



Louisiana

Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia

Policy # 00701

Original Effective Date: 04/13/2020

Current Effective Date: 04/13/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease is addressed separately in medical policy 00123.

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 Company considers peroral endoscopic myotomy as a treatment for pediatric and adult esophageal achalasia to be **investigational**.*

Background/Overview

Esophageal Achalasia

Esophageal achalasia is characterized by reduced numbers of neurons in the esophageal myenteric plexuses and reduced peristaltic activity, making it difficult for patients to swallow food and possibly leading to complications such as regurgitation, coughing, choking, aspiration pneumonia, esophagitis, ulceration, and weight loss. The estimated U.S. prevalence of achalasia is 10 cases per 100000, and the estimated incidence is 0.6 cases per 100000 per year.

Treatment

Treatment options for achalasia have included pharmacotherapy (eg, injections with botulinum toxin), pneumatic dilation, and laparoscopic Heller myotomy. Although the latter two are considered the standard treatments because of higher success rates and relatively long-term efficacy compared with pharmacotherapy, both are associated with a perforation risk of about 1%. Heller myotomy is the most invasive of the procedures, requiring laparoscopy and surgical dissection of the

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esophagogastric junction. One-year response rates of 86% and major mucosal tear rates requiring the subsequent intervention of 0.6% have been reported.

Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure developed in Japan. POEM is performed with the patient under general anesthesia. After tunneling an endoscope down the esophagus toward the esophageal-gastric junction, a surgeon performs the myotomy by cutting only the inner, circular lower esophageal sphincter muscles through a submucosal tunnel created in the proximal esophageal mucosa. POEM differs from laparoscopic surgery, which involves the complete division of both circular and longitudinal lower esophageal sphincter muscle layers. Cutting the dysfunctional muscle fibers that prevent the lower esophageal sphincter from opening allows food to enter the stomach more easily.

Note that the acronym POEM in this review refers to *peroral endoscopic myotomy*. POEMS syndrome, which has a similar acronym, is discussed in medical policy 00060.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

POEM uses available laparoscopic instrumentation and, as a surgical procedure, is not subject to regulation by the U.S. Food and Drug Administration.

Rationale/Source

Esophageal achalasia is characterized by reduced numbers of neurons in the esophageal myenteric plexuses and reduced peristaltic activity, making it difficult for patients to swallow food and possibly leading to complications such as regurgitation, coughing, choking, aspiration pneumonia, esophagitis, ulceration, and weight loss. Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure that uses the oral cavity as a natural orifice entry point to perform myotomy of the lower esophageal sphincter. This procedure is intended to reduce the total number of incisions needed and thus the overall invasiveness of surgery.

For adults who have achalasia who receive POEM, the evidence includes systematic reviews of observational studies, a randomized controlled trial, nonrandomized comparative studies, and case series. The relevant outcomes are symptoms, functional outcomes, health status measures, resource

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utilization, and treatment-related morbidity. The comparative studies have primarily reported similar outcomes for POEM and for Heller myotomy in symptom relief, as assessed by the Eckardt score. Some studies have shown a shorter length of stay and less postoperative pain with POEM. However, potential imbalances in patient characteristics in these nonrandomized studies might have biased the treatment comparisons. In the case series, treatment success at short follow-up periods was reported for a high proportion of patients treated with POEM. However, the incidence of adverse events was relatively high, with POEM-specific complications, including subcutaneous emphysema, pneumothorax, and thoracic effusion, reported across studies. Additionally, a substantial proportion of patients undergoing POEM developed gastroesophageal reflux disease and esophagitis and required treatment. Case series do not permit conclusions about the efficacy of POEM relative to established treatment, and long-term outcomes of the procedure are not well described in the literature. The evidence is insufficient to determine the effects of the technology on health outcomes.

For pediatric patients who have achalasia who receive POEM, the evidence includes several nonrandomized studies and a systematic review. The relevant outcomes are symptoms, functional outcomes, health status measures, resource utilization, and treatment-related morbidity. The studies reported treatment success for POEM based on decreases in Eckardt scores and lower esophageal sphincter pressure. No randomized clinical trials have been reported. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

American Gastroenterological Association Institute

The American Gastroenterological Association Institute (2017) published a clinical practice update on the use of peroral endoscopic myotomy (POEM) for the treatment of achalasia. Based on the expert review, the Institute made the following recommendations:

- POEM should be performed by experienced physicians in high-volume centers (competence achieved after an estimated 20 to 40 procedures)
- 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

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Louisiana

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Original Effective Date: 04/13/2020

Current Effective Date: 04/13/2020

- Patients receiving POEM should be considered high-risk to develop reflux esophagitis and be advised of management considerations (eg, proton pump inhibitor therapy and/or surveillance endoscopy) prior to undergoing POEM.

American Society of Gastrointestinal and Endoscopic Surgeons

The American Society of Gastrointestinal and Endoscopic Surgeons (2014) issued evidence-based, consensus guidelines on the use of endoscopy in the evaluation and management of dysphagia, including esophageal achalasia. The Society recommended that:

"...Endoscopic and surgical treatment options for achalasia should be discussed with the patient. In patients who opt for endoscopic management and are good surgical candidates, pneumatic dilation with large-caliber balloon dilators for the endoscopic treatment of achalasia was recommended....Long-term data and randomized trials comparing peroral endoscopic myotomy to conventional modalities of management are necessary before it can be adopted into clinical practice, but the procedure is becoming more widely used in expert centers."

American College of Gastroenterology

The American College of Gastroenterology (2013) issued clinical guidelines on the diagnosis and management of achalasia. POEM was discussed as an emerging therapy and stated to have promise as an alternative to the laparoscopic approach. The guidelines further stated that randomized prospective comparison trials are needed, and the procedure should be performed in the context of clinical trials.

Society of American Gastrointestinal and Endoscopic Surgeons

The Society of American Gastrointestinal and Endoscopic Surgeons (2012) issued evidence-based, consensus guidelines on the surgical management of esophageal achalasia. The guidelines stated that the POEM technique "is in its infancy and further experience is needed before providing recommendations."

International Society for Diseases of the Esophagus

The International Society for Diseases of the Esophagus (2018) published guidelines on the diagnosis and management of achalasia. The Society convened 51 experts from 11 countries, including several from the U.S., to systematically review evidence, assess recommendations using

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Louisiana

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the GRADE system, and vote to integrate the recommendations into the guidelines (>80% approval required for inclusion). Table 1 summarizes POEM recommendations.

Table 1. Recommendations for the Treatment of Achalasia

Recommendation	LOR	GOR
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 pneumatic dilations.	Conditional	Low
Pretreatment information on GERD, nonsurgical options (pneumatic dilation), 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	NA

GERD: gastroesophageal reflux disease; GOR: grade of recommendation; LOR: level of recommendation; NA: not applicable; POEM: peroral endoscopic myotomy.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

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Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03228758	Efficacy of Anterior Versus Posterior Myotomy Approach in Peroral Endoscopic Myotomy (POEM) for the Treatment of Achalasia - a Single Operator Analysis	290	Nov 2019
NCT01402518	Observational Study of the Peroral Endoscopic Myotomy (POEM) Procedure	100	Nov 2019
NCT01601678	Endoscopic Versus Laparoscopic Myotomy for Treatment of Idiopathic Achalasia: A Randomized, Controlled Trial	240	Dec 2020
NCT01832779	Prospective Evaluation of the Clinical Utility of Peroral Endoscopic Myotomy (POEM)	600	Dec 2022
NCT01793922	A Prospective Randomized Multi-center Study Comparing Endoscopic Pneumodilation and Per Oral Endoscopic Myotomy (POEM) as Treatment of Idiopathic Achalasia	150	Jan 2023
<i>Unpublished</i>			
NCT02138643	Laparoscopy Heller Myotomy With Fundoplication Associated Versus Peroral Endoscopic Myotomy (POEM)	30	Dec 2017 (last update posted April

NCT: national clinical trial.

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Louisiana

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03/05/2020 Medical Policy Committee review

03/11/2020 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 03/2021

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Policy # 00701

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Current Effective Date: 04/13/2020

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Code Type	Code
CPT	43499
HCPCS	No codes
ICD-10 Diagnosis	K22.0

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- 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

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