Subject: Peroral endoscopic myotomy (POEM) for Esophageal Achalasia		Original Effective Date: 12/9/21
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Contents

DISCLAIMER 1

Description of Procedure/Service/Pharmaceutical 1

Recommendation Clinical Criteria 2

Continuation of Therapy 2

Limitations 2

Summary of Medical Evidence 2

Coding Information 4

References 4

REVISION/REVIEW HISTORY: 7

DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina clinical policy document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Esophageal Achalasia

Esophageal achalasia (EA) results from progressive degeneration of ganglion cells in the myenteric plexus in the esophageal wall. It is characterized by the failure of relaxation of the lower esophageal sphincter (LES), often accompanied by a loss of peristalsis in the distal esophagus. The criterion standard for diagnosing achalasia is high-resolution esophageal manometry showing incomplete relaxation of theesophagogastric junction (EGJ) coupled with the absence of organized peristalsis. The primary treatment objective for EA is to relieve obstruction in the distal esophagus by disrupting or weakening the LES. Optimal treatment for EA, however, should also reverse the aperistalsis and restore LES function. Laparoscopic Heller myotomy (LHM) has been regarded as the standard treatment option for patients with EA who are deemed good surgical candidates. The technique 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. Other treatment options include botulinum toxin injection, and pneumatic dilation.

Peroral Endoscopic Myotomy

Peroral endoscopic myotomy (POEM) is transluminal endoscopic equivalent of surgical myotomy and a newer technique for the management of achalasia. The procedure involves guiding an endoscope through the esophagus, making an incision in the mucosa, creating a submucosal tunnel for access to the lower esophagus and gastroesophageal junction, and cutting the muscle fibers in the lower esophagus and proximal stomach. Internal incisions are closed with clips after myotomy is complete. 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.

RECOMMENDATION CLINICAL CRITERIA

Peroral endoscopic myotomy (POEM) is considered experimental, investigational and unproven for all indications including esophageal achalasia due to insufficient evidence in the peer reviewed medical literature.

CONTINUATION OF THERAPY

N/A

LIMITATIONS

N/A

SUMMARY OF MEDICAL EVIDENCE

At the current time, the evidence is insufficient to determine the safety and efficacy of POEM as a treatment for esophageal achalasia (EA). A very low-quality body of evidence, mainly from poor-quality studies, suggests that the safety and effectiveness of POEM may be at least comparable with Laparoscopic Heller Myotomy (LHM) for most outcomes for the treatment of adult patients with EA. There is uncertainty regarding optimal procedure techniques, patient selection criteria, and the comparative long-term durability and safety of the procedure.

Studies Comparing POEM with Laparoscopic Heller Myotomy (LHM): [3, 5, 6, 8, 9, 11, 13, 15, 16, 20, 22, 23, 26, 29]

Summary: The evidence consists of 16 studies (3 prospective cohort studies with historical controls, 2 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. Studies 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)

Studies Comparing POEM with Pneumatic Dilation (PD): [12, 16, 17, 20]

Summary: 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).

The only randomized controlled trial is summarized below:

Ponds et al (2019) conducted a randomized multicenter clinical trial to compare the effects of POEM vs pneumatic dilation as initial treatment of treatment-naive patients with achalasia. According to this study "This randomized multicenter clinical trial was conducted at 6 hospitals in the Netherlands, Germany, Italy, Hong Kong, and the United States. Adult patients with newly diagnosed achalasia and an Eckardt score greater than 3 who had not undergone previous treatment were included. The study was conducted between September 2012 and July 2015, the duration of follow-up was 2 years after the initial treatment, and the final date of follow-up was November 22, 2017. Participants were Randomized to receive POEM (n = 67) or pneumatic dilation with a 30-mm and a 35-mm balloon (n = 66), with stratification according to hospital. 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 pneumatic dilation group) and 126 (95%) completed the study. 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). Of the 14 prespecified secondary end points, no significant difference between groups was demonstrated in 10 end points. There was no significant between-group difference in median integrated relaxation pressure (9.9 mm Hg in the POEM group vs 12.6 mm Hg in the pneumatic dilation group; difference, 2.7 mm Hg [95% CI, -2.1 to 7.5]; P = .07) or median barium column height (2.3 cm in the POEM group vs 0 cm in the pneumatic dilation group; difference, 2.3 cm [95% CI, 1.0-3.6]; P = .05). Reflux esophagitis occurred more often in the POEM group than in the pneumatic dilation group (22 of 54 [41%]vs 2 of 29 [7%]; difference, 34% [95% CI, 12%-49%]; P = .002). Two serious adverse events, including 1 perforation, occurred after pneumatic dilation, while no serious adverse events occurred after POEM." The authors concluded that "among treatment-naive patients with achalasia, treatment with POEM compared with pneumatic dilation resulted in a significantly higher treatment success rate at 2 years, however there was no significance between the groups in difference of median integrated relaxation pressure or median barium column height."

Additional studies (meta-analysis, systematic reviews and retrospective case series) are included in the reference section. A summary of the largest systematic review and meta-analysis is below.

Schlottmann et al.; (2018) conducted a systematic review and meta-analysis of 53 studies using LHM (5834 patients) and 21 studies using POEM (1958 patients) for the treatment of esophageal achalasia. The probability for improvement in dysphagia at 24 months was 90% for patients receiving LHM and 93% for patients receiving POEM (p=0.01). Patients receiving POEM were significantly more likely to develop GERD. [24]

Professional Society Guidelines: [32-35]

American College of Gastroenterology (ACG): Clinical guideline. Diagnosis and management of achalasia. (2013): According to the ACG Guideline: "Randomized prospective comparison trials with standard laparoscopic myotomy and/or PD are needed and POEM should only be performed in the context of clinical trials with the understanding that other effective well-studied alternatives are available." [34]

American Gastroenterological Association (AGA): Clinical practice update, the use of per-oral endoscopic myotomy in achalasia: Expert review and best practice advice. (2017): According to the AGA summary: "POEM appears to be a safe, effective, and minimally invasive management option in achalasia in the short term; data on the long-term durability of POEM are not yet available. Given the complexity of this procedure, it should be performed by experienced physicians in high volume centers because an estimated 20-40 procedures are needed to achieve competence and 60 to achieve mastery. Existing uncontrolled reports suggest efficacy equal to or superior to LHM and emerging RCT data suggest POEM to be more effective than PD, but more likely to result in post-treatment reflux." [33]

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
43499	Unlisted procedure, esophagus

HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
K22.0	Achalasia of cardia

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