Molina Clinical Policy
Peroral Endoscopic Myotomy (POEM) for Esophageal Achalasia: Policy No. 385

Last Approval: 4/13/2023
Next Review Due By: April 2024

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Esophageal Achalasia (EA) is a primary esophageal motility disorder characterized by decreased numbers of neurons in the esophageal myenteric plexuses, resulting in increased pressure at the lower esophageal sphincter (LES) and esophageal aperistalsis. These abnormalities result in a functional obstruction at the gastroesophageal junction, impairing food emptying from the esophagus into the stomach and resulting in food stasis (Spechler 2021).. The symptoms and signs of achalasia are caused primarily by a failure of the LES to relax. The typical clinical presentation is slowly progressive dysphagia for both solids and liquids. Regurgitation is a common finding that can lead to pulmonary symptoms such as choking, coughing, aspiration, and pneumonia. High-resolution esophageal manometry (HRM) demonstrating incomplete relaxation of the esophagogastric junction (EGJ) in conjunction with the absence of organized peristalsis is the gold standard for diagnosing achalasia (Khashab et al. 2020). There is currently no known cure. Achalasia treatment options currently include pharmacologic (calcium channel blockers), pneumatic dilatation (PD), botulinum toxin injection, and surgical myotomy. Laparoscopic Heller myotomy (LHM) is the standard treatment option for EA patients who are considered good surgical candidates. It entails cutting the muscles at the end of the esophagus and at the top of the stomach, allowing the sphincter between the esophagus and stomach to remain open.

Peroral Endoscopic Myotomy (POEM) is an endoscopic complement to surgical myotomy and a novel, less invasive alternative to LHM for the treatment of esophageal achalasia. POEM is a natural orifice transmural endoscopic surgery (NOTES) technique. An endoscope is guided through the esophagus toward the esophageal-gastric junction during the procedure. The endoscopist cuts the esophageal mucosa and inserts the endoscope into the esophageal submucosa, creating a submucosal tunnel that extends distally into the gastric cardia. The muscularis propria muscle in and around the LES is severed with a diathermic scalpel introduced through the endoscope. POEM, unlike surgical myotomy, which is frequently performed in conjunction with fundoplication to avoid reflux, does not include an antireflux operation and may result in severe GERD. POEM is contraindicated in the following conditions: severe pulmonary disease; esophageal irradiation; esophageal malignancy; bleeding disorders, including coagulopathy and recent esophageal surgery; and endoscopic intervention, including endoscopic mucosal resection and endoscopic submucosal dissection (Friedel et al., 2014; Cho and Kim, 2018).

Regulatory

POEM uses available laparoscopic instrumentation and, as a surgical procedure, is not subject to regulation by the United States Food and Drug Administration (FDA). However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation.

Molina Healthcare, Inc. ©2023 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

COVERAGE POLICY

POEM for the treatment of symptomatic, esophageal achalasia **may be considered medically necessary** when **ONE** of the following **(I OR II)** is met:

I. POEM to treat achalasia **may be considered medically necessary** and covered when **ALL** the following criteria (A – E) are met:

A. Diagnosis of type I, II, or III esophageal achalasia established by high-resolution esophageal manometry (HRM) confirming **ONE** of the following:
   1. Incomplete relaxation of the lower esophageal sphincter (integrated relaxation pressure above the upper limit of normal), and aperistalsis in the distal two-thirds of the esophagus; **OR**
   2. Inconclusive findings and BOTH of the following criteria are met:
      a. Modified esophagram with timed emptying of a standardized barium volume (also known as "timed barium esophagram") indicating dilation of the esophagus, narrow esophagogastric junction, aperistalsis, and/or delayed emptying of barium; and
      b. Esophagogastric malignancy has been ruled out by appropriate means (e.g., upper endoscopy, endoscopic ultrasound with fine needle aspiration).

AND

B. Documentation of **ALL** the following
   1. History and physical exam, including a standardized, validated symptom assessment indicating symptomatic, esophageal achalasia (i.e., dysphagia for solids and liquids; heartburn unresponsive to a trial of proton pump inhibitor therapy); **AND**
   2. Eckardt symptom score is greater than 3; **AND**
   3. Gastroesophageal reflux disease (GERD) has been objectively ruled out as the primary cause of dysphagia and/or heartburn by either of the following when symptoms of heartburn are present:
      a. Reflux and/or esophagitis is not present on endoscopy; **and/or**
      b. 24-hour ambulatory esophageal pH monitoring rules out reflux.

AND

C. Member meets **ONE** of the following:
   1. POEM is recommended as the most appropriate procedure for the treatment of achalasia based on patient-specific parameters (Chicago Classification subtype, comorbidities, early vs. late disease, primary or secondary causes); **OR**
   2. Previous treatment of achalasia (e.g., pneumatic balloon dilation, botulinum toxin injection, or surgical myotomy).

AND

D. Member has been counseled on the risk of GERD and alternative treatments available with a lower incidence of post-procedure GERD, such as LHM and PD, appropriate for member's specific condition

AND

E. Member does **not** have any of the following conditions considered a contraindication to the POEM procedure:
   1. Severe erosive esophagitis
   2. Significant coagulation disorders
   3. Liver cirrhosis with portal hypertension
   4. Severe pulmonary disease
   5. Esophageal malignancy
   6. Prior therapy that may compromise the integrity of the esophageal mucosa or lead to submucosal fibrosis (e.g., radiation, endoscopic mucosal resection, or radiofrequency ablation)
      *Informational Note: Previous therapies for achalasia, such as PD, botulinum toxin injection, or LHM, are **not** contraindications to POEM.*

Molina Healthcare, Inc. ©2023 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

OR

II. Member with failed initial myotomy documented by *(include date of previous procedure and relevant supporting clinical documentation)* **ONE** of the following:

A. Recurrent symptoms after a prior POEM procedure on the opposite site of the esophagus with an Eckardt symptom score >3; **OR**

B. A failed LHM documented by recurrent or persistent symptoms.

LIMITATIONS AND EXCLUSIONS

The following are considered **contraindications/exclusions** based on insufficient evidence:

1. Severe erosive esophagitis
2. Significant coagulation disorders
3. Liver cirrhosis with portal hypertension
4. Severe pulmonary disease
5. Esophageal malignancy
6. Prior therapy that may compromise the integrity of the esophageal mucosa or lead to submucosal fibrosis (e.g., radiation, endoscopic mucosal resection, or radiofrequency ablation)

The following are considered **experimental, investigational and unproven** based on insufficient evidence:

1. Any indications other than those listed above, including the following POEM procedures:
   a. Diverticular peroral endoscopic myotomy (D-POEM)
   b. Gastric peroral endoscopic myotomy (G-POEM)
   c. Zenker peroral endoscopic myotomy (Z-POEM)

DURATION OF APPROVAL: ONE time authorization*
*A repeated POEM may be considered medically necessary for adults with recurrent symptoms after a prior POEM procedure on the opposite site of the esophagus with an Eckardt symptom score >3 and no contraindications. **New authorization request is required.**

PRESCRIBER REQUIREMENTS: Procedures must be performed by adequately trained, experienced physicians in a highly specialized center.

AGE RESTRICTIONS: 18 years of age or older

ADMINISTRATION:

1. Procedure performed in highly specialized centers with the staff to address any potential adverse events from POEM immediately, including but not limited to gastrointestinal or cardio-thoracic complications; **AND**
2. Refer to MHI Policy & Procedure: Specialty Medication Administration Site of Care Policy (MHI Pharm 11).

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

Molina Healthcare, Inc. ©2023 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

SUMMARY OF MEDICAL EVIDENCE

POEM appears to be generally safe and may achieve at least equivalent efficacy and harm outcomes to PD and LHM in the treatment of achalasia. Furthermore, studies suggest that POEM may benefit a subset of achalasia patients. Some of these patients are not surgical candidates or may refuse surgery if a less invasive treatment option is available. These patients may be appropriate candidates for a minimally invasive procedure like POEM. It should be highlighted, however, that the evidence includes low-quality studies indicating that POEM is likely to be at least as safe and effective as LHM for most treatment outcomes in adult patients with EA. Furthermore, systematic reviews with meta-analyses summarizing data from efficacy and safety outcomes for POEM were limited by the evidence base and the need for larger-scale, multicenter studies comparing POEM with standard achalasia treatments, as well as heterogeneity in procedures, techniques, and reporting outcomes (Talukdar et al., 2015; Wei et al., 2015; Patel et al., 2016; Awaiz et al., 2017; Repici et al., 2018; Schlottmann et al., 2018b; Aiolfi et al., 2019). There are additional questions about the best surgical method, patient selection criteria, and the long-term durability and safety of surgery. Because EA is a chronic condition that requires ongoing long-term treatment, more treatment data are required to determine the long-term efficacy and complications of POEM, as a major concern with POEM from clinical studies, systematic reviews, and meta-analyses has been the high rate of gastroesophageal reflux, despite the theoretical benefits of avoiding the esophagogastric junction dissection required for LHM (AGA 2017).

Studies Comparing POEM with LHM

The evidence consists of 17 studies (3 prospective cohort studies with historical controls, 3 prospective cohort studies, 2 retrospective cohort studies with historical controls, 6 retrospective cohort studies, 2 retrospective cohort studies with matched controls) comparing POEM with LHM. Several studies found no difference between POEM and LHM for symptom relief and found no difference between POEM and lower esophageal sphincter LHM for treatment success. One study favored POEM over LHM for treatment success. The studies also found no difference between POEM and LHM for LES pressure although one of these studies found better results for LHM than POEM in a second measure of LES. Several studies found no difference between POEM and LHM in weight change (Hungness et al., 2013; Bhayani et al., 2014; Kumagai et al., 2015; Kumbhari et al., 2015; Teitelbaum et al., 2015; Chan et al., 2016; Sanaka et al., 2016; Schneider et al., 2016; de Pascale et al., 2017; Docimo et al., 2017; Khashab et al., 2017; Hanna et al., 2018; Ramirez et al., 2018; Ali et al., 2019; Sanaka et al., 2019; Wirsching et al., 2019; Werner et al. 2019).

Studies Comparing POEM with Pneumatic Dilation (PD)

The evidence consists of 4 studies (1 RCT, 3 retrospective cohort studies) comparing POEM with PD. Some studies favored POEM over PD for symptom relief. One study found no difference. Studies favored POEM over PD for treatment success but found no difference between POEM and LHM for LES pressure. (Sanaka et al., 2016; Meng et al., 2017; Kim et al., 2019; Ponds et al., 2019). In the only RCT, Ponds et al. (2019) compared the effects of POEM vs PD as initial treatment of 133 treatment-naive adult patients with newly diagnosed achalasia and an Eckardt score greater than 3 who had not undergone previous treatment. POEM resulted in a higher rate of treatment success than pneumatic dilation at 2 years (92% versus 54%). There were no procedure-related adverse events after POEM, but there was one perforation with pneumatic dilation; reflux esophagitis developed more frequently after POEM than after pneumatic dilation (41% versus 7%). Two serious adverse events, including 1 perforation, occurred after PD, while no serious adverse events occurred after POEM. (Ponds et al., 2019).

Systematic Review and Meta-Analysis

Dirks et al. (2021) compared POEM to LHM and PD in 28 studies in a systematic review and meta-analysis (2 RCTs and 26 observational studies). Most POEM comparative studies included LHM (n=21), with a few that included POEM vs PD (n=8). One study compared all 3 procedures. In studies assessing POEM, shorter follow-up was common due to its novelty. Two studies compared POEM to PD and LHM in children. Only 1 study had predominantly type 3 achalasia as a baseline; the majority of included studies had predominantly type 2 and/or type 1 achalasia as a baseline. Most studies included had fewer than 100 patients in total. POEM had a similar efficacy to LHM, according to the findings. In an RCT and an observational study, POEM treated dysphagia better

Molina Healthcare, Inc. ©2023 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

than PD, and POEM required less reintervention than PD or LHM. POEM's safety profile was comparable to that of LHM and PD. POEM has similar outcomes to LHM and is more effective than PD, according to the authors.

Facciorusso et al. (2021) conducted a systematic review and network meta-analysis of first-line achalasia therapies. Each of the 3 treatments was evaluated in 6 RCTs that compared the efficacy of PD (n=260), LHM (n=309), and POEM (n=176) in individuals with achalasia. LHM was compared to PD in four studies, POEM was compared to PD in one study, and POEM was compared to LHM in another. Overall, low-quality data, based mostly on direct evidence, supported the use of POEM over PD for one-year treatment success, whereas no meaningful difference between LHM and POEM was seen. POEM, LHM, and PD, respectively, had a 5.3%, 3.7%, and 1.5% incidence of severe esophagitis. Procedure-related major adverse events were 1.4%, 6.7%, and 4.2% after POEM, LHM, and PD, respectively. POEM and LHM are comparable in terms of efficacy and may increase treatment success when compared to PD, according to the authors, albeit with limited confidence in estimates.

Aiolfi et al. performed a systematic review and meta-analysis using Bayesian random-effects networks to compare POEM to LHM and pneumatic dilation (Aiolfi, 2020). There was a total of 19 studies involving 4407 patients. Of these, 10 trials involving 645 patients directly compared POEM to LHM, but none directly compared POEM to pneumatic expansion. POEM was associated with improved dysphasia remission and Eckardt scores but was associated with a higher risk of GERD than LHM. The inclusion of arm-based indirect comparisons and the inherent bias associated with its dependence on observational studies are two of the limitations of this network meta-analysis.

Andolfi and Fisichella (2019), in a meta-analysis of mostly observational studies, included 20 studies (1575 patients) on botulinum toxin, PD, LHM, and POEM. LHM success rates in types I, II, and III achalasia were 81, 92, and 71%, respectively. Those for POEM were 95, 97, and 93%, respectively. POEM had a higher success rate than LHM for both type I and type III achalasia. In treating type II achalasia, POEM and LHM had comparable success rates. The analysis concluded that POEM is an effective treatment modality for achalasia types I and III, but it did not demonstrate superiority over LHM for achalasia type II. In patients with type II achalasia, PD had a lower but still acceptable success rate compared to POEM or LHM, according to the meta-analysis.

Schlottmann et al. (2018) conducted a systematic review and meta-analysis of 7792 patients across 53 studies using LHM (5834 patients) and 21 studies using POEM (1958 patients) for the treatment of esophageal achalasia. The probability of dysphagia improvement at 24 months was 90% in patients receiving LHM and 93% in patients receiving POEM (p=0.01). Limitations noted by the authors included the small number of controlled studies, heterogeneity in reported outcomes, and differences in follow-up time between treatment groups. Patients receiving POEM were significantly more likely to develop GERD.

Talukdar et al. (2015) conducted a systematic review and meta-analysis which included 29 studies (20 were eligible for meta-analyses and 5 compared POEM with LHM). The aim of the review was to determine the efficacy of POEM for the treatment of achalasia and compare it with LHM. Meta-analysis of Eckardt scores and changes in LES pressure and POEM showed statistically significant improvements in these results. There was high heterogeneity among the studies in these meta-analyses, and the authors reported significant publication bias for both outcomes. Furthermore, some of the studies may have had overlapping patient populations, which could cause an overestimation of the beneficial effect. There were no statistically significant differences in the reduction of postoperative pain, analgesic dose, hospital LOS, risk of adverse events, or development of symptomatic GERD. Procedure time was significantly less for POEM compared with LHM. The authors conclude that POEM is relatively efficacious and safe and is similar to LHM for most outcomes. However, they note several limitations of the evidence base and the need for larger-scale, multicenter studies comparing POEM with standard treatments for achalasia and comparing treatment-naïve patients with those for whom other treatments have failed.

Pediatric Patients with Achalasia

Zhong et al. (2021) conducted a systematic review and meta-analysis of the clinical outcomes of POEM for the treatment of achalasia in children. The review comprised 11 studies (N=389; 222 boys) published between January 2009 and June 2020. The patients' ages ranged from 5.5 to 15.2 years, and the length of their symptoms ranged from 1.7 to 26.4 months. The pooled technical success (completion of the POEM operation successfully) was obtained in 385 children (97.4%), while the pooled clinical success (reduction in Eckardt score to 3 during follow-up) was reached in 343 children. Following POEM, the Eckhardt score was cut by 6.76 points. In terms of adverse

Molina Healthcare, Inc. ©2023 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

events, the pooled major adverse event rate was 12.8%, with a 17.8% rate of gastroesophageal reflux. The authors concluded that POEM was effective and safe for the treatment of children with achalasia, however all included studies were observational.

Additional studies (meta-analysis, systematic reviews, and retrospective case series) are included in the reference section.

Spechler (2022), in an evidence-based peer-review, notes that the use of POEM is supported by clinical trials and observational data from highly specialized centers (Werner et al. 2019; Ponds et al., 2019; Inoue et al. 2015; Hungness et al., 2013). In patients with achalasia conditions that typically do not respond well to conventional therapies, such as "end stage" achalasia (markedly dilated, sigmoid esophagus), and in patients who have failed prior endoscopic and surgical achalasia treatments, favorable outcomes have been reported with POEM (UpToDate, 2022).

In a Health Technology Assessment (HTA), a comparative effectiveness review of the use of POEM for treating EA compared to either LHM or PD concluded that the existing evidence, primarily from low-quality studies, indicates that the POEM treatment has potential but unproven benefit, is generally safe, and may obtain results comparable to both LHM and PD for the majority of efficacy and harmful outcomes (Hayes, 2022). The evidence comparing POEM to LHM is moderate (16 studies), whereas evidence comparing POEM to PD is limited. It should be noted that there were no eligible randomized controlled trials found in the literature, and many of the findings from nonrandomized studies need to be confirmed through more rigorous study designs and longer follow-up periods. The HTA also noted a lack of discussion of the clinical significance of any differences detected from baseline or between groups in the evaluated studies and recommended that more studies of fair to good quality be conducted to determine the most effective treatment protocols for patients, patient selection criteria, and long-term outcomes.

National and Specialty Organizations

POEM may serve as a primary treatment for type I and II achalasia (as an alternative to pneumatic dilation and surgical myotomy) and a preferred treatment for type III achalasia (AGA 2017; ISDE 2018).

The **American College of Gastroenterology (ACG)** published evidence-based clinical guidelines on the diagnosis and treatment of achalasia in 2020. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework was used to rate the quality of the evidence and the strength of the recommendations. The two RCTs comparing POEM to LHM, or pneumatic dilation are included in the evidence review. The ACG issued the following recommendations based on their evaluation:

- POEM or LHM is more effective for type III achalasia when compared to PD
- POEM and PD have comparable symptom improvement in patients with types I or II achalasia
- POEM and LHM have comparable symptom improvement in patients with achalasia
- POEM is a safe option in patients with achalasia who have failed PD or LHM
- POEM is associated with a higher incidence of GERD when compared to LHM with fundoplication or PD

In 2013, the guidelines stated that POEM is considered an emerging therapy and concluded that the available evidence from prospective cohort studies suggests that POEM has promise as an alternative to the laparoscopic approach. The guidelines further stated that randomized prospective comparison trials are needed, and POEM should only be used in clinical trials, with the understanding that efficacious alternatives exist (Vaezi et al., 2013).

The **American Gastroenterological Association (AGA)** published a Clinical Practice Update on POEM use in achalasia in 2017 (Expert Review and Best Practice Advice, 2017). POEM appears to be safe and effective in the short term, according to the AGA, but long-term durability data is not yet available. Uncontrolled studies suggested that POEM is as effective as or better than LHM, but it is more likely to cause post-treatment reflux. The Institute made the following recommendations based on the expert review:

- POEM should be performed in high-volume centers by experienced physicians (an estimated 20 to 40 procedures are required to obtain competence and 60 to achieve mastery).
- If expertise is available, POEM should be considered primary therapy for type III achalasia, and Heller myotomy should be considered for all achalasia syndromes.

Molina Healthcare, Inc. ©2023 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

The **American Society of Gastrointestinal and Endoscopic Surgeons (ASGE)** issued consensus guidelines in 2014 on the use of endoscopy in the diagnosis and treatment of dysphagia, including esophageal achalasia. These guidelines suggest that, while POEM is being used more frequently in expert centers, long-term data and randomized trials comparing POEM to conventional modalities are needed before it can be used in clinical practice. The ASGE made no specific recommendations regarding the use of POEM in the treatment of achalasia.

In 2020, the ASGE published an evidence-based guideline on the treatment of achalasia, which was endorsed by both the American Neurogastroenterology and Motility Society and the Society of American Gastrointestinal and Endoscopic Surgeons. The methodological quality of systematic reviews was evaluated using the AMSTAR-2 tool, and the certainty of the body of evidence was rated as very low to high using the GRADE framework. ASGE rated the strength of each recommendation based on the overall quality of the evidence and an evaluation of the anticipated benefits and risks. ASGE utilized "we suggest" for weaker recommendations and "we recommend" for stronger ones. This guideline did not include either of the two RCTs of POEM that were available. ASGE issued the following recommendations in consideration of their analysis:

- “We suggest POEM as the preferred treatment for management of patients with type III achalasia." (Very low-quality evidence)
- "In patients with failed initial myotomy (POEM or LHM), we suggest PD or redo myotomy using either the same or an alternative myotomy technique (POEM or LHM)." (Very low-quality evidence)
- "We suggest that patients undergoing POEM are counseled regarding the increased risk of post-procedure reflux compared with PD and LHM. Based on patient preferences and physician expertise, post-procedure management options include objective testing for esophageal acid exposure, long-term acid suppressive therapy, and surveillance upper endoscopy." (Low quality evidence)
- We suggest that POEM and LHM 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." (Low quality evidence)

The **International Society for Diseases of the Esophagus (ISDE)** published guidelines for achalasia diagnosis and management (ISDE, 2018). The organization convened 51 experts from 11 countries, including several from the United States, to conduct a systematic review of the evidence, evaluate the recommendations using the GRADE method, and vote on which recommendations should be included in the guidelines (inclusion requires more than 80% approval). The POEM recommendations are summarized in the table below.

Recommendation	Level of Recommendation	Grade of Recommendation
POEM is an effective therapy for achalasia both in short- and medium-term follow-up with results comparable to Heller myotomy.	Conditional	Very Low
POEM is an effective therapy for achalasia both in short- and medium-term follow-up with results comparable to PDs.	Conditional	Low
Pretreatment information on GERD, nonsurgical options (PD), and surgical options with lower GERD risk (Heller myotomy) should be provided to patient.	Good practice	NA
POEM is feasible and effective for symptom relief in patients previously treated with endoscopic therapies.	Conditional	Very Low
POEM may be considered an option for treating recurrent symptoms after laparoscopic Heller myotomy.	Conditional	Low
Appropriate training (in vivo/in vitro animal model) and proctorship should be considered prior to a clinical program of POEM.	Good practice	N/A

The **Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)** published evidence-based guidelines for the use of POEM to treat achalasia in 2021 (Kohn, 2021). The expert panel made the following four recommendations for adults and children with achalasia:

- For adult and pediatric patients with type I and type II achalasia, POEM or LHM may be used for treatment based on a collaborative decision-making process between the surgeon and the patient (conditional recommendation; very low certainty evidence).
- For type III adult or pediatric achalasia, the panel recommends POEM over LHM (expert opinion).
- In patients with achalasia, the panel recommends POEM over PD (strong recommendation, moderate certainty evidence).
- For patients concerned about post-operative proton pump inhibitor use, the panel recommends either POEM or PD, depending on patient and surgeon preferences (conditional recommendation, very low certainty evidence).

Molina Healthcare, Inc. ©2023 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

SUPPLEMENTAL INFORMATION

Eckardt Symptom Score (ESS) is most frequently used for the evaluation of symptoms, stages, and efficacy of achalasia treatment. The ESS is a 4-item self-report scale measuring weight loss, chest pain, regurgitation, and dysphagia. Each item is graded on a score of 0 to 3 with a maximum score of 12. Score greater than or equal to 3 are considered active achalasia.

Eckardt Score for Symptomatic Evaluation in Achalasia				
Score	**Weight loss (kg)**	**Dysphagia**	**Retrosternal Pain**	**Regurgitation**
0	None	None	None	None
1	< 5	Occasional	Occasional	Occasional
2	5-10	Daily	Daily	Daily
3	> 10	Each meal	Each meal	Each meal

Subtypes of achalasia defined by the Chicago classification (Kahrilas et al. 2015):

- Type I (classic achalasia): 100% failed peristalsis and normal pan-esophageal pressurization
- Type II (achalasia with esophageal compression): 100% failed peristalsis and increased pan-esophageal pressurization with ≥ 20% of swallows
- Type III (spastic achalasia): abnormal peristalsis and premature contractions with ≥ 20% of swallows

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
43497	Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])
43499	Unlisted procedure, esophagus

HCPCS Codes – N/A

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

04/13/2023 MCPC	Policy reviewed and updated. No changes to coverage criteria. Updated 'Summary of Evidence' section and references.
04/13/2022 MCPC	Policy revised. Coverage position changed from E/I to medically necessary. Added coverage criteria and updated summary of evidence: systematic review and meta-analyses; Hayes's HTA (updated review in Jan 2022); updated SAGES guidelines.
12/08/2021 MCPC	Policy reviewed and updated, no changes in coverage criteria, updated references. Converted to new format. Notable revisions to the summary of evidence include: addition of relevant/updated systematic review and meta-analyses; addition of Hayes's comparative effectiveness review (updated review in April 2021); updated professional society guidelines and inclusion of relevant (ASGE; ISDE; SAGES)
12/09/2020 MCPC	New policy. IRO Peer Review. 10/8/20. Practicing Physician. Board certified in Gastroenterology.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: myotomy; achalasia; peroral endoscopic myotomy; POEM; esophageal achalasia I). No NCD identified. An LCD was available. (Available from CMS. Accessed February 2022.
2. ClinicalTrials.gov. National Library of Medicine; 2000 Feb 29 - [cited February 2019]. Available from ClinicalTrials.gov.

Molina Healthcare, Inc. ©2023 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

Peer Reviewed Publications

1. Aiolfi A, Bona D, Riva CG, et al. Systematic review and Bayesian Network meta-analysis comparing laparoscopic heller myotomy, pneumatic dilatation, and peroral endoscopic myotomy for esophageal achalasia. J Laparoendosc Adv Surg Tech A. Feb 2020; 30(2): 147-155. doi: 10.1089/lap.2019.0432. Epub 2019 Jul 31.
2. Ali AB, Khan NA, Nguyen DT, et al. Robotic and per-oral endoscopic myotomy have fewer technical complications compared to laparoscopic Heller myotomy. Surg Endosc. 2020 Jul;34(7):3191-3196. doi: 10.1007/s00464-019-07093-2.
3. Andolfi C, Fisichella PM. Meta-analysis of clinical outcome after treatment for achalasia based on manometric subtypes. Br J Surg 2019; 106:332.
4. Bhayani NH, Kurian AA, Dunst CM, et al. A comparative study on comprehensive, objective outcomes of laparoscopic Heller myotomy with per-oral endoscopic myotomy (POEM) for achalasia. Ann Surg. 2014;259(6):1098-1103.
5. Chan SM, Wu JC, Teoh AY, et al. Comparison of early outcomes and quality of life after laparoscopic Heller's cardiomyotomy to peroral endoscopic myotomy for treatment of achalasia. Dig Endosc. 2016;28(1):27-32. doi: 10.1111/den.12507. Epub 2015 Aug 11.
6. Cho YK, Kim SH. Current status of peroral endoscopic myotomy. Clin Endosc. 2018;51(1):13-18. doi: 10.5946/ce.2017.165. Epub 2018 Jan 31.
7. de Pascale S, Repici A, Puccetti F, Carlani E, Rosati R, Fumagalli U. Peroral endoscopic myotomy versus surgical myotomy for primary achalasia: single-center, retrospective analysis of 74 patients. Dis Esophagus. 2017;30(8):1-7. doi: 10.1093/dote/dox028.
8. Dirks RC, Kohn GP, Slater B, et al. Is peroral endoscopic myotomy (POEM) more effective than pneumatic dilation and Heller myotomy? A systematic review and meta-analysis. Surg Endosc. May 2021; 35(5): 1949-1962. doi: 10.1007/s00464-021-08353-w. Epub 2021 Mar 2.
9. Docimo S Jr, Mathew A, Shope AJ, et al. Reduced postoperative pain scores and narcotic use favor per-oral endoscopic myotomy over laparoscopic Heller myotomy. Surg Endosc. 2017;31(2):795-800. doi: 10.1007/s00464-016-5034-3. Epub 2016 Jun 23.
10. Facciorusso A, Singh S, Abbas Fehmi SM, et al. Comparative efficacy of first-line therapeutic interventions for achalasia: a systematic review and network meta-analysis. Surg Endosc. Aug 2021; 35(8): 4305-4314. doi: 10.1007/s00464-020-07920-x. Epub 2020 Aug 27. PMID 32856150.
11. Friedel D, Modayil R, Stavropoulos SN. Per-oral endoscopic myotomy: major advance in achalasia treatment and in endoscopic surgery. World J Gastroenterol. 2014;20(47):17746-17755. doi: 10.3748/wjg.v20.i47.17746.
12. Hanna AN, Datta J, Ginzberg S, Dasher K, Ginsberg GG, Dempsey DT. Laparoscopic Heller myotomy vs per oral endoscopic myotomy: patient-reported outcomes at a single institution. J Am Coll Surg. 2018;226(4):465-472.e461. doi: 10.1016/j.jamcollsurg.2017.12.050. Epub 2018 Feb 2.
13. Hungness ES, Teitelbaum EN, Santos BF, et al. Comparison of perioperative outcomes between peroral esophageal myotomy (POEM) and laparoscopic Heller myotomy. J Gastrointest Surg. Feb 2013;17(2):228-235. doi: 10.1007/s11605-012-2030-3. Epub 2012 Sep 28.
14. Inoue H, Sato H, Ikeda H, et al. Peroral Endoscopic Myotomy: A series of 500 patients. J Am Coll Surg 2015 Aug;221(2):256-64. doi: 10.1016/j.jamcollsurg.2015.03.057. Epub 2015 Apr 11. PMID: 26206634..
15. Kahrilas PJ, Bredenoord AJ, Fox M, International High Resolution Manometry Working Group, et al. The Chicago Classification of esophageal motility disorders, v3.0. Neurogastroenterol Motil. 2015 Feb;27(2):160-74. doi: 10.1111/nmo.12477.
16. Khashab MA, Kumbhari V, Tieu AH, et al. Peroral endoscopic myotomy achieves similar clinical response but incurs lesser charges compared to robotic Heller myotomy. Saudi J Gastroenterol. 2017;23(2):91-96. doi: 10.4103/1319-3767.203360.
17. Kim GH, Jung KW, Jung HY, et al. Superior clinical outcomes of peroral endoscopic myotomy compared with balloon dilation in all achalasia subtypes. J Gastroenterol Hepatol. 2019;34(4):659-665. doi: 10.1111/jgh.14616. Epub 2019 Feb 17.
18. Kumbhari V, Tieu AH, Onimaru M, et al. Peroral endoscopic myotomy (POEM) vs laparoscopic Heller myotomy (LHM) for the treatment of type III achalasia in 75 patients: A multicenter comparative study. Endosc Int Open. 2015;3(3):E195-E201. doi: 10.1055/s-0034-1391668. Epub 2015 Apr 13.
19. Kumagai K, Tsai JA, Thorell A, Lundell L, Hakanson B. Peroral endoscopic myotomy for achalasia. Are results comparable to laparoscopic Heller myotomy? Scand J Gastroenterol. 2015;50(5):505-512. doi: 10.3109/00365521.2014.934915. Epub 2015 Feb 24.
20. Meng G F, Li P, Wang Y, et al. Peroral endoscopic myotomy compared with pneumatic dilation for newly diagnosed achalasia. Surg Endosc. 2017;31(11):4665-4672. doi: 10.1007/s00464-017-5530-0. Epub 2017 Apr 14.
21. Ponds FA, Fockens P, Lei A, et al. Effect of peroral endoscopic myotomy vs pneumatic dilation on symptom severity and treatment outcomes among treatment-naive patients with achalasia: A randomized clinical trial. JAMA 2019; 322:134–144. doi:10.1001/jama.2019.8859,
22. Ramirez M, Zubieta C, Ciotola F, et al. Peroral endoscopic myotomy vs. laparoscopic Heller myotomy, does gastric extension length matter? *Surg Endosc.* 2018;32(1):282-288. doi: 10.1007/s00464-017-5675-x. Epub 2017 Jun 28.
23. Sanaka MR, Hayat U, Thota PN, et al. Efficacy of peroral endoscopic myotomy vs other achalasia treatments in improving esophageal function. World J Gastroenterol. 2016;22(20):4918-4925. doi: 10.3748/wjg.v22.i20.4918.
24. Sanaka MR, Thota PN, Parikh MP, et al. Peroral endoscopic myotomy leads to higher rates of abnormal esophageal acid exposure than laparoscopic Heller myotomy in achalasia. Surg Endosc. 2019;33(7):2284-2292. doi: 10.1007/s00464-018-6522-4. Epub 2018 Oct 19.
25. Schlottmann F, Luckett DJ, Fine J, et al. Laparoscopic heller myotomy versus Peroral Endoscopic Myotomy (POEM) for Achalasia: A systematic review and meta-analysis. Ann Surg 2018; 267:451. doi: 10.1097/SLA.0000000000002311.
26. Teitelbaum EN, Soper NJ, Pandolfino JE, et al. Esophagogastric junction distensibility measurements during Heller myotomy and POEM for achalasia predict postoperative symptomatic outcomes. Surg Endosc. 2015;29(3):522-528. doi: 10.1007/s00464-014-3733-1. Epub 2014 Jul 24.
27. Werner YB, Hakanson B, Martinek J, et al. Endoscopic or surgical myotomy in patients with idiopathic achalasia. N Engl J Med 2019; 381:2219-2229. doi: 10.1056/NEJMoa1905380.
28. Wirsching A, Boshier PR, Klevebro F, et al. Comparison of costs and short-term clinical outcomes of per-oral endoscopic myotomy and laparoscopic Heller myotomy. Am J Surg. 2019;218(4):706-711. doi: 10.1016/j.amjsurg.2019.07.026. Epub 2019 Jul 18.

National and Specialty Organizations

1. American College of Gastroenterology (ACG).
   a. Vaezi MF, Pandolfino JE, Yadlapati RH, Greer KB, Kavitt RT. ACG clinical guidelines: Diagnosis and management of achalasia. Am J Gastroenterol. 2020 Sep;115(9):1393-1411. doi: 10.14309/ajg.0000000000000731.

Molina Healthcare, Inc. ©2023 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

b. Vaezi M et al. ACG Clinical guideline: Diagnosis and management of achalasia. Am J Gastroenterol. 2013 Aug;108(8):1238-49; quiz 1250. doi: 10.1038/ajg.2013.196.

2. American Gastroenterological Association (AGA). Kahrilas P et al. Clinical practice update: The use of Per-Oral Endoscopic Myotomy in achalasia: Expert review and best practice advice from the AGA Institute. Gastroenterology 2017;153:1205–1211. doi: 10.1053/j.gastro.2017.10.001. Epub 2017 Oct 6. Available from AGA.

3. American Society for Gastrointestinal Endoscopy (ASGE)
   a. Khashab MA, Vela MF, Thosani N, et al. ASGE guideline on the management of achalasia. Gastrointest Endosc. 2020 Feb;91(2):213-227.e6. doi: 10.1016/j.gie.2019.04.231.
   b. American Society for Gastrointestinal Endoscopy (ASGE) Standards of Practice Committee, Pasha SF, Acosta RD, et al. The role of endoscopy in the evaluation and management of dysphagia. Gastrointest Endosc. 2014;79(2):191-201. doi: 10.1016/j.gie.2013.07.042. Epub 2013

4. International Society for Diseases of the Esophagus (ISDE). Zaninotto G, Bennett C, Boeckxstaens G, et al. The 2018 ISDE achalasia guidelines. Dis Esophagus. 2018 Sep 1;31(9). doi: 10.1093/dote/doy071.

5. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)
   a. Kohn GP, Dirks RC, Ansari MT, et al.(2021) SAGES guidelines for the use of peroral endoscopic myotomy (POEM) for the treatment of achalasia. Surg Endosc. May 2021; 35(5): 1931-1948. PMID 33564964
   b. Stefanidis D, Richardson W, Farrell TM, et al. SAGES guidelines for the surgical treatment of esophageal achalasia. Surg Endosc. Feb 2012; 26(2): 296-311. doi: 10.1007/s00464-011-2017-2. Epub 2011 Nov 2.

Other Authoritative Publications

1. DynaMed [Internet]. Ipswich (MA): EBSCO Information Services. 1995 - . Record No. T114877, Achalasia; [updated 2018 Nov 30, cited place cited date here]. Available from Dynamed. Registration and login required.
2. Hayes. Comparative effectiveness review: Peroral Endoscopic Myotomy for treatment of esophageal achalasia. Available from Hayes. Annual Review January 20, 2022. Accessed February 2023. Registration and login required.
3. UpToDate. Available from UpToDate. Registration and log in required. Accessed February 2023.
   a. Khashab M. Peroral endoscopic myotomy (POEM). Available from UpToDate. Updated September 22, 2021.
   b. Spechler, S. Overview of the treatment of achalasia. Available from UpToDate. Updated Jul 15, 2022.

Additional References (not cited in policy)

1. Awaiz A, Yunus RM, Khan S, Memon B, Memon MA. Systematic review and meta-analysis of perioperative outcomes of peroral endoscopic myotomy (POEM) and laparoscopic Heller myotomy (LHM) for achalasia. Surg Laparosc Endosc Percutan Tech. 2017;27(3):123-131.
2. Choné A, Familiari P, von Rahden B, et al. Multicenter evaluation of clinical efficacy and safety of Per-oral Endoscopic Myotomy in children. J Pediatr Gastroenterol Nutr 2019; 69:523.
3. Haito-Chavez Y, Inoue H, Beard KW, et al. Comprehensive analysis of adverse events associated with Per Oral Endoscopic Myotomy in 1826 patients: An international multicenter study. Am J Gastroenterol 2017; 112:1267.
4. Hungness ES, Sternbach JM, Teitelbaum EN, et al. Peroral Endoscopic Myotomy (POEM) after the learning curve: Durable long-term results with a low complication rate. Ann Surg 2016; 264:508.
5. Kahrilas PJ, Bredenoord AJ, Carlson DA, et al. Advances in management of esophageal motility disorders. Clin Gastroenterol Hepatol 2018; 16:1692.
6. Marano L, Pallabazzer G, Solito B, et al. Surgery or Peroral Esophageal Myotomy for achalasia: A systematic review and meta-analysis. Medicine (Baltimore) 2016; 95:e3001.
7. Orenstein SB, Raigani S, Wu YV, et al. Peroral endoscopic myotomy (POEM) leads to similar results in patients with and without prior endoscopic or surgical therapy. Surg Endosc 2015; 29:1064.
8. Repici A, Fuccio L, Maselli R, et al. GERD after per-oral endoscopic myotomy as compared with Heller's myotomy with fundoplication: A systematic review with meta-analysis. Gastrointest Endosc 2018; 87:934.
9. Stavropoulos SN, Modayil RJ, Friedel D, Savides T. The International Per Oral Endoscopic Myotomy Survey (IPOEMS): A snapshot of the global POEM experience. Surg Endosc 2013; 27:3322.
10. Teitelbaum EN, Dunst CM, Reavis KM, et al. Clinical outcomes five years after POEM for treatment of primary esophageal motility disorders. Surg Endosc 2018; 32:421.
11. Tyberg A, Seewald S, Sharaiha RZ, et al. A multicenter international registry of redo per-oral endoscopic myotomy (POEM) after failed POEM. Gastrointest Endosc 2017; 85:1208.
12. Yang J, Zeng X, Yuan X, et al. An international study on the use of Peroral Endoscopic Myotomy (POEM) in the management of esophageal diverticula: The first multicenter D-POEM experience. Endoscopy 2019; 51:346.
13. Zheng Z, Zhao C, Su S, et al. Peroral endoscopic myotomy versus pneumatic dilation – result from a retrospective study with 1-year follow-up. Z Gastroenterol. 2019;57(3):304-311.

Molina Healthcare, Inc. ©2023 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*