

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 reduced numbers of neurons in the esophageal myenteric plexuses resulting in increased lower esophageal sphincter (LES) pressure and esophageal aperistalsis. These abnormalities cause a functional obstruction at the gastroesophageal junction and lead to impaired emptying of food from the esophagus into the stomach with resulting food stasis (Spechler 2021). The symptoms and signs of achalasia are due primarily to failure of relaxation of the LES. The typical clinical presentation is slowly progressive dysphagia for both solids and liquids. Regurgitation is a common finding, which can lead to pulmonary symptoms such as choking, coughing, aspiration, and pneumonia. The criterion standard for diagnosing achalasia is high-resolution esophageal manometry (HRM) showing incomplete relaxation of the esophagogastric junction (EGJ) coupled with the absence of organized peristalsis (Khashab et al. 2020). No cure exists; however, therapies aim to decrease the resting pressure in the LES to a level at which the sphincter no longer impedes the passage of ingested material, enhance esophageal emptying, and prevent future dilatation of the esophagus. Current treatment options include pharmacologic (calcium channel blockers), pneumatic dilatation (PD), botulinum toxin injection, and surgical myotomy are all options for treating achalasia. Laparoscopic Heller myotomy (LHM) has been regarded as the standard treatment option for patients with EA who are deemed good surgical candidates and involves 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 the endoscopic complement of surgical myotomy and is a novel, less invasive alternative to LHM for management of esophageal achalasia. POEM is a natural orifice transmural endoscopic surgery (NOTES) technique. The procedure involves guiding an endoscope through the esophagus, toward the esophageal-gastric junction. The endoscopist makes an incision in the esophageal mucosa and inserts the endoscope into the esophageal submucosa, generating a submucosal tunnel that is continued distally into the gastric cardia. A diathermic scalpel is introduced via the endoscope to sever the muscularis propria muscle in and around the LES. In contrast to surgical myotomy, which is frequently performed in conjunction with fundoplication to avoid reflux, POEM does not include an antireflux operation and as a result, may cause severe GERD. Contraindications for POEM include 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.

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** of 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

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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.*

- 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: Procedure performed by adequately trained, experienced physicians specialists in 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 (P&P): 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.

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 the majority of 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-naïve 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. 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 than PD, and POEM required

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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.

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 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 (2021) noted in an UpToDate peer-review that the majority of POEM data published has originated from highly specialized centers (Ponds et al., 2019; Hungness et al., 2013; Inoue et al. 2016). Patients with achalasia who

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do not respond well to conventional therapies, such as type III (spastic) achalasia and "end stage" achalasia (markedly dilated, sigmoid esophagus), as well as those who have failed previous endoscopic and surgical achalasia treatments, have reported good results from POEM. Although there is agreement that POEM is the procedure of choice for the treatment of type III achalasia, the role of POEM in the treatment of achalasia continues to evolve. Furthermore, it has been proposed that patients receiving POEM be informed of the increased risk of post-procedure reflux as compared to other therapies.

Hayes

A comparative effectiveness review on the use of POEM for treating EA compared to either LHM or PD in a Health Technology Assessment 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. The evidence comparing POEM with LHM is moderate (16 studies), whereas evidence for POEM versus PD was presented is small (4 studies). It is noted that no eligible randomized controlled trials were identified 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 authors also noted the lack of discussion of 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 for additional studies of fair to good quality to determine the most effective treatment protocols for patients, patient selection criteria, and information on long-term outcomes (Health Technology Assessment; Jan 2022).

Professional Society Guidelines

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)** clinical guidelines for the diagnosis and management of achalasia were updated in 2020 and includes the following recommendations:

- 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 in 2017 on the use of POEM in achalasia (Expert Review and Best Practice Advice, 2017). The AGA noted that POEM appears to be safe and effective in the short term, but long-term durability data is not yet available. Existing uncontrolled reports suggested that POEM is as effective as or better than LHM, but that it is more likely to cause post-treatment reflux. Due to the procedure's complexity, it is also recommended that it be conducted by experienced physicians in high-volume centers, as it is estimated that 20-40 procedures are required to obtain competence and 60 to achieve mastery. Existing uncontrolled reports imply POEM is as effective as or better than LHM, and growing RCT data suggests POEM is more effective than PD, but more likely to cause post-treatment reflux.

The **American Society of Gastrointestinal and Endoscopic Surgeons (ASGE)** published consensus guidelines on the use of endoscopy in the evaluation and therapy of dysphagia, including esophageal achalasia, in 2014. These guidelines suggest that while POEM is being utilized more frequently in expert centers, long-term data and randomized trials comparing POEM to conventional modalities are required before it can be introduced into clinical practice. The ASGE provided no particular recommendations regarding the use of POEM in the management of achalasia.

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The ASGE published an evidence-based guideline on the treatment of achalasia in 2020. The term "we suggest" was used to denote weaker recommendations, whereas the phrase "we recommend" denoted stronger recommendations. Both of the RCTs on POEM that were available were not included in the guideline. Based on their findings, the ASGE made the following recommendations:

- "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)** issued guidelines on the diagnosis and management of achalasia. 51 experts from 11 countries, including several from the United States, were convened by the organization to conduct a systematic evaluation 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) (ISDE 2018). The recommendations made by POEM 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 its own evidence-based guidelines for the use of POEM to treat achalasia in 2021 (Kohn, 2021). Four suggestions were reached by the expert group for adults and children with achalasia. These include the following:

- Adult and pediatric patients with type I and type II achalasia may be treated with POEM or LHM based on collaborative decision-making between surgeon and patient (conditional recommendation; very low certainty evidence).
- For type III adult or pediatric achalasia, the panel suggests POEM over LHM (expert opinion).
- In patients with achalasia, the panel recommends POEM over PD (strong recommendation, moderate certainty evidence).
- For patients who are concerned about post-operative proton pump inhibitor use, the panel suggests using 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.

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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 $\geq 20\%$ of swallows
- Type III (spastic achalasia): abnormal peristalsis and premature contractions with $\geq 20\%$ of swallows

CODING & BILLING INFORMATION

CPT Codes

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

HCCPS 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

4/13/2022 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.
12/8/2021 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)
12/9/2020 MCPC	New policy. IRO Peer Review. 10/8/20. Practicing Physician. Board certified in Gastroenterology.

REFERENCES

Government Agencies

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International Society for Diseases of the Esophagus (ISDE)

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APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.

Centers for Medicare & Medicaid Services (CMS)

No National Coverage Determination (NCD) was located addressing POEM for treatment of EA on November 2021 (search [CMS Advanced Search Database](#) by the keywords myotomy or achalasia or esophagus or esophageal in all documents). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.