



Louisiana

Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia and Gastroparesis

Policy # 00701

Original Effective Date: 04/13/2020

Current Effective Date: 04/08/2024

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: Hematopoietic Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome is addressed separately in medical policy 00060.

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

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 Company may consider peroral endoscopic myotomy (POEM) as a treatment for esophageal achalasia to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility may be considered for peroral endoscopic myotomy (POEM) as a treatment for esophageal achalasia to be medically appropriate when **ALL** of the following criteria are met:

- The individual is 18 years or older; **AND**
- Has an established diagnosis of primary achalasia (I, II or III) based on esophageal manometry; **AND**
- Eckardt symptom score is greater than 3 (see Policy Guideline section); **AND**
- There is no history of esophageal malignancy, radiation therapy, radiofrequency ablation or previous open surgery of the stomach or esophagus.

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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 Company considers peroral endoscopic myotomy (POEM) when the coverage criteria are not met and for all other indications to be **investigational**.*

Based on review of available data, the Company considers gastric peroral endoscopic myotomy as a treatment for gastroparesis to be **investigational**.*

Policy Guidelines

The three types of achalasia defined by the Chicago Classification include:

- Type I – Classic Achalasia – incomplete lower esophageal sphincter (LES) relaxation, aperistalsis and absence of esophageal pressurization with 100% failed peristalsis and a distal contractile integral (DCI) < 100mgHg.
- Type II – Incomplete LES relaxation, aperistalsis and panesophageal pressurization in at least 20% of swallows.
- Type III – (Spastic Achalasia) – Incomplete LES relaxation and premature contractions in at least 20% of swallows.

Eckardt symptom score is based on a 4-item self-report scale measuring weight loss in kilograms (kg), chest pain, regurgitation, and dysphagia. Each item is graded 0 to 3, with a maximum score of 12. Scores greater than or equal to 3 are considered suggestive of active achalasia:

| Score | Dysphagia | Regurgitation | Retrosternal pain | Weight loss (kg) |
|-------|------------|---------------|-------------------|------------------|
| 0 | None | None | None | None |
| 1 | Occasional | Occasional | Occasional | <5 |
| 2 | Daily | Daily | Daily | 5-10 |
| 3 | Each meal | Each meal | Each meal | >10 |

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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 100,000, and the estimated incidence is 0.6 cases per 100,000 per year.

Treatment

Treatment options for achalasia have included pharmacotherapy (eg, injections with botulinum toxin), pneumatic dilation, and laparoscopic Heller myotomy. Although the latter 2 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 esophagogastric junction. One-year response rates of 86% and major mucosal tear rates requiring subsequent intervention of 0.6% have been reported.

Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure developed in Japan. This procedure 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 (LES) 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 LES muscle layers. Cutting the dysfunctional muscle fibers that prevent the LES 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 in medical policy 00060 Hematopoietic Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome.

Gastroparesis

Gastroparesis is characterized by symptoms of nausea, vomiting, bloating, early satiety, and pain, which is caused by delayed gastric emptying without mechanical obstruction. The estimated U.S.

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prevalence of difficult to ascertain due to the weak correlation of symptoms with gastric emptying which results in a high rate of underdiagnosis. Using data from 1996 to 2006, the estimated incidence per 100,000 persons, adjusted for age, was 9.6 for men and 37.8 for women.

Treatment

Treatment options for gastroparesis have included dietary modification (smaller meal sizes, avoidance of carbonated beverages, smoking or high doses of alcohol, and in some cases enteral nutrition via jejunostomy), optimization of hydration and glycemic control, pharmacotherapy (eg, antiemetics or Metoclopramide, or off-label medications for symptom control such as domperidone, erythromycin, tegaserod or centrally acting antidepressants), gastric electrical stimulation, venting gastrostomy, feeding jejunostomy, intra-pyloric botulinum injection, partial gastrectomy, and pyloroplasty. Gastric peroral endoscopic myotomy (G-POEM), which endoscopically performs the equivalent of pyloroplasty, is being investigated for the treatment of gastroparesis. G-POEM myotomizes the pylorus rather than the circular LES but otherwise consists of the same techniques described above.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

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.

Description

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

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procedure that uses the oral cavity as a natural orifice entry point to perform myotomy of the lower esophageal sphincter (LES). This procedure is intended to reduce the total number of incisions needed and thus the overall invasiveness of surgery. Gastric peroral endoscopic myotomy (G-POEM) is a similar procedure with the exception that it myotomizes the pylorus rather than LES.

Summary of Evidence

For adults who have achalasia who receive peroral endoscopic myotomy (POEM), the evidence includes systematic reviews of primarily observational studies, 4 randomized controlled trials (RCTs), and nonrandomized comparative studies. Relevant outcomes are symptoms, functional outcomes, health status measures, resource utilization, and treatment-related morbidity. Compared with pneumatic dilation (PD) or laparoscopic Heller myotomy (LHM), findings from RCTs demonstrated that POEM had a similar or greater treatment success rate based on the Eckardt score and similar or fewer overall adverse event rates. However, POEM had significantly higher rates of endoscopically confirmed reflux esophagitis and more daily proton-pump inhibitor use at 24 months. An important conduct limitation of the RCTs is that blinded assessment of outcomes was not used. Given that the primary outcome was based on subjective patient report of symptoms, this is a potential source of bias. Additionally, a potential relevance limitation is that the RCTs did not include any US sites. The comparative observational studies have primarily reported similar outcomes for POEM and for LHM 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.

For pediatric individuals who have achalasia who receive POEM, the evidence includes several nonrandomized studies and 3 systematic reviews. 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 (LES) pressure. No RCTs have been reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For adults who have gastroparesis who receive gastric POEM (G-POEM), the evidence includes 2 meta-analyses, 1 RCT, and several nonrandomized studies. All studies included in these reviews were observational. Relevant outcomes are symptoms, functional outcomes, health status measures, resource utilization, and treatment-related morbidity. The studies generally reported treatment

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success for G-POEM based on a decrease in Gastroparesis Cardinal Symptom Index (GCSI) score and ranged from 60.7% at 1 year to 75% at 3 years in the meta-analyses. One RCT comparing G-POEM to sham was identified which found greater rates of treatment success and gastric retention at 6 months follow-up in the G-POEM group. Both the RCT and the largest observational study found the greatest treatment effect in patients who had a diabetic etiology for gastroparesis. Study limitations include small number of participants, insufficient follow-up to define long-term effects, and results may not be generalizable to the general population (performed by experienced endoscopist). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Large, controlled trials with longer follow-up are needed to identify the individuals most suited for the procedure.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Gastroenterology

In 2020, the American College of Gastroenterology (ACG) issued evidence-based clinical guidelines on the diagnosis and management of achalasia. The quality of the evidence and the strength of recommendations were rated based on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework. The evidence review includes the 2 randomized controlled trials (RCTs) of peroral endoscopic myotomy (POEM) compared to laparoscopic Heller myotomy (LHM) or pneumatic dilation (PD). Based on their evaluation, the ACG made the following recommendations:

- "In patients with achalasia who are candidates for definite therapy, PD, LHM, and POEM are comparable effective therapies for type I or type II achalasia and POEM would be a better treatment option in those with type III achalasia."
- "We suggest that POEM or PD result in comparable symptomatic improvement in patients with types I or II achalasia." (GRADE quality=Low, Recommendation strength=Conditional)

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- "We recommend that POEM and LHM result in comparable symptomatic improvement in patients with achalasia." (GRADE quality=Moderate; Recommendation strength=Strong)
- "We recommend tailored POEM or LHM for type III achalasia as a more efficacious alternative disruptive therapy at the lower esophageal sphincter compared to PD." (GRADE quality=Moderate; Recommendation strength=Strong)
- "We suggest that in patients with achalasia, POEM compared with LHM with fundoplication or PD is associated with a higher incidence of GERD [gastroesophageal reflux disease]." (GRADE quality=Moderate; Recommendation strength=Strong)
- "We suggest that POEM is a safe option in patients with achalasia who have previously undergone PD or LHM." (GRADE quality=Low; Recommendation strength=Strong)

American Gastroenterological Association Institute

In 2017, the American Gastroenterological Association Institute published a clinical practice update on the use of 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
- 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.

In 2023, the American Gastroenterological Association Institute issued a clinical practice update commentary regarding gastric peroral endoscopic myotomy for gastroparesis. Based on an expert review the following recommendations were provided:

- Gastric POEM (G-POEM), also called peroral endoscopic pyloromyotomy, should be considered for patients with medically refractory gastroparesis
 - 1) Have undergo esophagogastroduodenoscopy to confirm no mechanical gastric outlet obstruction
 - 2) had a solid phase gastric emptying scan (GES) confirming delayed gastric emptying, preferably with retention >20% at 4 hours

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- 3) have moderate to severe symptoms including nausea and vomiting as the dominant symptoms on the gastroparesis cardinal symptom index
 - Patients who have failed gastric electrical stimulator therapy, pyloric stenting and botulinum toxin injection should be offered G-POEM but failure of these alternatives therapies should not be a prerequisite.
- G-POEM should not be offered to the following patients:
 - Patients with opioid dependence should be weaned off opioids whenever possible and have their gastric emptying re-evaluated.
 - Most patients with postinfectious gastroparesis should not be offered G-POEM
- G-POEM should only be performed by interventional endoscopists with expertise or training in third-space endoscopy
- Patients should remain on a liquid diet for at least 24 hours before G-POEM to minimize residual gastric contents
- A high-definition gastroscope, with a waterjet, affixed with a clear distal cap, should be used to perform G-POEM. And a modern electrosurgical generator capable of modulating power based on tissue resistance and circuit impedance is necessary for G-POEM.

American Society of Gastrointestinal and Endoscopic Surgeons

In 2020, the American Society of Gastrointestinal and Endoscopic Surgeons (ASGE) issued an evidence-based guideline on the management of achalasia. The methodologic quality of systematic reviews was assessed using the Methodological Quality of Systematic Reviews-2 (AMSTAR-2) tool and the certainty of the body of evidence was rated as very low to high based on the GRADE framework. ASGE rated the strength of individual recommendations based on the aggregate evidence quality and an assessment of the anticipated benefits and harms. ASGE used the phrase "we suggest" to indicate weaker recommendations and "we recommend" to indicate stronger recommendations. This guideline did not include either of the 2 available RCTs of POEM. Based on their evaluation, ASGE issued 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 laparoscopic Heller myotomy), we suggest PD or redo myotomy using either the same or an alternative myotomy technique (POEM or laparoscopic Heller myotomy)." (Very low quality evidence)

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- "We suggest that patients undergoing POEM are counseled regarding the increased risk of postprocedure reflux compared with PD and laparoscopic Heller myotomy. Based on patient preferences and physician expertise, postprocedure 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 laparoscopic Heller myotomy 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)

These 2020 ASGE guidelines were endorsed by the American Neurogastroenterology and Motility Society and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES).

International Society for Diseases of the Esophagus

In 2018, the International Society for Diseases of the Esophagus 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 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 PD. | Conditional | Low |
| Pretreatment information on GERD, nonsurgical options (PD), and surgical options with lower GERD risk (Heller myotomy) should be provided to the patient. | Good practice | NA |
| POEM is feasible and effective for symptom relief in patients previously treated with endoscopic therapies. | Conditional | Very low |

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| | | |
|--|---------------|-----|
| 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; PD: pneumatic dilation; POEM: peroral endoscopic myotomy.

Society of American Gastrointestinal and Endoscopic Surgeons

In 2020, SAGES endorsed the guideline on the management of achalasia issued by ASGE (2020) as described above.

In 2021, SAGES issued its own evidence-based guidelines for the use of POEM for the treatment of achalasia. The expert panel agreed on 4 recommendations for adults and children with achalasia.

These include:

- The panel suggests that adult and pediatric patients with type I and II achalasia may be treated with either POEM or LHM based on surgeon and patient's shared decision making (conditional recommendation; very low certainty evidence).
- The panel suggests POEM over LHM for type III adult or pediatric achalasia. (expert opinion)
- The panel recommends POEM over PD in patients with achalasia (strong recommendation, moderate certainty evidence)
- For the subgroup of patients who are particularly concerned about the continued use of proton pump inhibitors post-operatively, the panel suggests that either POEM or PD can be used based on joint patient and surgeon decision-making (conditional recommendation, very low certainty evidence)

U.S. Preventive Services Task Force Recommendations

Not applicable.

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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.

Table 2. Summary of Key Trials

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|----------------|---|--------------------|--|
| <i>Ongoing</i> | | | |
| NCT01601678 | Endoscopic Versus Laparoscopic Myotomy for Treatment of Idiopathic Achalasia: A Randomized, Controlled Trial | 240 | Apr 2023 (last update posted June 2023) |
| NCT01832779 | Prospective Evaluation of the Clinical Utility of Peroral Endoscopic Myotomy (POEM) | 600 | Dec 2022 (last update posted May 2023) |
| NCT01793922 | A Prospective Randomized Multi-center Study Comparing Endoscopic Pneumodilation and Per Oral Endoscopic Myotomy (POEM) as Treatment of Idiopathic Achalasia | 150 | Jan 2023 (last update posted Feb 2023) |
| NCT04434781 | Gastric Per-Oral Endoscopic Myotomy (G-POEM) for the Treatment of Gastroparesis: A Database Repository | 75 | Aug 2024 |
| NCT05830994 | Randomized Sham-controlled Trial Investigating Efficacy of Gastric Peroral Endoscopic Myotomy in Treatment of Diabetic Gastroparesis | 20 | Jun 2025 |

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| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|--------------------|--|--------------------|---|
| NCT04869670 | A Pilot and Feasibility Trial of G-POEM for Gastroparesis to Assess Safety, Physiological Mechanisms and Efficacy | 30 | Jun 2025 |
| NCT02518542 | Per Oral Endoscopic Myotomy (POEM) and Prolonged Dilatation (PRD) as Additional Endoscopic Treatment Options for Achalasia and Other Esophageal Motility Disorders | 400 | Jun 2027 |
| <i>Unpublished</i> | | | |
| NCT02138643 | Laparoscopy Heller Myotomy With Fundoplication Associated Versus Peroral Endoscopic Myotomy (POEM) | 30 | Dec 2017 (last update posted April 2017) |
| NCT03228758 | Efficacy of Anterior Versus Posterior Myotomy Approach in Peroral Endoscopic Myotomy (POEM) for the Treatment of Achalasia - a Single Operator Analysis | 89 | May 2019 (last update posted May 2020) |

NCT: national clinical trial.

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- 03/05/2020 Medical Policy Committee review
- 03/11/2020 Medical Policy Implementation Committee approval. New policy.
- 03/04/2021 Medical Policy Committee review
- 03/10/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 10/01/2021 Coding update
- 12/20/2021 Coding update
- 03/03/2022 Medical Policy Committee review
- 03/09/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 03/02/2023 Medical Policy Committee review
- 03/08/2023 Medical Policy Implementation Committee approval. Added a “When Services May Be Eligible for Coverage” section. Revised the investigational statement. Added a Policy Guidelines section.
- 03/07/2024 Medical Policy Committee review
- 03/13/2024 Medical Policy Implementation Committee approval. Title changed from “Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia” to “Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia and Gastroparesis.” Added an investigational statement for gastric peroral endoscopic myotomy as a treatment for gastroparesis.

Next Scheduled Review Date: 03/2025

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|------------------|--|
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| HCPCS | No codes |
| ICD-10 Diagnosis | All related diagnoses |

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

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- 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.

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