BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Peroral Endoscopic Myotomy (POEM) for Treatment of Esophageal Achalasia and Refractory Gastroparesis

Policy #: 537
Category: Surgery

Latest Review Date: November 2020
Policy Grade: C

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after November 22, 2019:

Blue Advantage will treat **peroral endoscopic myotomy (POEM)** as a treatment for pediatric and adult esophageal achalasia as a **non-covered** benefit and as **investigational**.

Blue Advantage will treat **peroral endoscopic pyloromyotomy** as a treatment for refractory gastroparesis as a **non-covered** benefit and as **investigational**.

Blue Advantage will treat **endoscopic closure devices** (e.g. Overstitch, Over the Scope clip [OTSC]) as a **non-covered** benefit and as **investigational**.

Effective for dates of service on and after May 17, 2018 and prior to November 22, 2019:

Blue Advantage will treat **peroral endoscopic myotomy (POEM)** as a treatment for esophageal achalasia as a **non-covered benefit** and as **investigational.**

Blue Advantage will treat **peroral endoscopic pyloromyotomy** as a **treatment for refractory gastroparesis** as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat **endoscopic closure devices** (e.g. Overstitch, Over the Scope clip [OTSC]) as a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure developed in Japan. POEM is performed with the patient under general anesthesia. For esophageal achalasia, 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 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. For refractory gastroparesis, the same technique is utilized, but a tunnel is typically created 5cm proximal to the pylorus, then an antral myotomy is performed in addition to pyloromyotomy through the submucosal tunnel.

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. 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 has the intent of reducing the total number of incisions needed and, thus, reducing the overall invasiveness of surgery.

Achalasia has an estimated prevalence in the United States of ten cases per 100,000, with an incidence of 0.6 cases per 100,000 per year. Treatment options for achalasia have traditionally included pharmacotherapy such as injections with botulinum toxin, pneumatic dilation, and laparoscopic Heller myotomy (LHM). Although the last two are considered the mainstay of treatment because of higher success rates and relative long-term efficacy compared to pharmacotherapy and botulinum toxin injections, they both are associated with a perforation risk of about 1%. Laparoscopic 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 rates of major mucosal tears 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.

Refractive Gastroparesis
Gastroparesis is delayed gastric emptying when there is no mechanical obstruction. Symptoms include nausea, vomiting, bloating, or abdominal pain. Gastroparesis can be idiopathic, diabetic, or post-surgical. Gastroparesis is initially treated by modifying diet, optimizing glycemic control, and medications. When these treatments fail, a surgical procedure may be required. The POEM procedure has been modified to be performed in the stomach to attempt to treat refractory gastroparesis.

Please note that the acronym POEM in this policy refers to peroral endoscopic myotomy. POEMS syndrome, which uses a similar acronym, is discussed in medical policy #415 (*Hematopoietic Stem-Cell Transplantation for Plasma Cell Dyscrasias, including Multiple Myeloma and POEMS Syndrome*).

KEY POINTS:
The most recent literature review was updated through September 5, 2020.

Summary
For adults who have achalasia who receive peroral endoscopic myotomy, the evidence includes systematic reviews, 2 randomized controlled trials, nonrandomized comparative studies, and case series. The relevant outcomes are symptoms, functional outcomes, health status measures, resource utilization, and treatment-related morbidity. Compared with pneumatic dilation 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 showed mostly similar outcomes with POEM versus laparoscopic Heller myotomy for the outcome of symptom relief as assessed by the Eckardt score. Some studies showed a shorter length of stay and less postoperative pain with POEM. However, potential imbalance in patient characteristics in these nonrandomized studies may bias the comparisons between treatments. In the case series studies, treatment success at short follow-up periods was reported for a high proportion of patients treated with POEM. However, 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 esophagitis requiring treatment. The case series studies do not allow conclusions about the efficacy of POEM relative to established treatment. 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.

For individuals who receive POEM for refractive gastroparesis, the evidence consists of small prospective and retrospective non randomized studies. Relevant outcomes are symptoms and treatment related morbidity. Studies have shown the procedure is feasible and short term results have decreased symptoms, however; the studies are small, there are no RCTs comparing this to other treatments, and additional long term data are needed to determine the effects of this technology on health outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

American College of Gastroenterology

In 2020, the American College of Gastroenterology 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 GRADE framework. The evidence review includes the 2 RCTs of POEM compared to LHM or pneumatic dilation. Based on their evaluation, the College 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)
- "We recommend that POEM and LHM result in comparable symptomatic improvement in patients with achalasia." (GRADE quality=Moderate; Recommendation strength=Strong)
- "We recommend that 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." (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

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
- 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

In 2014, the American Society of Gastrointestinal and Endoscopic Surgeons (ASGE) 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."

In 2020, 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 Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework. ASGE rated the strength of individual recommendation 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 pneumatic dilation or redo myotomy using either the same or an alternative myotomy technique (POEM or laparoscopic Heller myotomy)." (Very low quality evidence)
- "We suggest that patients undergoing POEM are counseled regarding the increased risk of postprocedure reflux compared with pneumatic dilation 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).

ASGE does not have a guideline or consensus statement regarding endoscopic peroral pyloromyotomy or endoscopic suturing devices.

Society of American Gastrointestinal and Endoscopic Surgeons
In 2011, SAGES issued an evidence-based, consensus guideline on the surgical management of esophageal achalasia. The guideline stated that the POEM technique "is in its infancy and further experience is needed before providing recommendations."

SAGES does not have a guideline or consensus statement regarding endoscopic peroral pyloromyotomy or endoscopic suturing devices.

American College of Gastroenterology
The American College of Gastroenterology (2013) issued a clinical guideline 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 guideline further states that randomized prospective comparison trials are needed, and the procedure should be performed in the context of clinical trials.

ACG does not have a guideline or consensus statement regarding endoscopic peroral pyloromyotomy or endoscopic suturing devices.

Society of American Gastrointestinal and Endoscopic Surgeons
In 2012, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) 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."

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

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

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Peroral endoscopic myotomy, POEM**, Esophageal achalasia, endoscopic suturing devices, Overstitch, over the scope clip, OTSC, GPOEM, G-POEM, refractory gastroparesis, gastroparesis

****NOTE**: FOR **POEMS Syndrome**, refer to **Policy 415** *Single or Tandem Courses of Hematopoietic Stem-cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome*

APPROVED BY GOVERNING BODIES:
POEM uses available laparoscopic instrumentation and, as a surgical procedure, is not subject to regulation by the U.S. Food and Drug Administration (FDA).

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT Codes:

There are no specific CPT codes for these procedures. They would likely be reported with an unlisted procedure code.

For esophageal achalasia:

43499 unlisted procedure, esophagus

For refractory gastroparesis:

43999 unlisted procedure, stomach

There are no specific CPT codes for endoscopic closure devices. It would likely be reported with the unlisted procedure, stomach code 43999.

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POLICY HISTORY:

Adopted for Blue Advantage, October 2013
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