* 2013; 45(3):161-6.

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X. POLICY HISTORY

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MP-1.143	CAC 11-26-13 New policy. BCBSA adopted. Peroral endoscopic myotomy for the treatment of achalasia is considered investigational.
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