Peroral Endoscopic Myotomy (POEM)

Medicare Advantage Medical Policy No.: MNG-010

The Health Plan reserves the right to amend this policy and procedure at any time. Exceptions to this policy and procedure will be made on a case-by-case basis at the total discretion of the Health Plan.

Original Effective Date: March 1, 2024
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Instructions for use

This policy serves to provide guidance in determining coverage based on medical necessity. It also gives a list of resources used to create these guidelines. Medical necessity determinations will be made in accordance with generally accepted standards of medical practice, taking into account credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and the views of the physicians practicing in relevant clinical areas, and other relevant factors, as they relate to the member's clinical circumstances.

Medicare Advantage Members

Coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: www.cms.gov/medicare-coverage-database/help/mcd-bene-help.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria will be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of the coverage criteria and is to be used by all plans and lines of business unless Federal or State law, contract language, including member or provider contracts, take precedence over the policy.

Basic Requirements for Clinical Appropriateness:

1. Before diagnostic or therapeutic intervention, a clinician must confirm the diagnosis or establish the likelihood based on a history and physical exam and, when appropriate, a review of laboratory studies, previous diagnostic testing and response to any prior interventions, specifically relevant to the clinical situation.
2. An alternative treatment or other appropriate intervention should not offer any greater benefit based on standards of medical practice and/or current literature.
3. The potential benefit to the patient should outweigh the risk of the diagnostic or therapeutic intervention.
4. A reasonable likelihood of the intervention changing management and/or leading to an improved outcome for the patient must exist, based on the clinical evaluation, current literature and standards of medical practice.

If these requirements are not apparent in the request for authorization, including the clinical documentation provided, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

Simultaneous ordering of multiple diagnostic or therapeutic interventions and/or repeated diagnostic or therapeutic interventions in the same anatomic area may be denied, unless individual circumstances support the medical necessity of performing interventions simultaneously or repeatedly. This should be apparent in clinical documentation or in peer-to-peer conversations.

Peroral Endoscopic Myotomy (POEM)

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider peroral endoscopic myotomy (POEM) as a treatment for esophageal achalasia to be eligible for coverage.**

When Services are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers peroral endoscopic myotomy (POEM) when the coverage criteria are not met and for all other indications to be investigational.*

Coverage Indications, Limitations, and/or Medical Necessity

Achalasia is a disorder of the esophagus that makes it difficult for food and liquid to pass into the stomach. Achalasia results from the degeneration of ganglion cells in the myenteric plexus in the wall of the esophagus. This degeneration leads to failure of relaxation of the lower esophageal sphincter (LES) together with loss of peristalsis in the distal esophagus. The most common symptoms in patients with achalasia are dysphagia for solids and liquids as well as regurgitation of undigested foods or saliva. Additional symptoms include chest pain, heartburn, and difficulty belching. Complications of achalasia may include progressive dilation of the esophagus (megaesophagus) possibly leading to esophagectomy. Patients with achalasia are also at increased risk of developing esophageal cancer. Achalasia can be treated with pneumatic dilatation (PD), botulinum toxin injection, and surgical myotomy. Laparoscopic Heller Myotomy (LHM) is the most common surgical myotomy procedure for treatment of achalasia.

Peroral Endoscopic Myotomy (POEM) is the endoscopic complement of surgical myotomy and is a newer, less invasive procedure for the management of achalasia. POEM is an endoscopic procedure, which creates a tunnel in the submucosal layer of the esophagus and proximal stomach. Through this submucosal tunnel, an esophageal and gastric myotomy are made using a flexible endoscope.[1] The

POEM procedure is performed in 4 steps: 1) mucosal incision/entry into the submucosa, 2) creation of a submucosal tunnel, 3) myotomy, and 4) closure of the mucosal incision.[6 7 8 12 21 23 24 31]

POEM is a form of natural orifice transluminal endoscopic surgery (NOTES). The procedure is performed perorally, without any incisions in the chest or abdomen. The advantage of this approach is to reduce procedure-related pain and return patients to regular activities sooner than surgeries requiring external incisions.

POEM may be considered medically necessary for treatment of symptomatic, monometrically proven primary idiopathic achalasia, types I, II, or III. Prior to performing a POEM procedure, it is crucial to confirm that patients have the correct diagnosis of achalasia and the following documentation must be included in the clinician's preoperative evaluation:

- History and physical exam – including a standardized, validated symptom assessment form completed by all patients (i.e., Eckardt score ≥3);
- High-resolution esophageal manometry (HRM) – achalasia is subclassified according to the Chicago Classification of esophageal motility disorders, which is based upon the result of a high-resolution esophageal manometry test;
- Contrast esophagram– findings on contrast esophagram that are suggestive of achalasia include a narrowed esophagogastric junction (EGJ) with a "bird-beak" appearance and esophageal aperistalsis. Late or end-stage achalasia may give the appearance that the esophagus is significantly dilated, angulated, and tortuous, giving it a sigmoid shape35;
- Esophagogastroduodenoscopy (EGD) – EGD sometimes reveals a dilated esophagus that contains residual material with normal appearing esophageal mucosa.

Contraindications — If one of the following conditions is present, the patient should not undergo POEM:

- Severe erosive esophagitis
- Significant coagulation disorders
- Liver cirrhosis with portal hypertension
- Severe pulmonary disease
- Esophageal malignancy

Prior therapy that may compromise the integrity of the esophageal mucosa or lead to submucosal fibrosis, including recent esophageal surgery, radiation, endoscopic mucosal resection or radiofrequency ablation

Previous therapies for achalasia, such as PD, botulinum toxin injection, or LHM, are not contraindications to POEM.

Prior to treatment with POEM, patients should be educated on the risk of gastroesophageal reflux disease (GERD). Also, follow-up acid suppression treatment should be considered after POEM. Patients should be counseled that treatments exist with a lower incidence of post-procedure GERD, such as LHM and PD.

POEM is considered a safe but complex procedure. POEM will be considered medically reasonable and necessary only if it is performed by adequately trained, experienced physicians in high-volume centers.

These centers must have the available staff to address any potential adverse events from POEM immediately, including but not limited to gastrointestinal or cardio-thoracic complications.

Summary of Evidence

POEM appears to be highly beneficial in the short-term management of achalasia. According to a 2014 (Stavropoulos, et al.) Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) POEM White Paper Committee, clinical success, defined as a post-treatment Eckardt score of ≤3 and/or a >50% decrease in the LES pressure, was achieved in 82% to 100% of patients.

Additional studies documented similar patient improvements after POEM using either a timed barium esophagram or quality of life (QOL) assessment:

Sharata, et al. (2015) reported on a consecutive patient cohort with clinical and objective outcomes. Comprehensive data was collected prospectively on all subjects undergoing POEM from October 2010 to November 2013 at a single institution. Subjects were classified based on HRM results. Operative data and immediate outcomes were reviewed. Symptom scores, HRM, and timed barium swallow (TBS) were performed prior to the procedure. Subjects were asked to undergo routine postoperative testing 6-12 months following surgery with the addition of standard 24-hour pH to the preoperative protocol. Morbidity was defined as requiring additional procedures or prolonged hospital stay >2 days. 100 POEM patients were included in the final analysis. The mean age was 58 years (18-83 years). Results demonstrated that the primary presenting symptoms included dysphagia 81, chest pain 10, and regurgitation 9. The mean follow-up was 16 months. HRM diagnoses were 75 achalasia (30 type I, 43 type II, 2 type III), 12 nutcracker esophagus, 5 diffuse esophageal spasm (DES), and 8 isolated hypertensive non-relaxing LES. The mean operative time was 128 minutes. The median hospital length of stay (LOS) was 1 day. The overall morbidity was 6%; all these patients were treated endoscopically or with conservative management without further sequelae. The average LES resting/residual pressure significantly decreased (44.3/22.2 to 19.6/11.7 in millimeters of mercury). Esophageal emptying improved from 40% to 90% on TBS with 93% patients demonstrating >90% emptying at 1 minute. Of the achalasia patients, 36% (17/47) showed some return of normal peristalsis (≥70% peristalsis) on post-op HRM. Abnormal acid exposure was present on postoperative testing in 38% of patients (26/68). Of these, 14 patients were asymptomatic. No reflux patient required any additional antireflux procedure. Eckardt scores decreased from 6 to 1. Dysphagia was improved or eliminated in 97% of patients with a complete resolution accomplished in 89%. Complete dysphagia relief was better for achalasia patients (46/47 patients; 97.8%) vs. non-achalasia patients (17/24; 70.8%). Of those with preoperative chest pain, 91.5% reported complete relief. 4 patients have refractory dysphagia. 2 non-achalasia patients underwent subsequent LHM and 2 are improved following serial endoscopic dilatations. Sharata, et al. were able to conclude that despite reflux in 1 out of 3 of patients, POEM provides excellent relief of dysphagia (97%) and chest pain (91.5%) for patients with esophageal spastic disorders with acceptable procedural morbidity.

Teitelbaum, et al. (2013) looked at the effect on anatomic and functional outcomes regarding the differences in POEM vs. LHM since an antireflux procedure is not performed in POEM with mobilization of the hiatus.26 This study looked at patients who underwent LHM or POEM and had both a pre- and postoperative timed barium esophagogram (TBE). TBEs were performed with 200 mL of contrast, with radiographs taken at 1, 2, and 5 minutes. Results demonstrated that a total of 17 LHM and 12 POEM patients had undergone pre- and postoperative TBEs. Both groups had decreased column heights postoperatively at 1, 2, and 5 minutes (LHM: pre, 15.6, 12.7, 11.3 cm vs. post, 3.6, 2.5, 1.8 cm; P<.001 and POEM: pre, 14.7, 11, 9.4 cm vs. post, 4.4, 2.5, 1.2 cm; P<.001). There was no difference between

procedures in changes from baseline column height. Both operations resulted in decreased esophageal width and less angulation between the esophageal body and EGJ. The authors concluded that POEM and LHM produce a similar short-term anatomic and functional result at the EGJ. POEM results in a similar narrowing and straightening of the esophagus despite the fact that POEM does not include hiatal mobilization.

Verlaan, et al. (2013) published a prospective trial to evaluate the effect of POEM on esophagogastric function.28 The study included patients aged >17 years with achalasia and an Eckardt score of ≥3. Before and 3 months post-POEM, 10 consecutive patients underwent esophageal manometry, TBEs, and EndoFLIP® as well as an EGD. Patient symptom scores were found to be significantly reduced post-POEM (1, interquartile range [IQR 0-1] vs. 8 [IQR 4-8]; P = .005). LES pressure decreased significantly (6.0 mmHg [IQR 2.6-7.4] vs. 19.0 mmHg [IQR 13.0-28.0]; P = .008). Esophageal emptying increased significantly, and a 5-minute barium column measured 2.3 cm (IQR 0-3.2 cm) vs. 10.1 cm (IQR 5.7-10.8 cm; P = .005). EGJ distensibility increased significantly (6.7 mm2/mmHg [IQR 3.8-16.6] vs. 1.0 mm2/mmHg [IQR 0.4-2.3]; P = .02) at 50 mL. 6 of 10 patients had signs of reflux esophagitis. Of these patients, 3 were symptomatic. The authors concluded that POEM improves esophagogastric function and suggests improved long-term clinical results.

Vigneswaran, et al. (2015) evaluated the QOL following POEM.29 All patients who presented to their institution for surgical management of achalasia after 2011 were asked to complete QOL (SF-36), dysphagia, reflux severity index, and GERD questionnaires while in the clinic preoperatively and at 3 weeks, 6 months, and 1 year postoperatively. Patients who underwent a POEM procedure (n = 37), demonstrated a significant improvement in dysphagia scores, reflux severity scores, and GERD scores ($p<0.05$) at each time point. SF-36 questionnaires specifically demonstrated a significant improvement in several concepts. At 3 weeks, emotional well-being scores were significantly higher ($p = 0.006$). At 6 months, emotional well-being ($p = 0.039$), social functioning ($p = 0.038$), and general health ($p = 0.029$) were all significantly higher. At 1 year, role limitations due to physical health ($p = 0.001$) and social functioning ($p = 0.002$) were significantly higher. The investigators concluded that there is a significant improvement in several measures of QOL after POEM, which is comparable to that seen after LHM.

Additional studies provided an assessment of the intermediate to long-term efficacy of POEM:

Li, et al. (2018) conducted a large cohort study of 564 patients post-POEM for achalasia.9 After a median follow-up of 49 months, the Eckardt score (median score, 8 vs. 2 [$P < 0.05$]) and LES pressure (29.7 mmHg vs. 11.9 mmHg [$P < 0.05$]) were both improved post-POEM. The clinical success rates, estimated by the Kaplan-Meier survival function, at 1, 2, 3, 4, and 5 years were 94.2%, 92.2%, 91.1%, 88.6%, and 87.1% respectively. Clinical reflux occurred in 37.3% of participants post-POEM. The study concluded that POEM was a safe and effective long-term treatment for achalasia.

Werner, et al. (2016) published a retrospective study of 80 patients who were followed for a minimum of 2 years.32 The main outcome was the rate of POEM failures, defined by an Eckardt score of >3, related to follow-up time. 80 patients (mean age 44.9 years, 54% men) were followed clinically for 29 months (range 24-41). 77 patients (96.3%) achieved initial clinical response. Of those patients, clinical recurrences (later failures) were seen in a further 14 cases (17.7%), accounting for a total failure rate of 21.5%, making an overall success rate of POEM of 78% at 24 to 49 months. In a multivariate analysis, age and endoscopic reflux signs were independent predictors of treatment success. Endoscopic evidence of reflux esophagitis, mostly Los Angeles grade A/B, were seen in 37.5% (37/72) at the 2-year control. Conclusions from this published retrospective analysis, show a high initial success rate of POEM, which is

followed by a mid-term recurrence rate of 18%. Reflux esophagitis, although mild, is frequent and should likely be treated by regular low-dose proton pump inhibitor (PPI) therapy.

Inoue, et al. (2015) conducted a retrospective study of 500 consecutive achalasia patients.4 POEM was successfully completed in all patients, with adverse events observed in 3.2%. 2 months following POEM, reductions in symptom scores (Eckardt score 6.0±3.0 vs. 1.0±2.0, p<0.0001) and LES pressures (25.4±17.1 vs. 13.4±5.9 mmHg, p<0.0001) were achieved, and this persisted at 3 years post-POEM. Sixty-one patients were followed for 3 years or longer. Ninety-one percent of the patients achieved clinical success at 1 to 2 years post-POEM. This number decreased to 88% at 3 years. Gastroesophageal reflux was seen in 16.8% of patients at 2 months and 21.3% at 3-year follow-up. The authors were able to conclude that POEM was successfully completed in all cases, even when extended indications, such as extremes of age, previous interventions, or sigmoid esophagus were present. Adverse events were rare (3.2%) with no mortalities. POEM appears to be a safe and effective treatment for achalasia; there are relatively few contraindications, and the procedure may be used as either first or second-line therapy.

A retrospective study conducted by Hungness, et al. (2016) looked at 115 consecutive patients who underwent POEM at a single, high-volume center.3 Treatment success was defined as an Eckardt score ≤3 without reintervention. Gastroesophageal reflux was defined by abnormal pH-testing or reflux esophagitis >Los Angeles grade A. Results showed that for the 115 patients, operative time was 101±29 minutes, with 95% (109/115) of patients discharged on postoperative day 1. Clavien-Dindo grade III complications occurred in 2.7%, 1 of which required diagnostic laparoscopy to rule out Veress needle injury to the gallbladder. The rate of grade I complications was 15.2%. The overall success rate was 92% at an average of 28 months post-POEM (range 12-52 months). The success rate was slightly higher for nonspastic achalasia (94%) than for type III achalasia or spastic motility disorders (90%). Objective evidence of reflux was found in 40% of all patients and 33% for patients with a body mass index <35 kg/m2 and no hiatal hernia. Conclusions from this study showed that POEM, performed by experienced surgeons, provided long-lasting symptomatic relief in 94% of patients with nonspastic achalasia and 90% of patients with type III achalasia/spastic esophageal motility disorders, with a low rate of complications. The rate of gastroesophageal reflux was similar to previous studies of both POEM and LHM.

In a single-center retrospective study of 23 patients with achalasia, Teitelbaum, et al. (2018) evaluated patients that underwent POEM and were greater than 5 years removed from their operation.25 The mean Eckardt score improved at 6 months (0.6) post-POEM compared with the baseline (6.4). This improvement was maintained at 2 years post-POEM. Eckardt scores worsened between 2 and 5 years (mean current 1.7 vs. preoperative 6.4, p < 0.001). 19 patients (83%) with achalasia remained asymptomatic (Eckardt ≤3) and none required retreatment for symptoms at a median follow-up of 65 months. POEM resulted in a successful alleviation of symptoms in the majority of patients after 5 years.

The efficacy and safety of POEM has been compared to LHM:

Marano, et al. (2016) conducted a meta-analysis to investigate the efficacy and safety of POEM compared with LHM for the treatment of achalasia.11 The databases of PubMed®, Medline®, Cochrane, and Ovid were systematically searched between January 1, 2005 and January 31, 2015, with the medical subject headings (MeSH) and keywords "achalasia," "POEM," "per oral endoscopic myotomy," "peroral endoscopic myotomy," "laparoscopic Heller myotomy" (LHM), and "Heller myotomy." All types of study designs including adult patients with diagnosis of achalasia were selected. The total number of included patients was 486 (196 in POEM group and 290 in LHM group). No differences existed between POEM and LHM in reduction in Eckardt score (MD=-0.659, 95% CI: -1.70 to 0.38, P=0.217), operative time (MD=-0.354, 95% CI: -1.12 to 0.41, P=0.36), postoperative pain scores (MD=-1.86, 95% CI: -5.17 to 1.44,

P=0.268), analgesic requirements (MD=-0.74, 95% CI: -2.65 to 1.16, P=0.445), and complications (OR=1.11, 95% CI: 0.5-2.44, P=0.796). Length of hospital stay was significantly lower for POEM (MD=-0.629, 95% CI: -1.256 to -0.002, P=0.049). Significant reduction in symptomatic gastroesophageal reflux rate showed greater improvement with LHM compared to POEM (OR=1.81, 95% CI: 1.11-2.95, P=0.017). All included studied were not randomized. Also, all selected studies did not report the results of follow-up longer than 1 year. POEM appeared to represent a safe and efficacious procedure that is comparable to the safety profile and efficacy of LHM for achalasia at a short-term follow-up.

Park, et al. (2019) conducted a meta-analysis to compare the efficacy between POEM and Heller myotomy.16 Fifteen studies were evaluated with 1213 total patients. Follow-up ranged from 2-46.2 months in the POEM group and 2-54.2 months in the Heller myotomy group. Eckardt scores were lower in the post-POEM group compared to the post Heller myotomy group (pooled standard mean difference [SMD], -0.58; 95% CI, -1.03 to -0.13). Length of myotomy was greater in the POEM group (pooled SMD, 0.63; 95% CI, 0.42-0.84). No difference between the groups was seen in reflux symptoms (pooled risk ratio [RR], 1.03; 95% CI, 0.61-1.73) and pathologic reflux on pH monitoring (pooled RR, 1.22; 95% CI, 0.67-2.25). Erosive esophagitis, evaluated by endoscopy, appeared to be less common in the Heller myotomy group (pooled RR, 1.88; 95% CI, 0.98-3.62).

Werner, et al. (2019) conducted a multicenter, randomized trial to compare POEM with LHM plus Dor's fundoplication in patients with symptomatic achalasia.33 The primary end point was clinical success, which was defined as an Eckardt symptom score of <3 (range, 0 to 12, with higher scores indicating more severe symptoms of achalasia) without the use of additional treatments, at the 2-years post-POEM. A noninferiority margin of -12.5 percentage points was used in the primary analysis. Secondary end points included adverse events, esophageal function, Gastrointestinal Quality of Life Index score (GIQLI) (range, 0 to 144, with higher scores indicating better function), and gastroesophageal reflux. A total of 221 patients were randomly assigned to undergo either POEM (112 patients) or LHM plus Dor's fundoplication (109 patients). Each randomly assigned group showed equal clinical success at 2-years, 83.0% of patients in the POEM group and 81.7% of patients in the LHM group (difference, 1.4 percentage points; 95% confidence interval [CI], -8.7 to 11.4; P = 0.007 for noninferiority). Compared with LHM, POEM was associated with a lower rate of serious adverse events (2.7% of patients in the POEM group vs. 7.3% of patients in the LHM group). Improvement in esophageal function from baseline to 24 months did not differ significantly between the treatment groups (difference, -0.75 mmHg; 95% CI, -2.26 to 0.76), nor did improvement in the score on the QOL (difference, 0.14 points; 95% CI, -4.01 to 4.28). POEM was associated with a higher rate of reflux esophagitis (57% of patients in the POEM group and 20% of patients in the LHM group at 3 months; 44% vs. 29% at 2 years). POEM was considered to be equally effective to LHM plus Dor's fundoplication in controlling symptoms of achalasia at 2 years. Gastroesophageal reflux was more common among patients who underwent POEM than among those who underwent LHM.

In a meta-analysis of >7000 patients in over 70 cohort studies, Schlottmann, et al. (2018) compared the outcome of POEM and LHM for the treatment of esophageal achalasia.19 A Medline literature search of articles on LHM and POEM for the treatment of achalasia was performed. The main outcomes measured were improvement of dysphagia and posttreatment GERD. Linear regression was used to model the effect of each procedure on the different outcomes. Mean follow-up was significantly longer for LHM (41.5 vs. 16.2 mo, P<0.0001). Predicted probabilities for improvement in dysphagia at 12 months were 93.5% for POEM and 91.0% for LHM (P = 0.01), and at 24 months were 92.7% for POEM and 90.0% for LHM (P = 0.01). POEM resulted in higher incidences of GERD symptoms (OR 1.69, 95% CI 1.33-2.14, P<0.0001), as evidenced by erosive esophagitis (OR 9.31, 95% CI 4.71-18.85, P<0.0001), and as

evidenced by pH monitoring (OR 4.30, 95% CI 2.96-6.27, P<0.0001). POEM also was associated with a slightly longer hospital stay by 1 day (P = 0.04). Short-term results showed that POEM is more effective than LHM in relieving dysphagia. However, it is also associated with a high incidence of pathologic reflux.

POEM in comparison with PD:

Ponds, et al. (2019) compared the effects of POEM vs. PD as initial treatment of treatment-naive patients with achalasia in a randomized multicenter clinical trial.17 133 randomized adult patients with newly diagnosed achalasia and an Eckardt score >3 who had not undergone previous intervention were included. The duration of follow-up was 2 years after the initial treatment. Patients were randomized to receive POEM (n = 67) or PD with a 30-mm and a 35-mm balloon (n = 66), with stratification according to hospital. The primary outcome was treatment success (defined as an Eckardt score ≤3 and the absence of severe complications or re-treatment) at the 2-year follow-up. Of the 133 randomized patients, 130 (mean age, 48.6 years; 73 [56%] men) underwent treatment (64 in the POEM group and 66 in the PD group) and 126 (95%) completed the study. POEM resulted in a higher rate of treatment success than PD at 2 years (92% in the POEM group vs. 54% in the PD group), a difference of 38% ([95% CI, 22%-52%]; P < .001). 0 cm in the PD group; difference, 2.3 cm [95% CI, 1.0-3.6]; P = .05. No serious procedure related events occurred after POEM, while 2 serious adverse events, including 1 perforation, occurred after PD. Reflux esophagitis developed more often in the POEM group compared to PD (41% vs. 7%); difference, 34% [95% CI, 12%-49%]; P = .002). This study showed that among treatment-naive patients with achalasia, POEM compared with PD resulted in a significantly higher treatment success rate at 2 years. The results help support consideration of POEM as the primary endoscopic therapy for patients with achalasia.

POEM has been shown to be safe and effective for the treatment of patients with achalasia who have failed prior endoscopic or surgical treatment10,15,20:

According to the International Per Oral Endoscopic Myotomy Survey (IPOEMS), 40% of POEM procedures were performed in patients who previously underwent endoscopic treatment for achalasia.23 Submucosal fibrosis resulting from previous botulinum toxin injection or PD may make the dissection more difficult; however, the consensus among those performing POEM was the efficacy of the procedure was not jeopardized.

Studies have shown that POEM is a valid option of rescue treatment for those who develop recurrent symptoms or receive no relief from their current symptoms post-Heller myotomy:

Zhou, et al. (2013) observed that approximately 20% of patients post-LHM for achalasia either had persistence or recurrence of their symptoms.36 The authors prospectively included 12 patients with recurrent or persistent symptoms (defined by established methods and an Eckardt score of ≥4) 2 to 38 years (mean of 12 years) after previous Heller myotomy. After undergoing a successful POEM procedure, at a mean follow-up of 10.4 months, treatment success (defined as an Eckardt score of ≤3) was achieved in 11 of 12 patients with a significant reduction in the Eckardt score (91.7 %; mean score pre- vs. post-treatment 9.2 vs. 1.3; P<0.001). Further outcome measures demonstrated a lower LES pressure following POEM. Mean LES pressure was 29.4 mmHg pre-treatment and 13.5 mmHg post-treatment (P<0.001). 1 patient developed mild reflux symptoms and required intermittent treatment with PPIs. No serious complications related to POEM occurred. Conclusions from this study showed that previous Heller myotomy does not prevent successful POEM. POEM may be a potential treatment for failed Heller myotomy with treatment success in >90% of cases.

In an additional study by Onimaru, et al. (2013), 10 patients underwent successful POEM procedures, without complications, after failed surgical myotomy.14 All patients in whom surgical myotomy failed received PD as the first line "rescue" treatment, and only if PD failed were patients considered for rescue POEM. Three months post-POEM, a significant reduction in both mean LES resting pressures (22.1±6.6 mmHg vs. 10.9±4.5 mmHg, p<0.01) and Eckardt scores (6.5±1.3 vs. 1.1±1.3, p<0.001) were observed. Short-term results of POEM for failed surgical myotomy were considered excellent.

A study by Vigneswaran, et al. (2014) looked at 5 patients who underwent redo myotomy with POEM after failed LHM.30 POEM patients were able to achieve a significant reduction in Eckardt scores 6.8 vs. 0.6; p <0.05) after approximately 5 months. The authors concluded that POEM can be safely performed using a similar technique as for primary myotomy apart from creating the myotomy laterally along the right side of the esophagus and lesser curvature, thus avoiding the prior anterior myotomy.

In a multicenter study by Ngamruengphong, et al. (2017), the authors conducted a retrospective cohort study of 180 patients with achalasia who underwent POEM.13 The patients were divided into 2 groups, 90 patients with prior LHM and 90 patients without prior LHM. Clinical response was defined by a decrease in Eckardt scores to ≤3. Adverse events were graded according to criteria set by the American Society for Gastrointestinal Endoscopy (ASGE). Technical success, clinical success, and rates of adverse events were compared between groups after a median of 8.5 months. The technical success rates (98% of patients in the LHM group vs. 100% of patients in the non-LHM group (P = .49)) and the adverse event rates (8% in the LHM group vs. 13% in the non-LHM group; P = .23) were comparable between the groups. The clinical success rate was lower in the group of patients who underwent prior LHM (81% vs. 94%; P = .01). Symptomatic reflux and reflux esophagitis after POEM were similar between groups. Conclusions from this study showed that POEM is safe and effective for patients with achalasia who underwent prior failed LHM. The rate of clinical success in patients with prior LHM was lower than in those without prior LHM; however, the safety profile of POEM is comparable between the 2 groups.

Tyberg, et al. (2017) conducted a multicenter retrospective study of 46 patients with failed POEM for achalasia.27 Redo POEM was technically successful in 100% and clinically successful in 85%. The mean Eckardt score decreased from pre-redo-POEM of 4.3±2.48 to post-POEM of 1.64±1.67, significant difference of 2.58 (P <.00001). Repeat POEM appears to be an effective and safe technique in patients with persistent or recurrent symptoms following a previous POEM procedure. Typically, the redo-POEM procedure is performed on the opposite side of the esophagus.

POEM is considered a safe procedure that has a low rate of post-procedure complications when performed by experienced operators.34 Most adverse events that occur with POEM can be managed expectantly, medically, or endoscopically. An international multicenter study by Haito-Chavez, et al. (2017) included 1862 patients who underwent POEM.2 One-hundred thirty-seven patients experienced 1 or more complications with a prevalence of 7.5%. Of the 156 total complications, 116 were mild, 31 moderate, and 9 severe. 51 inadvertent mucosotomies were reported in 2.8% of patients.

GERD is the most common late adverse event with POEM. Depending on the study, the prevalence of GERD following POEM ranges between 20-57%.22

A meta-analysis by Repici, et al. (2018) found that the prevalence of GERD was higher post-POEM than post-LHM with fundoplication.18 The rate of postprocedural symptoms was 19.0% (95% confidence interval [CI], 15.7%-22.8%) post-POEM and 8.8% (95% CI, 5.3%-14.1%) post-LHM. The rate of abnormal pH study was 39.0% (95% CI, 24.5%-55.8%) post-POEM and 16.8% (95% CI, 10.2%-26.4%) post-LHM, respectively. The rate of esophagitis after POEM was 29.4% (95% CI, 18.5%-43.3%) post-POEM and 7.6% (95% CI, 4.1%-13.7%) post-LHM. The study concluded that the incidence of GERD appears to be more

frequent after POEM when compared to after LHM with fundoplication. In order to prevent long-term complications from reflux, clinicians should ensure appropriate treatment for GERD following POEM.

American Gastroenterological Association (AGA)

The American Gastroenterological Association's (AGA, 2017) Clinical Practice Updates Committee proposed the following recommendations regarding POEM based on expert opinion and relevant publications5: 1) patient-specific parameters (Chicago Classification subtype, comorbidities, early vs. late disease, primary or secondary causes) should be reviewed along with published efficacy data when evaluating the need for achalasia treatment; 2) POEM should be performed by experienced physicians in high-volume centers because an estimated 20-40 procedures are needed to achieve competence; 3) POEM should be considered as primary therapy for type III achalasia when the expertise is available; 4) POEM should be considered as a treatment option comparable with LHM for any of the achalasia syndromes when expertise is available; and 5) post-POEM patients should be considered high risk to develop reflux esophagitis and educated pre-POEM on the management of this potential complication (potential indefinite PPI therapy and/or surveillance endoscopy).

International Society for Diseases of the Esophagus (ISDE)

The International Society for Diseases of the Esophagus (ISDE): achalasia guidelines (2018) proposed and endorsed the Esophageal Achalasia Guidelines (I-GOAL) from a systematic literature review.35 Fifty-one experts from 11 countries and 3 representatives from patient support associations participated in the drafting of the guidelines. Regarding the treatment of achalasia with POEM, the ISDE recommended POEM as an effective treatment both in short- and medium-term follow-up with results comparable to LHM and PD for symptom improvement. They also recommended that POEM is an effective and feasible treatment for achalasia patients who were previously treated with endoscopic therapies as well as those who experience recurrence of symptoms following LHM. Further recommendations included that pre-POEM patients are educated on the risk of GERD and follow-up acid suppression therapy considered; patients who desire a treatment with a lower incidence of post-procedure GERD, such as PD or LHM, should be counseled that these options are available; appropriate training with in vivo/in vitro animal models and adequate supervision should be considered prior to performing POEM independently.

Analysis of Evidence (Rationale for Determination)

The available evidence suggests that POEM is generally safe and may achieve at least similar results as PD and LHM for most efficacy and harms outcomes regarding treatment of achalasia. Evidence also suggests that a select group of patients with achalasia would benefit from POEM. Some of these patients are not appropriate surgical candidates or do not desire to undergo surgery if there is a less invasive option available for treatment. These patients could potentially benefit from a non-invasive procedure such as POEM.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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Policy History

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Utilization Management Committee review and approval: 03/19/2024

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Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	43497, 43499
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

    1. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    2. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient’s health insurance contract contains language that differs from the Health Plan Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.