



BlueCross BlueShield
of Alabama

Name of Policy:

Peroral Endoscopic Myotomy (POEM) for Treatment of Esophageal Achalasia and Refractory Gastroparesis

Policy #: 537

Category: Surgery

Latest Review Date: March 2018

Policy Grade: C

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure developed in Japan. POEM is performed with the patient under general anesthesia. For esophageal achalasia, 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. For refractory gastroparesis, the same technique is utilized, but a tunnel is typically created 5cm proximal to the pylorus, then an antral myotomy is performed in addition to pyloromyotomy through the submucosal tunnel.

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. 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.

Achalasia has an estimated prevalence in the United States of ten cases per 100,000, with an incidence of 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 (LHM). 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. One-year response rates of 86% and rates of major mucosal tears requiring subsequent intervention of 0.6% have been reported.

Refractive Gastroparesis

Gastroparesis is delayed gastric emptying when there is no mechanical obstruction. Symptoms include nausea, vomiting, bloating, or abdominal pain. Gastroparesis can be idiopathic, diabetic, or post-surgical. Gastroparesis is initially treated by modifying diet, optimizing glycemic control, and medications. When these treatments fail, a surgical procedure may be required. The POEM procedure has been modified to be performed in the stomach to attempt to treat refractory gastroparesis.

Please note that the acronym POEM in this policy refers to peroral endoscopic myotomy. POEMS syndrome, which uses a similar acronym, is discussed in medical policy #415 (*Hematopoietic Stem-Cell Transplantation for Plasma Cell Dyscrasias, including Multiple Myeloma and POEMS Syndrome*).

Policy:

Peroral endoscopic myotomy (POEM) as a treatment for esophageal achalasia does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered investigational.

Peroral Endoscopic pyloromyotomy as a treatment for refractory gastroparesis does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered investigational.

Endoscopic closure devices (e.g. Overstitch, Over the Scope clip [OTSC]) do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered investigational.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature review was updated through September 14, 2017.

Esophageal Achalasia

Systematic Reviews

Several systematic reviews have evaluated the outcomes of POEM. Three reviews have summarized outcomes of case series studies. The systematic review by Akintoye et al (2016) evaluated outcomes for 2373 patients from 36 studies. 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 systematic review by Crespín et al (2016) evaluated outcomes for 1299 patients from 19 studies. Improvements in Eckardt score 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 (2015) evaluated outcomes for 1122 patients from 22 studies. Eckardt scores changed from 6.8 baseline to 1.2 postoperatively. There were improvements in lower esophageal sphincter (LES) pressure and symptoms.

Two systematic reviews only selected studies in which POEM was compared to an alternative surgical treatment. Only the results of the systematic review by Marano et al (2016) are cited here because it includes the period of time covered in the other review and includes more patients and studies. In this study, outcomes for 486 patients (196 receiving POEM, 290 receiving laparoscopic Heller myotomy [LHM]) from 11 studies were evaluated. None were randomized. Reviewers rated all studies to have a moderate risk of bias. No information on

differences in severity of disease between treatment groups was provided. There were no significant difference 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: Systematic Reviews

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

Nonrandomized Comparative Studies

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. 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 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.

In a retrospective study of a prospective database at Oregon Health & Sciences University (Portland, Oregon), Bhayani et al compared outcomes in 37 patients who underwent POEM and 64 patients who underwent LHM for achalasia. Full-thickness esophageal injury occurred in four POEMs patients, and eight esophageal and three 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 six 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 six months, resting LES pressure was higher in the POEM group compared with the LHM group (16 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 one or less, clinical response was more frequent in the POEM group than the LHM group (98.0% vs 80.8%, $p=.01$). 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 different procedures had different characteristics. POEM patients were older, had higher BMI, and had more prior treatments. After treatment, patients undergoing all 3 procedures had significant improvements in measurements made 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 aged 65 years of age and older. All were treated successfully, with decreases in Eckhardt score. At a mean follow-up of 21.8 months for POEM and 35 months for pneumatic dilation, 1 POEM case failed and 2 pneumatic dilation procedures failed.

Section Summary: Nonrandomized Comparative Studies

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 or pneumatic dilation), potential confounding and selection bias make the outcome comparison uncertain. The comparative studies did not report long-term outcomes.

Case Series

Inoue et al (2015) reported outcomes on 500 consecutive patients at one Japanese institution. Outcomes were available for variable proportion of patients at various time intervals after the procedure; 302 (60.4%) at two months, 102 (27.6% of 370) at one to two years, and 61 (58.1% of 105) at more than three years. The median Eckardt score at all time points was one. 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. Outcomes at one year were available for 102 patients. Clinical success as defined as an Eckardt score of three 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 and colleagues (2013) reported on outcomes of 70 patients who underwent POEM at five centers in Europe and North America. The mean follow-up period was ten months (range, 3 to 12 months). Follow-up evaluation at six months and one-year showed sustained treatment success of 89% and 82%, respectively. The mean Eckardt score pretreatment was 6.9 compared with 1.3 at six 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 three 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%.

Teitelbaum et al also evaluated one-year outcomes after POEM. Forty-one patients who were treated at Northwestern University (Evanston, Illinois) and were more than one 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 two (probably overlapping) patient cohorts who underwent POEM for achalasia at a single center in China. Quality of life was assessed at pretreatment and at one-year follow-up using the Short Form 36 health-related quality-of-life questionnaire; 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's 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's t-test, $p < 0.001$), and mean (SD) MCS improved from 44 (13) to 67 (15) (Student's t-test, $p = 0.003$). Incidence of intraoperative subcutaneous emphysema and pneumothorax was 12% and 1%, respectively; postoperative esophagitis developed in 6%.

The study by Ren and colleagues (2012) highlights some of these 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% 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.

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 ten months after rescue POEM. Studies have also been undertaken comparing different POEM techniques; comparable outcomes have been reported between patients undergoing full-thickness versus circular myotomy.

Section Summary: Case Series Studies

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

Refractory Gastroparesis

In 2015, Shlomovitz et al reported on early human experience with per-oral endoscopic pyloromyotomy (POP) performed on 7 patients. Preoperative work up included upper endoscopy and gastric emptying study. One perioperative complication of a GI bleed was reported 2 weeks post operatively which required transfusions and endoscopic clipping of a pyloric channel ulcer. Two minor complications were reported of 1 patient having difficulty swallowing and 1 patient developed hospital acquired pneumonia. Both complications delayed discharge by at least 1 day. The authors reported 6 out of 7 patients experienced significant symptomatic improvement following the procedure. Three month GES follow-up on 5 patients showed normal gastric emptying on 4 patients. One patient did not respond and subsequently underwent an additional procedure- which also failed to significantly improve symptoms. The authors conclude by stating the early follow-up suggests promising symptomatic improvement as well as objective improvement in gastric emptying; but additional clinical experience is required to establish the role of this technique in managing gastroparesis.

In 2017, Rodriguez et al reported on short term improvement of symptoms after the G-POEM procedure in 47 patients. Patients in the study had a preoperative and a 3 month postoperative gastric emptying study. The average pre-procedure percentage of retained food at 4 hours was 37% compared to an average post-procedure percentage of 20% (p<0.03). The average pre-procedure Gastroparesis Cardinal Symptom Index (GCSI) score was 4.6 compared to and average post-procedure GCSI score of 3.3 (p<0.001). There was one death reported within 30 days of the procedure which was unrelated to the procedure. The authors conclude the procedure is safe and feasible for refractory gastroparesis, but additional follow-up is required to determine the long term success of this approach.

In 2018, Malik et al reported on symptom improvement using the G-POEM procedure for refractory gastroparesis in 13 patients. There were no procedure-related side effects. The authors stated that of 11 patients completing follow-up questionnaires, eight were improved subjectively (four patients reported considerably better, four patients somewhat better, one unchanged, and two worse). Individual symptom severity scores tended to improve, particularly vomiting, retching, and loss of appetite. Of six patients that had post-G-POEM gastric emptying studies (GES); four were improved, unchanged in one, and worsened in one. The authors concluded that G-POEM for refractory gastroparesis appears to be feasible and safe with the majority of patients reporting improved symptoms; but further experience is needed to determine the efficacy and safety of this procedure.

Summary

For individuals who have achalasia who receive peroral endoscopic myotomy, 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 showed mostly similar outcomes with POEM versus Heller myotomy for the outcome of symptom relief as assessed by the Eckardt score. Some studies showed shorter length of stay and less postoperative pain with POEM. However, potential imbalance in patient characteristics in these nonrandomized studies may bias the comparisons between treatments. In the case series 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. The case series studies do not allow conclusions about the efficacy of POEM relative to established treatment. 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 individuals who receive POEM for refractive gastroparesis, the evidence consists of small prospective studies. Relevant outcomes are symptoms and treatment related morbidity. Studies have shown the procedure is feasible and short term results have decreased symptoms, however; the studies are small, there are no RCTs comparing this to other treatments, and long term data are needed to determine the effects of this technology on health outcomes. The evidence is insufficient.

Practice Guidelines and Position Statements

American Society of 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.”

ASGE does not have a guideline or consensus statement regarding endoscopic peroral pyloromyotomy or endoscopic suturing devices.

Society of American Gastrointestinal and Endoscopic Surgeons

In 2011, SAGES 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.”

SAGES does not have a guideline or consensus statement regarding endoscopic peroral pyloromyotomy or endoscopic suturing devices.

American College of Gastroenterology

In 2013, the American College of Gastroenterology issued a clinical guideline 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 guideline further states that randomized prospective comparison trials are needed, and the procedure should be performed in the context of clinical trials.

ACG does not have a guideline or consensus statement regarding endoscopic peroral pyloromyotomy or endoscopic suturing devices.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Key Words:

Peroral endoscopic myotomy, POEM**, Esophageal achalasia, endoscopic suturing devices, Overstitch, over the scope clip, OTSC, GPOEM, G-POEM, refractory gastroparesis, gastroparesis

****NOTE:** FOR **POEMS Syndrome**, refer to **Policy 415 Single or Tandem Courses of Hematopoietic Stem-cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome**

Approved by Governing Bodies:

POEM uses available laparoscopic instrumentation and, as a surgical procedure, is not subject to regulation by the U.S. Food and Drug Administration (FDA).

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply.

FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT Codes:

There are no specific CPT codes for these procedures. They would likely be reported with an unlisted procedure code.

For esophageal achalasia:

43499 unlisted procedure, esophagus

For refractory gastroparesis:

43999 unlisted procedure, stomach

There are no specific CPT codes for endoscopic closure devices. It would likely be reported with the unlisted procedure, stomach code 43999.

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Policy History:

Medical Policy Panel, September 2013

Medical Policy Group, September 2013 (3): New policy; does not meet medical criteria for coverage and therefore considered investigational

Medical Policy Administration Committee, October 2013

Available for comment September 24 through November 7, 2013

Medical Policy Panel, September 2014

Medical Policy Group, September 2014 (3): 2014 Updates to Description, Key Points & References; no change in policy statement

Medical Policy Panel, November 2015

Medical Policy Group, December 2015 (4): Updates to Key Points and References. No change to policy statement.

Medical Policy Panel, November 2016

Medical Policy Group, January 2017 (4): Updates to Key Points and References. No change to policy statement.

Medical Policy Panel, November 2017

Medical Policy Group, November 2017(4): Updates to Key Points and References. No change to policy statement.

Medical Policy Group, March 2018 (4): Added previously investigational technique (G-POEM) and device (endoscopic closure devices) to policy. Added CPT codes 43999 and 43499 to Current Coding. Other updates to Description, Key Points, Key Words, and References.

Medical Policy Administration Committee, April 2018

Available for comment April 2 through May 16, 2018

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.