

# Regence

Medical Policy Manual

Surgery, Policy No. 196

## ***Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia***

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### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

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 (LES) in patients with achalasia.

### **MEDICAL POLICY CRITERIA**

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

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

### **CROSS REFERENCES**

1. [Gastroesophageal Reflux Surgery](#), Surgery, Policy No. 186

### **BACKGROUND**

#### **ACHALASIA**

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. Treatment options for achalasia have traditionally included pharmacotherapy such as injections with botulinum toxin, pneumatic dilation, and laparoscopic Heller myotomy (LHM).<sup>[1, 2]</sup> Although the latter 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. One-year response rates of 86% and rates of major mucosal tears requiring subsequent intervention of 0.6% have been reported.<sup>[3]</sup>

## **PERORAL ENDOSCOPIC MYOTOMY**

Peroral endoscopic myotomy (POEM) is an 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.

The POEM procedure was developed in Japan by Dr. Haruhiro Inoue and is performed with the patient under general anesthesia.<sup>[2, 4]</sup> 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. POEM differs from laparoscopic surgery, which involves complete division of both circular and longitudinal LES muscle layers. The dysfunctional muscle fibers that prevent the LES from opening are cut in order to allow food to enter the stomach more easily.

## **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

## **EVIDENCE SUMMARY**

In order to isolate the specific therapeutic effects of POEM and adequately control for placebo effects and individual patient differences (clinical and demographic, known and unknown), well-designed randomized clinical trials (RCTs) that compare POEM with the current standard of care are necessary.

The RCT is the most rigorous and reliable study design for demonstrating a causal relationship between the therapy under investigation and the health outcomes of interest. This form of study is necessary in order to understand whether an intervention such as POEM can positively impact the health outcomes of patients with achalasia. Although informative, evidence from observational, nonrandomized studies describing POEM outcomes is of limited utility in establishing causal relationships. Therefore, well-designed, RCTs are needed to establish whether treatment with POEM improves health outcomes in patients with achalasia compared to established, standard surgical treatments.

## **SYSTEMATIC REVIEWS**

Multiple systematic reviews and meta-analyses have been published to evaluate POEM as a

treatment for achalasia. Several systematic reviews include overlapping studies, but these reviews have variable objectives; assessing data on POEM alone, LHM alone, and POEM compared to LHM or pneumatic dilation. The reviews primarily include observational studies.

Vespa (2023) conducted a review of 11 studies in which 2342 patients received POEM with a median follow-up time of 48 months. Patients were evaluated for clinical success and postoperative reflux rates and the pooled clinical success rate was 87.3% and the pooled symptomatic reflux rate was 22%. The quality of the included studies were limited, although the authors concluded that there was long-term clinical efficacy based on the review.

Shiu (2022) conducted a review of 24 studies including 1987 patients comparing POEM to other surgical interventions including botulinum toxin injection (BTI), pneumatic dilation (PD), BTI + PD, LHM without fundoplication, LHM followed with Dor or Toupet fundoplication, and POEM using either the anterior or posterior approach.<sup>[5]</sup> When compared with PD, POEM with anterior approach, POEM with posterior approach, LHM plus Toupet, and LHM plus Dor were all significantly superior to the other regimens in short-term efficacy. POEM with anterior approach and LHM plus Dor showed better improvement in mid-term efficacy. BTI showed a significantly lower efficacy than PD in both periods.

Dirks (2021) compared POEM to pneumatic dilation and LHM in a meta-analysis that included 21 studies on HM and eight studies on pneumatic dilation.<sup>[6]</sup> Only one RCT for each comparison was identified, and only two studies included an average follow-up of greater than two years. POEM was associated with improved efficacy compared to pneumatic dilation but not LHM. Patient-reported reflux between 6- and 12-month follow-up was worse with POEM compared to dilation in three studies (risk ratio [RR] 2.67, 95% CI 1.02 to 7.00).

A systematic review comparing POEM to LHM, published by Martins (2020), included a meta-analysis of 12 cohort studies with a total of 893 patients (POEM n=359, LHM n=534).<sup>[7]</sup> Follow-up in the studies varied from nine weeks to over 200 weeks. Seven of the studies included Eckardt scores, two of which had significantly different pre-operative levels between groups. In an analysis that excluded these two studies, the POEM group had a small but statistically significant reduction in Eckardt score compared with LHM (mean difference [MD] -0.257, 95% confidence interval [CI] -0.512 to -0.002, p=0.04). No differences were seen between groups for postoperative reflux or operative time, based on data from seven studies.

Zhong (2020) published a meta-analysis of seven studies comparing POEM (n=298) to pneumatic dilation (n=321)<sup>[8]</sup>. The clinical success rate and change in Eckardt scores favored the POEM group (MD 1.19, 95% CI 0.78 to 1.60, p<0.00001), however the risk of GERD and other complications was higher for POEM compared with pneumatic dilation (RR 4.17, 95% CI 1.52 to 11.45, p=0.006, and RR 3.78, 95% CI 1.41 to 10.16, p=0.008, respectively).

Li (2019) published a systematic review evaluating the long-term efficacy and safety POEM treatment for achalasia.<sup>[9]</sup> Ten studies, published between 2015 and 2017, included a total of 373 patients with a mean follow-up time of 30 months. Of the 372 patients who underwent POEM, 34.8% had a prior treatment history including LHM. Clinical success measures included an Eckardt score ≤ 3. The rate of late occurring gastroesophageal reflux was 10.2%. The review was limited by the sample size, predominance of studies from a single country (eight from China and two from the U.S.) and the lack of statistical analysis.

Aiolfi (2020) performed a systematic review and network meta-analysis comparing POEM to LHM and pneumatic dilation.<sup>[10]</sup> Nineteen studies were included in analysis (total n=4,407),

including five RCTs and 14 observational studies, however only 6.8% of patients underwent POEM, while 50.4% underwent LHM and 42.8% underwent pneumatic dilation. Post-procedure Eckardt scores were significantly lower for POEM patients compared with LHM and PD (standardized MD -0.06, 95% CI -1.4 to -0.2 and standardized MD -1.2, 95% CI -2.3 to -0.2, respectively) and dysphagia remission was also significantly improved in POEM patients compared with LHM and PD (RR 1.21, 95% CI 1.04 to 1.47, and RR 1.40, 95% CI 1.14 to 1.79, respectively). POEM was associated with a higher rate of postoperative GERD than LHM or PD (RR 1.75, 95% CI 1.35 to 2.03 and RR 1.36, 95% CI 1.18 to 1.68, respectively).

Lee (2019) published a systematic review and meta-analysis evaluating POEM for the treatment of pediatric achalasia.<sup>[11]</sup> Twelve studies, published between 2013 and 2018, with a total of 146 patients (53.68% female), were included in the analysis. There was a reduction in the Eckardt score of 6.88 points (MD 6.88, 95% CI 6.28 to 7.48,  $p<0.001$ ) and a reduction in LES pressure of 20.73 mmHg (MD 20.73, 95% CI 15.76 to 25.70,  $p<0.001$ ). Improvement or resolution of short- and long-term achalasia symptoms was experienced in 93% of patients. The meta-analysis was limited by several of the including studies being case series (5/12) with no control groups or comparators, all of the studies having a sample size of less than 30, and by limited long-term follow-up.

Schlottmann (2018) compared POEM to LHM in 53 and 21 studies of POEM and LHM, respectively (total  $n=1,958$ ).<sup>[12]</sup> Mean follow-up was significantly longer for studies of LHM (41.5 vs. 16.2 months,  $p<0.0001$ ). Short-term results indicated that POEM was more effective than LHM in relieving dysphagia, but it was associated with a very high incidence of pathologic reflux (odds ratio [OR] for GERD symptoms 1.69, 95% CI 1.33 to 2.14,  $p<0.0001$ ; GERD evidenced by erosive esophagitis OR 9.31, 95% CI 4.71 to 18.85,  $p<0.0001$ ; and GERD evidence by pH monitoring OR 4.30, 95% CI 2.96 to 6.27,  $p<0.0001$ ). Length of hospital stay was also 1.03 days longer after POEM ( $p=0.04$ ).

Awaiz (2017) compared the safety and effectiveness of POEM and laparoscopic Heller myotomy (LHM) in a systematic review and meta-analysis of seven comparative trials totaling 483 patients (LHM  $n=250$ , POEM  $n=233$ ).<sup>[13]</sup> The review was conducted in accordance with PRISMA methodology, and study methodological quality was assessed using the Modified Newcastle-Ottawa scale. Several variables were found to have a high degree of heterogeneity, including prior endoscopic treatment, long-term GERD, operating time, and length of hospital stay – which limits generalizability of conclusions. Although evidence suggests POEM may be superior to LHM in short-term follow-up, the authors concluded that meaningful comparison of POEM to LHM is impossible in the absence of data beyond one year.

Systematic reviews by Zhang (2016)<sup>[14]</sup> and Marano (2016)<sup>[15]</sup> included studies from the same time period. Because the Marano review assessed more patients and studies, only their results are summarized here. The study evaluated outcomes for 486 patients (196 receiving POEM, 290 receiving LHM) from 11 studies. None were randomized. Reviewers rated all studies as having 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.

A systematic review by Akintoye (2016) evaluated outcomes for 2,373 patients from 36 studies.<sup>[16]</sup> Clinical success rates were achieved in 98% of patients (95% CI 97% to 100%) and mean Eckardt scores decreased from baseline at 1, 6, and 12 months. (The Eckardt score

grades four 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  $\geq 4$  represent treatment failure.<sup>[17]</sup>)

Crespin (2016) published a systematic review that evaluated outcomes for 1,299 patients from 19 studies.<sup>[18]</sup> Improvements in Eckardt scores were statistically significant in all studies. The most frequently reported complications were mucosal perforation, pneumothorax, pneumoperitoneum, and subcutaneous emphysema.

A systematic review by Patel (2016) evaluated outcomes for 1,122 patients from 22 studies.<sup>[19]</sup> Eckardt scores dropped from 6.8 at baseline to 1.2 postoperatively. There were improvements in LES pressure and symptoms.

Talukdar (2014) published a systematic review and meta-analysis assessing POEM and LHM as treatments for achalasia.<sup>[20]</sup> Of the 29 studies, 19 evaluated change in Eckardt scores after POEM, which showed a significant reduction with an overall effect size of -7.95 ( $p < 0.001$ ). Sixteen studies evaluated the change in resting LES after POEM; there was significant improvement in the resting LES pressure with an overall effect size of -7.28 ( $p < 0.001$ ). Five studies compared POEM and LHM. There were no statistically significant differences between POEM and LHM in reduction in Eckardt score (overall effect size [Z] -1.77,  $p = 0.078$ ), post-operative pain scores (Z -0.691,  $p = 0.489$ ) and analgesic requirements (Z -0.755,  $p = 0.450$ ), length of hospital stay (Z -1.41,  $p = 0.156$ ), adverse events (Z 1.227,  $p = 0.220$ ), and symptomatic gastroesophageal reflux/reflux esophagitis (Z -1.41,  $p = 0.156$ ); however, POEM had significantly lower operative time compared with LHM (Z -2.220,  $p = 0.026$ ). The review was limited by the lack of randomization, potential overlapping populations in separate reports, heterogeneity of the included studies, and the lack of long-term follow-up.

Additional systematic reviews have been published that address a limited population or outcome or address the same body of literature of other published systematic reviews.<sup>[21-24]</sup> For example, a meta-analysis by Huang (2020) evaluated outcomes in nine studies of POEM in patients with a prior Heller myotomy and reported clinical success in 90% of patients and significant lowering in Eckardt score, LES pressure, and integrated relaxation pressure.<sup>[25]</sup> A meta-analysis by Zhong (2020) included only quality-of-life (QoL) questionnaire outcomes from 12 studies and reported increases in these measures following POEM,<sup>[26]</sup> and additional meta-analyses by this group have evaluated POEM in specific populations, including geriatric patients,<sup>[27]</sup> children,<sup>[28]</sup> and patients with prior interventions.<sup>[29, 30]</sup>

## **RANDOMIZED CONTROLLED TRIALS**

Saleh (2023) published a randomized trial comparing POEM to PD in patients with achalasia after LHM.<sup>[31]</sup> The primary outcome in this trial was treatment success, defined by Eckardt score of less than or equal to 3 and the absence of unexpected re-treatment. A total of 90 patients were included and success rates from the POEM group (62.2%) were higher than the success rates in the PD group (26.7%) in patients with recurrent or persistent symptoms following LHM. Secondary outcomes (e.g., reflux esophagitis, esophageal sphincter pressure, integrated relaxation pressure) were better in the POEM group, except for reflux esophagitis in which there was no difference between groups.

Werner (2019) published a randomized, multicenter, non-inferiority trial comparing POEM and LHM plus Dor's fundoplication in 221 achalasia patients.<sup>[32]</sup> The primary endpoint of the trial was clinical success, defined as an Eckardt score of  $\leq 3$  at tow-year follow-up, without

additional treatment. Other outcomes assessed included adverse events, esophageal function measures, gastroesophageal reflux, and the Gastrointestinal QoL Index score. In a modified intention-to-treat analysis, which included patients who underwent randomization and the assigned surgical procedure, the two-year clinical success rates were similar between groups (83.0% for POEM and 81.7% for LHM plus Dor's). LES pressure and QoL measures were also not significantly different between groups. At the two-year follow-up, 44% of POEM patients and 29% of LHM patients had reflux esophagitis by endoscopy.

Ponds (2019) reported results of a randomized multicenter trial comparing POEM (n=67) to pneumatic dilation (n=66), conducted at six hospitals in the Netherlands, Germany, Italy, Hong Kong, and the United States.<sup>[33]</sup> Adult patients (mean age 48.6 years, 56% men) with newly diagnosed achalasia and an Eckardt score  $\geq 3$  who had not undergone previous treatment were included (130 of the 133 randomized patients received treatment). At two-years follow-up, treatment success (defined as an Eckardt score  $\leq 3$  and the absence of severe complications or re-treatment) occurred in 58 of 63 patients (92%) in the POEM group vs. 34 of 63 (54%) in the pneumatic dilation group, a difference of 38% (95% CI 22% to 52%,  $p<0.001$ ). Fourteen other secondary endpoints were reported, none of which were statistically significantly different. In total, seven serious adverse events occurred, two of which were related to pneumatic dilation, and five were unrelated to the study. One pneumatic dilation patient experienced perforation after dilation and required 13 days of hospitalization, and another patient as admitted for one night with severe chest pain assumed to be related to perforation. In total, adverse events were more common after POEM than pneumatic dilation (67% of patients vs. 22%). POEM patients experienced reflux esophagitis, reflux symptoms, Candida esophagitis, ulcer at the esophagogastric junction that healed after PPI treatment, and peri-procedural mucosal tear that was managed conservatively and healed at endoscopy performed one week later. In the pneumatic dilation group, reported adverse events included reflux esophagitis, reflux symptoms, Candida esophagitis, and belching/dyspepsia. Limitations of this study included the lack of a strict intention-to-treat analysis. Patients who were randomized and did not go on to receive treatment were not included in final analysis. However, sensitivity analysis suggests this would not have had a significant effect on final outcomes. Longer-term follow-up is not available for this study, since primary outcomes were assessed at two years. Given the pathophysiology of achalasia, the authors pointed this out as a limitation. The study was also limited by the lack of blinding, lack of intention-to-treat analysis, and by the follow-up time starting at treatment initiation rather than at randomization.

## **NONRANDOMIZED STUDIES**

### **Comparative Studies**

A number of comparative nonrandomized studies have compared the safety and efficacy of POEM with a standard of care treatment for achalasia. Those with more than 50 patients that were not included in the aforementioned meta-analyses are summarized here.

Shea (2020) compared POEM to Heller myotomy in a retrospective study of patients treated for achalasia at a single center in the U.S.<sup>[34]</sup> The cohort of 141 patients included 97 treated with Heller myotomy and 44 treated with POEM from 2009 to 2018. Of these, 82 patients (58%) completed a follow-up phone survey at least nine months after the procedure. Similar rates of dysphagia resolution, defined as an Eckardt score  $\leq 3$ , were seen for the procedures, with a median follow-up of three years for myotomy patients and one year for POEM patients.

Li (2018) published a single-center study assessing POEM for the treatment of achalasia.<sup>[35]</sup> Between 2010 and 2012, 564 consecutive patients were included with a median follow-up of 49 months. Mean Eckardt score decreased from 8 to 2 ( $p<0.05$ ) and the median lower esophageal sphincter pressure decreased from 29.7mm Hg to 11.9mm Hg ( $p<0.05$ ). Fifteen failures occurred within three months, 23 between three months and three years, and 10 after three years. Major perioperative adverse events (AEs) occurred in 36 (6.4%) patients, including delayed mucosal barrier failure ( $n=3$ ), delayed bleeding ( $n=3$ ), hydrothorax ( $n=6$ ), and pneumothorax ( $n=21$ ). Ninety-three (16.5%) patients experienced mucosal injuries, and 48 patients required nasogastric tube placement at the end of the procedure. Other minor AEs included estimated blood loss  $>200\text{mL}$  ( $n=3$ ), subcutaneous emphysema ( $n=1$ ), and pneumoperitoneum ( $n=1$ ). The study was limited by a high loss to follow-up and poor patient compliance at diagnostic tests. Also, late initiation of  $\text{CO}_2$  insufflation may have made the AE rate unrealistically high.

Docimo (2016) published a retrospective study comparing POEM and LHM for individuals with achalasia.<sup>[36]</sup> Patients who underwent POEM ( $n=44$ ) or LHM ( $n=122$ ) between 2006 and 2015 were included. There was no difference in average pain scores for POEM and LHM after the first 24 hours ( $2.7\pm 2.067$  vs.  $3.29\pm 1.980$ ,  $p=0.472$ ) or at time of discharge ( $1.6\pm 2.420$  vs.  $2.09\pm 2.157$ ,  $p=0.0657$ ). The POEM group required significantly fewer narcotics while hospitalized than the LHM group ( $35.8\text{mg}$  vs.  $101.8\text{mg}$ ,  $p<0.001$ ), and fewer POEM patients needed a prescription for a narcotic analgesic at discharge (6.81% vs. 92.4%,  $p<0.001$ ). Also, the average length of stay was 31.2 hours for POEM and 55.79 for LHM ( $p<0.001$ ). The study was limited by its retrospective nature and its lack of randomization and blinding.

In a retrospective study of patients with type III achalasia, Kumbhari (2015) compared outcomes for 49 patients who underwent POEM and 25 patients who underwent LHM.<sup>[37]</sup> Defining clinical response as a reduction in Eckardt score of no more than 1, clinical response was more frequent in the POEM group (98.0%) than the LHM group (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 favored POEM (OR 11.32,  $p=0.06$ ). Procedure times were shorter with POEM. There was no difference in length of stay. The overall rate of AEs was lower in the POEM group (6% vs. 27%,  $p=0.01$ ).

## Noncomparative Studies

In recent years, many case series reported improved clinical outcomes following POEM with follow-up ranging from two months to a mean of 30 months.<sup>[38-49]</sup> Many were included in the systematic reviews discussed above. Several specifically evaluated post-operative reflux.<sup>[38, 42, 44, 46, 48]</sup> In one study, POEM was not associated with clinically significant refractory GERD<sup>[46]</sup>; in another study, a high rate of reflux on pH testing was associated with POEM, though the objective pH measurement did not correlate with subjective patient symptom surveys<sup>[44]</sup>. Several authors concluded that the preliminary data suggest POEM may be a minimally invasive, safe, and efficacious treatment option for achalasia, however, large, prospective randomized studies are necessary to make conclusions.

At least two small case series 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.<sup>[50, 51]</sup> Studies have also compared different POEM techniques and comparable outcomes have been reported between patients undergoing full-

thickness versus circular myotomy.<sup>[52]</sup> An international survey of 16 centers (seven in North America, five in Asia, and four in Europe, some of which were high-volume centers [ $\geq 30$  POEMs per center]) reported 841 POEM procedures performed as of July 2012.<sup>[53]</sup>

## EVIDENCE SUMMARY

For individuals who have achalasia who receive POEM, the evidence includes systematic reviews of observational studies, two RCTs, nonrandomized comparative studies, and case series. The relevant outcomes are symptoms, functional outcomes, health status measures, resource utilization, and treatment-related morbidity. The comparative studies have primarily reported similar outcomes for POEM and for LHM in 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 might 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, the 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 gastroesophageal reflux disease and 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.

## PRACTICE GUIDELINE SUMMARY

### AMERICAN COLLEGE OF GASTROENTEROLOGY

The American College of Gastroenterology (2020) issued a clinical guideline on the diagnosis and management of achalasia.<sup>[54]</sup> The quality of the evidence and the strength of recommendations were rated based on the GRADE framework. The evidence review included the two RCTs of POEM compared to LHM or pneumatic dilation (PD). Based on their evaluation, the guidelines included the following recommendations:

- "In patients with achalasia who are candidates for definite therapy, PD, LHM, and POEM are comparable effective therapies for type I or type II achalasia and POEM would be a better treatment option in those with type III achalasia."
- "We suggest that POEM or PD result in comparable symptomatic improvement in patients with types I or II achalasia." (GRADE quality: low, recommendation strength: conditional)
- "We recommend that POEM and LHM result in comparable symptomatic improvement in patients with achalasia." (GRADE quality: moderate, recommendation strength: strong)
- "We recommend that tailored POEM or LHM for type III achalasia as a more efficacious alternative disruptive therapy at the lower esophageal sphincter compared to PD." (GRADE quality: moderate, recommendation strength: strong)
- "We suggest that in patients with achalasia, POEM compared with LHM with fundoplication or PD is associated with a higher incidence of GERD." (GRADE quality: moderate, recommendation strength: strong)
- We suggest that POEM is a safe option in patients with achalasia who have previously undergone PD or LHM. (GRADE quality: low, recommendation strength: strong)



## **AMERICAN SOCIETY OF GASTROINTESTINAL AND ENDOSCOPIC SURGEONS**

The American Society of Gastrointestinal and Endoscopic Surgeons (2014) issued evidence-based, consensus guidelines on the use of endoscopy in the evaluation and management of dysphagia, including esophageal achalasia.<sup>[55]</sup> There were no recommendations for peroral endoscopic myotomy, though the discussion included the following:

“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.”

## **SOCIETY OF AMERICAN GASTROINTESTINAL AND ENDOSCOPIC SURGEONS**

The Society of American Gastrointestinal and Endoscopic Surgeons (2021) issued a consensus guideline on the surgical management of esophageal achalasia. The guideline included the following recommendations:<sup>[56]</sup>

- The Guideline panel suggests that adult and pediatric patients with type I and II achalasia may be treated with either POEM or laparoscopic Heller myotomy based on surgeon and patient's shared decision-making. (conditional recommendation, very low certainty evidence)
- Based on their collective experience, the panel suggests POEM over laparoscopic Heller myotomy for type III adult or pediatric achalasia. (expert opinion)
- The Guideline panel recommends peroral endoscopic myotomy over pneumatic dilation in patients with achalasia. (strong recommendation, moderate certainty evidence)
- For the subgroup of patients who are particularly concerned about the continued use of PPI [proton pump inhibitors] post-operatively, the panel suggests that either POEM or pneumatic dilation can be used based on joint patient and surgeon decision-making. (conditional recommendation, very low certainty evidence)

## **AMERICAN SOCIETY OF GASTROINTESTINAL ENDOSCOPY**

The American Society of Gastrointestinal Endoscopy (2020) published guidelines for the management of achalasia.<sup>[57]</sup> The guidelines include the following recommendations regarding POEM:

- Laparoscopic Heller myotomy, pneumatic dilation, and POEM are effective therapeutic modalities for patients with achalasia. Decision between these treatment options should depend on achalasia type, local expertise, and patient preference (evidence quality: high)
- We suggest POEM as the preferred treatment for management of patients with type III achalasia (evidence quality: very low)
- We suggest that patients undergoing POEM are counseled regarding the risk of postprocedure reflux compared with pneumatic dilation and laparoscopic Heller myotomy. Based on patient preferences and physician expertise, postprocedure management options include objective testing for esophageal acid exposure, long-term acid suppressive therapy, and surveillance upper endoscopy. (evidence quality: low)
- We suggest that POEM and laparoscopic Heller myotomy are comparable treatment options for management of patients with achalasia types I and II, and the treatment option should be based on shared decision-making between the patient and provider. (evidence quality: low)

## INTERNATIONAL SOCIETY FOR DISEASES OF THE ESOPHAGUS

The International Society for Diseases of the Esophagus (2018) published guidelines on the diagnosis and management of achalasia.<sup>[58]</sup> The Society convened 51 experts from 11 countries, including several from the U.S., to systematically review evidence, assess recommendations using the GRADE system, and vote to integrate the recommendations into the guidelines (>80% approval required for inclusion). POEM recommendations are summarized below:

- POEM is an effective therapy for achalasia both in short- and medium-term follow-up with results comparable to Heller myotomy. (level of recommendation [LOR]: conditional, GRADE: very low)
- POEM is an effective therapy for achalasia both in short- and medium-term follow-up with results comparable to pneumatic dilations. (LOR: conditional, GRADE: low)
- Pretreatment information on GERD, nonsurgical options (pneumatic dilation), and surgical options with lower GERD risk (Heller myotomy) should be provided to patient. (LOR: good practice, GRADE: not applicable)
- POEM is feasible and effective for symptom relief in patients previously treated with endoscopic therapies. (LOR: conditional, GRADE: very low)
- POEM may be considered an option for treating recurrent symptoms after laparoscopic Heller myotomy. (LOR: conditional, GRADE: low)
- Appropriate training (in vivo/in vitro animal model) and proctorship should be considered prior to a clinical program of POEM. (LOR: good practice, GRADE: not applicable)

## SUMMARY

There is not enough research to know if peroral endoscopic myotomy (POEM) improves overall health outcomes for people with esophageal achalasia compared with other treatments. While some clinical practice guidelines suggest that POEM may be an effective treatment, these recommendations are generally based on a low level of evidence. Therefore, the use of POEM as a treatment of esophageal achalasia is considered investigational.

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## CODES

Codes	Number	Description
CPT	43497	Lower esophageal myotomy, transoral
	43499	Unlisted procedure, esophagus
HCPCS	None	

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