Last Approval: 04/09/2025 Next Review Due By: April 2026



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 an esophageal motility disorder characterized by progressive degeneration of neurons in the esophageal myenteric plexuses, resulting in impaired relaxation of the lower esophageal sphincter (LES) and loss of peristalsis in the distal esophagus. These abnormalities lead to functional obstruction at the gastroesophageal junction and impaired emptying from the esophagus into the stomach, often resulting in food stasis. As disease progression is gradual, patients typically experience symptoms for years before seeking medical care and are often treated for other disorders, such as gastroesophageal reflux disease (GERD), before EA is diagnosed (¹Spechler and Pandolfino 2024).

The typical clinical presentation for EA is progressive dysphagia of both solids and liquids, and often accompanied by regurgitation. Some patients may also experience weight loss, chest pain, heart burn, or difficulty belching. While endoscopy may reveal esophageal dilation, food retention, or a tight appearing esophagogastric junction, these findings are not diagnostic of achalasia and the endoscopy may in fact be normal, especially in early stages of the disease. A standard or timed barium esophagram can be used to aid diagnosis but may also be unrevealing. According to the Chicago Classification system, EA is subtyped into type I, type II, and type III achalasia based on esophageal motility patterns seen during manometry. (Khashab et al. 2020; ¹Spechler and Pandolfino 2024).

The gold standard for diagnosing EA is high-resolution esophageal manometry (HRM), which shows incomplete relaxation of the LES manifested as elevated integrated relaxation pressure, and the absence of organized peristalsis. While there is currently no known cure for EA, treatment options may include pneumatic dilatation, myotomy, and botulinum toxin injections or pharmacologic therapy for patients who are poor candidates for invasive therapy. Laparoscopic Heller myotomy (LHM) with partial fundoplication is the most common operative procedure used to treat EA, which involves surgical incision of the LES muscle fibers to relieve obstruction. Pneumatic dilation, LHM, and peroral endoscopic myotomy are considered comparable effective therapies for patients with type I or type II achalasia (²Spechler and Pandolfino 2024; Oelschlager and Petersen 2024)

Peroral Endoscopic Myotomy (POEM) is a minimally invasive, endoscopic alternative to LHM for the treatment of EA, and a form of natural orifice transluminal endoscopic surgery, which is a minimally invasive surgical technique that avoids external incisions and instead accesses the internal organs through natural orifices. Like LHM, POEM works by disrupting the LES to relieve obstruction and improve esophageal emptying. It's been proposed as the procedure of choice for type III achalasia, as it can deliver a longer myotomy that is generally not possible with pneumatic dilation or LHM (²Spechler and Pandolfino 2024; Khashab 2023).

However, unlike LHM, which is frequently performed with fundoplication to reduce reflux, POEM does not include an anti-reflux procedure, leading to a higher incidence of GERD. Patients undergoing POEM should be counseled on the increased risk of post procedure reflux compared with other treatments such as LHM or pneumatic dilation. Other adverse events associated with POEM include pneumoperitoneum, subcutaneous emphysema, pneumothorax, mucosotomy, and bleeding (2Spechler and Pandolfino 2024; Khashab 2023).

Last Approval: 04/09/2025 Next Review Due By: April 2026



COVERAGE POLICY

Medically Necessary

Peroral Endoscopic Myotomy (POEM) for the treatment of esophageal achalasia may be **considered medically necessary** when <u>ALL</u> the following criteria are met:

- 1. Member is 18 years of age or older
- 2. Absence of ALL the following contraindications:
 - a. Significant coagulation disorders
 - b. Severe erosive esophagitis
 - c. Severe pulmonary disease
 - d. Liver cirrhosis with portal hypertension
 - e. Esophageal malignancy
 - f. Prior esophageal interventions that may compromise submucosal integrity (e.g., esophageal irradiation, endoscopic mucosal resection, endoscopic submucosal dissection, or recent esophageal surgery)
- 3. Diagnosis of type I, II, or III achalasia, established by high-resolution esophageal manometry confirming <u>ONE</u> of the following:
 - a. 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
 - b. Inconclusive findings despite a timed barium esophogram indicating dilation of the esophagus, narrow esophagogastric junction, aperistalsis, and/or delayed emptying of barium <u>AND</u> an esophagogastric malignancy has been ruled out by appropriate means (e.g., upper endoscopy, endoscopic ultrasound with fine needle aspiration)
- 4. Member has been counseled on the risk of gastroesophageal reflux disease (GERD) and alternative treatments available with a lower incidence of post-procedure GERD, such as laparoscopic Heller myotomy and pneumatic dilation
- 5. Documentation of ALL the following:
 - a. History and physical exam, including a standardized, validated symptom assessment indicating symptomatic esophageal achalasia (i.e., dysphagia to solids and liquids, heartburn unresponsive to a trial of proton pump inhibitor therapy)
 - b. Eckardt symptom score > 3
 - c. 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:
 - i. Absence of reflux or esophagitis on endoscopy
 - ii. 24-hour ambulatory esophageal pH monitoring rules out reflux

Continuation of Therapy

1. Repeat POEM may be **considered medically necessary** for adults with an Eckardt symptom score > 3 and no contraindications, following a prior POEM on the opposite site of the esophagus that failed to relieve symptoms. **A new authorization request is required.**

Not Medically Necessary

POEM for any indication other than esophageal achalasia is considered **experimental**, **investigational**, **and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes, including the following:

- 1. Diverticular peroral endoscopic myotomy (D-POEM)
- 2. Gastric peroral endoscopic myotomy (G-POEM)
- 3. Zenker peroral endoscopic myotomy (Z-POEM)

Last Approval: 04/09/2025 Next Review Due By: April 2026



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.

SUMMARY OF MEDICAL EVIDENCE

There is a moderate and growing body of evidence, including randomized controlled trials (RCTs), prospective and retrospective studies, systematic reviews, and meta-analyses, supporting the safety and efficacy of peroral endoscopic myotomy (POEM) for the treatment of esophageal achalasia (EA) in adults. When compared to established alternatives such as laparoscopic Heller myotomy (LHM) or pneumatic dilation (PD), POEM demonstrates comparable clinical outcomes and may offer specific advantages, particularly in patients with type III achalasia.

Randomized Controlled Trials

Ponds et al. (2019) conducted a RCT comparing the effect of POEM versus PD on symptom severity and treatment outcomes among patients with treatment-naive achalasia. The primary outcome of the trial was measuring success of the treatment as defined by a reduction in the patient's Eckardt score to less than or equal to 3 and the absence of severe complications or need for re-treatment. Notable secondary outcomes were complication rates, presence of reflux esophagitis based on endoscopy findings, esophageal acid exposure, reflux symptoms, and proton pump inhibitor use. One hundred and thirty patients were randomized and underwent treatment to receive POEM (n = 64) or PD (n = 66). One hundred and twenty-six completed the two-year study for a 95% completion rate. The primary outcome of treatment success 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%-52%]; P<.001). Outcomes were assessed at the 3 months, 1 year, and 2 years follow ups via symptoms and questionnaires, high-resolution manometry, and timed barium esophagogram. There were a total of 7 severe adverse events recorded, two of which were attributed to PD, the remaining five occurred independent of the study, with none being attributed to POEM. The most common minor adverse event attributed to POEM was reflux esophagitis, which was observed significantly more frequently in patients treated with POEM than with pneumatic dilation (22 of 54 patients [41%] in the POEM group, of whom 19 [35%] were assigned grade A-B and 3 [6%] were assigned grade C, vs 2 of 29 [7%] in the pneumatic dilation group, all of whom were assigned grade A; absolute difference, 34% [95% CI, 12%-49%]; P = .002). The authors conclude that POEM is effective and more successful at treating achalasia than PD; however, due to its more invasive nature and risk of reflux esophagitis that patients should be offered counseled in the risk and benefits of each procedure.

Kuipers et al. (2022) conducted a five year follow up analysis of the Ponds et al. (2019) RCT comparing POEM versus PD in treatment naïve achalasia. Patients available for five year follow up were 62 patients in the POEM group and 63 patients in the PD group. POE demonstrated superior long term success rates with 50 (81%) patients in the POEM group had treatment success, compared with 25 (40%) in the PD group, an adjusted absolute difference of 41% (95% CI 25-57; p<0·0001). Endoscopy results revealed patients still in clinical remission had reflux esophagitis in 14 (33%) of 42 patients in the POEM group (12 [29%] grade A or B, two [5%] grade C or D) versus two (13%) of 16 patients in the PD group (two [13%] grade A or B, none grade C or D; p=0·19). There were no severe adverse events between the two and five year follow ups for either procedure.

Systematic Reviews and Meta-Analyses

Sobral et al. (2024) conducted a systematic review and meta-analysis comparing POEM and LHM with fundoplication for the treatment of achalasia. The review included 20 retrospective observational studies published between 2010 and 2022, for a total of 5,139 participants (n = 5139), with 1,394 undergoing POEM and 3,745 undergoing LHM with fundoplication. Surgical and postoperative outcomes included clinical success (defined as an Eckardt score \leq 3), operative time, intraoperative and postoperative complications (including Clavien-Dindo grades), length of stay (LOS), reintervention rates, postoperative pain, incidence of GERD symptoms, use of proton pump inhibitors (PPIs), and esophagitis. Statistical analysis utilized risk ratios (RR) and mean differences (MD), with significance defined as p < 0.05. POEM was found to have significantly shorter operative time (mean: 116.8 minutes vs. 150.5 minutes for LHM, MD -33.80, p < 0.00001) and reduced length of stay (mean: 2.1 days vs. 2.7 days, MD - 0.55, p = 0.0001), though both outcomes showed high heterogeneity. Based on two studies, POEM also had lower

Last Approval: 04/09/2025 Next Review Due By: April 2026



postoperative pain, as measured by duration of analgesic use (mean: 1.6 days vs. 2.3 days, MD -0.91, p = 0.03). Clinical success was higher in the POEM group (91.2% vs. 82.3%, RR 1.08, p = 0.010) with low heterogeneity, though the postoperative Eckardt score did not differ significantly between groups when measured as a continuous variable. There were no statistically significant differences in intraoperative complications (11.1% for POEM vs. 8.9% for LHM, RR 1.21, p = 0.48), overall postoperative complications (7.7% vs. 5.7%, RR 0.89, p = 0.62), or complications corresponding to Clavien-Dindo grades I-IV. Reintervention rates were lower in the POEM group (10.7% vs. 17.4%), though this did not reach statistical significance (RR 0.62, p = 0.06). The occurrence of GERD symptoms, use of PPIs, and rates of esophagitis did not significantly differ between the two groups despite the lack of fundoplication in POEM. The authors note that while POEM does not include an anti-reflux mechanism, its less invasive nature may preserve esophageal function and limit reflux in some cases. The authors concluded that POEM and LHM are both safe and effective treatments for achalasia. POEM was associated with better outcomes regarding operative time, hospital stay, postoperative pain, and clinical success with a tendency toward fewer recurrences.

North and Tewari (2024) conducted a systematic review comparing POEM to LHM and pneumatic dilation (PD) in the treatment of EA. A total of 31 studies were included and analyzed, three of which were RCTs (Conte et al. 2020; Ponds et al. 2019; Werner et al. 2019). The medium to long term efficacy results were increased efficacy of POEM over PD, with additional statistically significant improvements in treatment success rates (100 vs. 50% with Eckardt < 3) noted in type III achalasia patients retrospectively at 1 year follow-up. POEM and LHM had similar efficacy in the medium to long term follow up, with a retrospective analysis of 98 patients observed significantly longer time to treatment failure in POEM groups compared to LHM despite no difference in Eckardt scores at 36 months. As far as symptom reoccurrence and retreatment rates, POEM had significantly less of each compared to PD. LHM and POEM lead to comparable symptom recurrence and re-treatment rates. Overall, evidence supports effective symptom improvement after POEM, with the improvement appearing to be especially beneficial in type III achalasia patients, the subtype that poses significant difficulties in treatment. POEM appears to be more likely to result in long lasting benefit without the need to undergo additional intervention. While results are generally equivalent between POEM and LHM patients, POEM seems superior to PD, with comparably low adverse event rates across all treatment modalities. Significantly higher POEM patients experience gastroesophageal reflux disease symptoms following the procedure, which may be managed conservatively compared to symptoms of achalasia using proton pump inhibitors. The authors emphasize that POEM and LHM require significant skill and experience to be carried out effectively. Additionally, the authors highlight the limitations of the analysis, being most study designs included are retrospective without matching, introducing the possibility of bias, few of the included studies undertook follow-up of POEM patients beyond 24 months compared to longer follow-up in LHM and PD patients leading to potential missed recurrence in POEM patients, and while financial implications were considered in this study no formal economic model was formulated. The authors suggest further high quality RCTs are needed to corroborate the findings and to reduce risk of bias.

Latha Kumar et al. (2023) conducted a systematic review comparing the clinical efficacy, safety, and postoperative outcomes of POEM versus LHM with fundoplication for the treatment of achalasia. The review included two RCTs, seven observational studies, and two systematic reviews, for a total population of 2,127 patients (n = 2127), with 981 undergoing POEM and 1,146 undergoing LHM with fundoplication. Overall, both POEM and LHM significantly improved symptoms as measured by the Eckardt score. Some individual studies noted a higher initial success rate and greater Eckardt score reduction in POEM compared to LHM, particularly in patients with achalasia type III and Chagas studies. But overall, there was no statistically significant difference in symptom relief or esophageal function improvement between POEM and LHM. POEM was associated with a shorter procedure time in several studies and generally fewer adverse events, although it varied across studies. Hospital stays were similar with some studies reporting shorter stays with POEM. The review noted that while POEM may offer procedural advantages, such as less blood loss and shorter operative duration, the clinical impact of these differences remains modest. pH monitoring showed that abnormal esophageal acid exposure and elevated DeMeester score were significantly more common after POEM than LHM in multiple studies. For instance, in a retrospective cohort study (n = 88) by Sanaka et al. (2019), 48.4% of POEM patients had abnormal acid exposure compared to 13.6% of LHM patients (p < 0.001), and abnormal DeMeester scores were found in 54.8% vs. 17.4% respectively (p = 0.005). Endoscopic findings also supported this, with studies showing significantly higher rates of esophagitis following POEM. For example, in a single center RCT by de Moura et al. (2022), esophagitis rates were 64.6% in POEM patients at 12 months compared to 11.1% in LHM (p = 0.002). Despite the increased incidence of GERD, subjective GERD symptom scores were not consistently different between groups. Overall, the review found that POEM and LHM are similarly effective in relieving achalasia symptoms and improving esophageal function. POEM offers advantages in terms of shorter

Last Approval: 04/09/2025 Next Review Due By: April 2026



procedure time and possibly fewer adverse events, but it carries a higher risk of postoperative reflux and esophagitis due to the lack of fundoplication. The authors recommend that surgeons consider both the efficacy and risk of reflux when choosing between procedures and suggest that POEM may be especially beneficial in select subpopulations, such as those with type III achalasia.

Zhang et al. (2023) conducted a systematic review and meta-analysis on the mid- and long-term outcomes of POEM for the treatment of achalasia. Twenty-one studies were included, totaling 2, 698 patients, with a minimum follow up of two years. The pooled clinical success rates of POEM in studies with 2-, 3-, 4-, and 5-year follow-ups were 91.3% (95% confidence interval [CI] 88.4-93.6%), 90.4% (95% CI 88.1-92.2%), 89.8% (95% CI 83.6-93.9%), and 82.2% (95% CI 76.6-86.7%), respectively. The pooled long-term clinical success rates for type I, II, and III achalasia were 86.1% (95% CI 80.9-90.1%; I2 = 0%), 87.9% (95% CI 84.2-90.8%; I2 = 48.354%), and 83.9% (95% CI 72.5-91.2%; I2 = 0%), respectively. The pooled incidence of symptomatic reflux and reflux esophagitis was 23.9% (95% CI 18.7-29.9%) and 16.7% (95% CI 11.9-23.1%), respectively. The authors concluded that POEM is associated with a long-term clinical success of 82.2% after 5 years of follow-up; however, they recommended more high quality RCTs comparing POEM with LHM and PD with long term follow up periods are necessary to further demonstrate the long-term safety and efficacy of POEM.

Facciorusso et al. (2021) conducted a systematic review and network meta-analysis of first-line achalasia therapies. Three treatments were 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.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Shiwaku et al. (2022) conducted a large-scale cohort study to assess the risk factors and long-term course of gastroesophageal reflux disease (GERD) and reflux esophagitis following POEM. A total of 2905 patients with achalasia-related esophageal motility disorders treated with POEM were analyzed for reflux esophagitis, severe reflux esophagitis (Los Angeles classification C or D), and symptomatic GERD across 14 high volume centers. Severe reflux esophagitis was diagnosed in 219 patients (7.5 %) and was associated with the risk factors of age \geq 65 years (RR 1.72), previous treatments (RR 2.21), Eckardt score \geq 7 (RR 0.68), sigmoid-type achalasia (RR 1.40), and esophageal myotomy > 10 cm (RR 1.59). Symptomatic GERD was diagnosed in 458 patients (15.9 %) and was associated with the risk factors of symptom duration \geq 10 years (RR 1.28), achalasia diagnosis (RR 0.68), integrated relaxation pressure \geq 26 (RR 0.60), and posterior myotomy (RR 0.80). were associated with symptomatic GERD. The incidence of symptomatic GERD was lower at 5-year follow-up compared with that after 1 year (P = 0.04), particularly in PPI users (P < 0.001). PPI use was also found to be more effective for reflux esophagitis at 5-year follow-up (P = 0.03) than after 1 year (P = 0.08). The authors concluded that while the rate of severe esophagitis was low after POEM, that previous treatments in older patients should be avoided prior to POEM to reduce the risk of contracting severe esophagitis post POEM procedure.

National and Specialty Organizations

The American College of Gastroenterology (ACG) (Vaezi 2020) 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

Last Approval: 04/09/2025 Next Review Due By: April 2026



The American Gastroenterological Association (AGA) (Kahrilas 2017) published a Clinical Practice Update on POEM use in achalasia stating that POEM appears to be both as effective or better than LHM, and safe and effective in the short term, but long-term durability data is not yet available. 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).
- If expertise is available, POEM should be considered primary therapy for type III achalasia
- If expertise is available, POEM should be considered comparable to Heller myotomy for any achalasia syndromes
- Patients receiving POEM should be considered high-risk to develop reflux esophagitis and be advised of management considerations (e.g., proton pump inhibitor therapy and/or surveillance endoscopy) prior to undergoing POEM

The American Society of Gastrointestinal and Endoscopic Surgeons (ASGE) (Khashab et al. 2020) 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) (Zaninotto 2018) published guidelines for achalasia diagnosis and management. 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) (Kohn 2021) published evidence-based guidelines for the use of POEM to treat achalasia. The expert panel made the following four recommendations for adults and children with achalasia:

Policy No. 385 Last Approval: 04/09/2025 Next Review Due By: April 2026



- 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)

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):

- 1. Type I (classic achalasia): 100% failed peristalsis and normal pan-esophageal pressurization
- 2. 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 (Current Procedural Terminology)

| Code | Description |
|-------|---|
| 43497 | Lower esophageal myotomy, transoral (i.e., peroral endoscopic myotomy [POEM]) |
| 43499 | Unlisted procedure, esophagus |

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

| 04/09/2025 | Policy revised. Removed prescriber and administration requirements. Removed criteria requiring failed treatment prior to POEM or determination that POEM is the most appropriate treatment. IRO peer reviewed on March 26, 2025, by a practicing physician board certified in Gastroenterology. |
|------------|---|
| 04/10/2024 | Policy reviewed. No changes to coverage criteria. |
| 04/13/2023 | Policy reviewed and updated. No changes to coverage criteria. |
| 04/13/2022 | 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. IRO |
| | peer reviewed on April 7, 2022, by a practicing physician board certified in Gastroenterology. |
| 12/08/2021 | 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/undated systematic review and meta-analyses: addition of Hayes's |

Last Approval: 04/09/2025 Next Review Due By: April 2026



comparative effectiveness review (updated review in April 2021); updated professional society guidelines and inclusion of

relevant (ASGE; ISDE; SAGES)

New policy. IRO Peer Review on 10/8/20 by a practicing physician board certified in Gastroenterology.

REFERENCES

12/09/2020

- de Moura ETH, Jukemura J, Ribeiro IB, Farias GFA, de Almeida Delgado AA, Coutinho LMA, et al. Peroral endoscopic myotomy vs laparoscopic myotomy and partial fundoplication for esophageal achalasia: A single-center randomized controlled trial. World J Gastroenterol. 2022 Sep 7;28(33):4875-4889. doi: 10.3748/wjg.v28.i33.4875. PMID: 36156932; PMCID: PMC9476850.
- Facciorusso A, Singh S, Abbas Fehmi SM, Annese V, Lipham J, Yadlapati R. Comparative efficacy of first-line therapeutic interventions for achalasia: a systematic review and network meta-analysis. Surg Endosc. 2021 Aug;35(8):4305-4314. doi: 10.1007/s00464-020-07920-x. PMID: 32856150; PMCID: PMC8011535.
- 3. Kahrilas PJ, Katzka D, Richter JE. Clinical Practice Update: The Use of Per-Oral Endoscopic Myotomy in Achalasia: Expert Review and Best Practice Advice From the AGA Institute. Gastroenterology. 2017 Nov;153(5):1205-1211. doi: 10.1053/j.gastro.2017.10.001. PMID: 28989059; PMCID: PMC5670013.
- 4. Khashab MA. Peroral endoscopic myotomy (POEM). Updated August 11, 2023. Literature review current through February 2025. Accessed March 20, 2025. https://uptodate.com
- 5. 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. PMID: 31839408.
- 6. Kohn GP, Dirks RC, Ansari MT, et al. SAGES guidelines for the use of peroral endoscopic myotomy (POEM) for the treatment of achalasia. Surg Endosc. 2021 May;35(5):1931-1948. doi: 10.1007/s00464-020-08282-0. PMID: 33564964.
- 7. Kuipers T, Ponds FA, Fockens P, et al. Peroral endoscopic myotomy versus pneumatic dilation in treatment-naive patients with achalasia: 5-year follow-up of a randomised controlled trial. Lancet Gastroenterol Hepatol. 2022 Dec;7(12):1103-1111. doi: 10.1016/S2468-1253(22)00300-4. Epub 2022 Oct 4. PMID: 36206786.
- Latha Kumar A, Sadagopan A, et al. Comparison of the Clinical Efficacy, Safety, and Postoperative Outcomes Between Peroral Esophageal Myotomy and Laparoscopic Heller's Myotomy With Fundoplication: A Systematic Review. Cureus. 2023 Sep 7;15(9):e44877. doi: 10.7759/cureus.44877. PMID: 37818506; PMCID: PMC10561531.
- North A, Tewari N. Peroral endoscopic myotomy compared to laparoscopic Heller myotomy and pneumatic dilation in the treatment of achalasia: a systematic review. Dis Esophagus. 2024 Jan 1;37(1): doad055. doi: 10.1093/dote/doad055. PMID: 37539633; PMCID: PMC10762503.
- 10. Oelschlager BK, Petersen RP. Surgical myotomy for achalasia. Updated November 08, 2024. Literature review current through February 2025. Accessed March 20, 2025. https://uptodate.com
- 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 Jul 9;322(2):134-144. doi: 10.1001/jama.2019.8859. PMID: 31287522: PMCID: PMC6618792.
- 12. Sanaka MR, Thota PN, Parikh MP, Hayat Ü, Gupta NM, Gabbard S, et al. Peroral endoscopic myotomy leads to higher rates of abnormal esophageal acid exposure than laparoscopic Heller myotomy in achalasia. Surg Endosc. 2019 Jul;33(7):2284-2292. doi: 10.1007/s00464-018-6522-4. Epub 2018 Oct 19. PMID: 30341655.
- Sobral J, Machado M, Barbosa JP, Barbosa J. Achalasia: laparoscopic Heller myotomy with fundoplication versus peroral endoscopic myotomy-a systematic review and meta-analysis. Esophagus. 2024 Jul;21(3):298-305. doi: 10.1007/s10388-024-01063-x. Epub 2024 May 22. PMID: 38775883; PMCID: PMC11199208.
- 14. ¹Spechler SJ, Pandolfino JE. Achalasia: Pathogenesis, clinical manifestations, and diagnosis. Updated July 03, 2024. Literature review current through February 2025. Accessed March 20, 2025. https://uptodate.com
- 15. ²Spechler SJ, Pandolfino JE. Overview of the treatment of achalasia. Updated October 25, 2024. Literature review current through February 2025. Accessed March 20, 2025. https://uptodate.com
- 16. Shiwaku H, Sato H, Shimamura Y, et al. Risk factors and long-term course of gastroesophageal reflux disease after peroral endoscopic myotomy: A large-scale multicenter cohort study in Japan. Endoscopy. 2022 Sep;54(9):839-847. doi: 10.1055/a-1753-9801. Epub 2022 Feb 16. Erratum in: Endoscopy. 2022 Sep;54(9):C13. doi: 10.1055/a-1778-9730. PMID: 35172368.
- 17. 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.000000000000731. PMID: 32773454; PMCID: PMC9896940.
- 18. Zaninotto G, Bennett C, Boeckxstaens G, Costantini M, Ferguson MK, Pandolfino JE, et al. The 2018 ISDE achalasia guidelines. Dis Esophagus. 2018 Sep 1;31(9). doi: 10.1093/dote/doy071. PMID: 30169645.
- 19. Zhang H, Zeng X, Huang S, et al. Mid-Term and Long-Term Outcomes of Peroral Endoscopic Myotomy for the Treatment of Achalasia: A Systematic Review and Meta-Analysis. Dig Dis Sci. 2023 Apr;68(4):1386-1396. doi: 10.1007/s10620-022-07720-4. PMID: 36260203.