

Molina Clinical Policy

Peroral Endoscopic Myotomy (POEM) for Esophageal Achalasia:

Policy No. 385

Last Approval: 04/10/2024

Next Review Due By: April 2025



DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Esophageal Achalasia (EA) is a primary esophageal motility disorder characterized by decreased numbers of neurons in the esophageal myenteric plexuses, resulting in increased pressure at the lower esophageal sphincter (LES) and esophageal aperistalsis. These abnormalities result in a functional obstruction at the gastroesophageal junction caused primarily by a failure of the LES to relax, which impairs food emptying from the esophagus into the stomach and results in food stasis (Spechler 2022). The typical clinical presentation is slowly progressive dysphagia for both solids and liquids. Regurgitation is a common finding that can lead to pulmonary symptoms such as choking, coughing, aspiration, and pneumonia. High-resolution esophageal manometry demonstrating incomplete relaxation of the esophagogastric junction in conjunction with the absence of organized peristalsis is the gold standard for diagnosing achalasia (Khashab et al. 2020). There is currently no known cure. Achalasia treatment options include pharmacologic intervention, pneumatic dilatation, botulinum toxin injection, and surgical myotomy. Laparoscopic Heller myotomy is the standard treatment option for EA patients who are considered good surgical candidates. It entails 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.

Peroral Endoscopic Myotomy (POEM) is an endoscopic complement to surgical myotomy and a novel, less invasive alternative to Laparoscopic Heller myotomy for the treatment of EA. POEM is a natural orifice transmural endoscopic surgical technique. An endoscope is guided through the esophagus toward the esophageal-gastric junction during the procedure. The endoscopist cuts the esophageal mucosa and inserts the endoscope into the esophageal submucosa, creating a submucosal tunnel that extends distally into the gastric cardia. The muscularis propria muscle in and around the LES is severed with a diathermic scalpel introduced through the endoscope. POEM, unlike surgical myotomy which is frequently performed in conjunction with fundoplication to avoid reflux, does not include an anti-reflux operation and may result in severe gastroesophageal reflux disease (Spechler 2023).

COVERAGE POLICY

Peroral Endoscopic Myotomy (POEM) for the treatment of symptomatic esophageal achalasia **may be considered medically necessary** when **ALL** the following criteria are met:

- A. Diagnosis of type I, II, or III esophageal achalasia established by high-resolution esophageal manometry confirming ONE of the following:
 1. Incomplete relaxation of the lower esophageal sphincter (integrated relaxation pressure above the upper limit of normal), and aperistalsis in the distal two-thirds of the esophagus
 2. Inconclusive findings despite a timed barium esophogram indicating dilation of the esophagus, narrow esophagogastric junction, aperistalsis, and/or delayed emptying of barium **AND** an esophagogastric malignancy has been ruled out by appropriate means (e.g., upper endoscopy, endoscopic ultrasound with fine needle aspiration).

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- B. Member has been counseled on the risk of Gastroesophageal reflux disease (GERD) and alternative treatments available with a lower incidence of post-procedure GERD, such as Laparoscopic Heller myotomy and pneumatic balloon dilation, appropriate for member's specific condition
- C. Documentation of **ALL** the following
 1. History and physical exam, including a standardized, validated symptom assessment indicating symptomatic esophageal achalasia (i.e., dysphagia for solids and liquids; heartburn unresponsive to a trial of proton pump inhibitor therapy)
 2. Eckardt symptom score > 3
 3. GERD has been objectively ruled out as the primary cause of dysphagia and/or heartburn by either of the following when symptoms of heartburn are present:
 - i. Reflux and/or esophagitis is not present on endoscopy
 - ii. 24-hour ambulatory esophageal pH monitoring rules out reflux
- D. POEM is recommended based on **ONE** of the following:
 1. As the most appropriate procedure for the treatment of achalasia based on patient-specific parameters (Chicago Classification subtype, comorbidities, early vs. late disease, primary or secondary causes)
 2. Failed treatment as evidence by Member having recurrent and persistent symptoms documented, an Eckardt symptom score >3, and dated documentation of ONE of the following treatments for EA:
 - i. Treatment with pneumatic balloon dilation
 - ii. Botulinum toxin injection
 - iii. Laparoscopic Heller myotomy

LIMITATIONS AND EXCLUSIONS

- A. The Member must be free from ALL the following **contraindications/exclusions**:
 1. Severe erosive esophagitis
 2. Significant coagulation disorders
 3. Liver cirrhosis with portal hypertension
 4. Severe pulmonary disease
 5. Esophageal malignancy
 6. Prior therapy that may compromise the integrity of the esophageal mucosa or lead to submucosal fibrosis (e.g., radiation, endoscopic mucosal resection, or radiofrequency ablation)

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

- B. The following are considered **experimental, investigational, and unproven** based on insufficient evidence:
 1. Any indications other than those listed above, including the following POEM procedures:
 - i. Diverticular peroral endoscopic myotomy (D-POEM)
 - ii. Gastric peroral endoscopic myotomy (G-POEM)
 - iii. Zenker peroral endoscopic myotomy (Z-POEM)

CONTINUATION OF THERAPY: A repeated POEM may be considered medically necessary for adults with an Eckardt symptom score >3 and no contraindications after a prior POEM procedure on the opposite site of the esophagus that did not relieve symptoms. **New authorization request is required.**

PRESCRIBER REQUIREMENTS: Procedures must be performed by adequately trained, experienced physicians in a highly specialized center.

AGE RESTRICTIONS: 18 years of age or older

ADMINISTRATION:

- A. Procedure performed in highly specialized centers with the staff to address any potential adverse events from POEM immediately, including but not limited to gastrointestinal or cardio-thoracic complications.
- B. Refer to MHI Policy & Procedure: Specialty Medication Administration Site of Care Policy (MHI Pharm 11).

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but

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is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

North and Tewari (2024) conducted a systematic review comparing peroral endoscopic myotomy (POEM) to laparoscopic Heller myotomy (LHM) and pneumatic dilation (PD) in the treatment of esophageal achalasia (EA). A total of 31 studies were included and analyzed, three of which were RCTs (Conte et al. 2020; Ponds et al. 2019; Werner et al. 2019). The medium to long term efficacy results were increased efficacy of POEM over PD, with additional statistically significant improvements in treatment success rates (100 vs. 50% with Eckardt <3) noted in type III achalasia patients retrospectively at 1 year follow-up. POEM and LHM had similar efficacy in the medium to long term follow up, with a retrospective analysis of 98 patients observed significantly longer time to treatment failure in POEM groups compared to LHM despite no difference in Eckardt scores at 36 months. As far as symptom reoccurrence and retreatment rates, POEM had significantly less of each compared to PD. LHM and POEM lead to comparable symptom recurrence and re-treatment rates. Overall, evidence supports effective symptom improvement after POEM, with the improvement appearing to be especially beneficial in type III achalasia patients, the subtype that poses significant difficulties in treatment. POEM appears to be more likely to result in long lasting benefit without the need to undergo additional intervention. While results are generally equivalent between POEM and LHM patients, POEM seems superior to PD, with comparably low adverse event rates across all treatment modalities. Significantly higher POEM patients experience gastroesophageal reflux disease symptoms following the procedure, which may be managed conservatively compared to symptoms of achalasia using proton pump inhibitors. The authors emphasize that POEM and LHM require significant skill and experience to be carried out effectively. Additionally, the authors highlight the limitations of the analysis, being most study designs included are retrospective without matching, introducing the possibility of bias, few of the included studies undertook follow-up of POEM patients beyond 24 months compared to longer follow-up in LHM and PD patients leading to potential missed recurrence in POEM patients, and while financial implications were considered in this study no formal economic model was formulated. The authors suggest further high quality RCTs are needed to corroborate the findings and to reduce risk of bias.

Zhang et al. (2023) conducted a systematic review and meta-analysis on the mid- and long-term outcomes of POEM for the treatment of achalasia. Twenty-one studies were included, totaling 2, 698 patients, with a minimum follow up of two years. The pooled clinical success rates of POEM in studies with 2-, 3-, 4-, and 5-year follow-ups were 91.3% (95% confidence interval [CI] 88.4-93.6%), 90.4% (95% CI 88.1-92.2%), 89.8% (95% CI 83.6-93.9%), and 82.2% (95% CI 76.6-86.7%), respectively. The pooled long-term clinical success rates for type I, II, and III achalasia were 86.1% (95% CI 80.9-90.1%; I² = 0%), 87.9% (95% CI 84.2-90.8%; I² = 48.354%), and 83.9% (95% CI 72.5-91.2%; I² = 0%), respectively. The pooled incidence of symptomatic reflux and reflux esophagitis was 23.9% (95% CI 18.7-29.9%) and 16.7% (95% CI 11.9-23.1%), respectively. The authors concluded POEM is associated with a long-term clinical success of 82.2% after 5 years of follow-up; however, they recommended more high quality RCTs comparing POEM with LHM and PD with long term follow up periods are necessary to further demonstrate the long-term safety and efficacy of POEM. These results are echoed in the systematic review and meta-analysis conducted by Vespa et al. (2023).

Ciomperlik et al. (2023) conducted a systematic review comparing the quality of life (QOL) in patients treated with POEM vs LHM vs PD. Six studies were analyzed, for a total of nine publications, as a few of the studies had follow up publications. Across the nine publications there was no significant difference in QOL at 12 to 36 months except for one study in which QOL was significantly higher in patients who underwent LHM as opposed to PD at 3 years; however, at 5 years there was no difference. PD was associated with the highest rates of dysphagia recurrence and reintervention vs POEM that had the lowest rates of dysphagia recurrence and reintervention rates. POEM was also associated with the lowest rates of perforation/leak. The authors concluded that QOL across the three interventions were comparable, with POEM favorable due to its low symptom recurrence/reintervention and perforation/leak rates; however, due to the high specialized training necessary to perform the procedure there are barriers to its widespread use.

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Dirks et al. (2021) conducted a systematic review and meta-analysis comparing the efficacy of POEM compared to LHM and PD. The review included 28 studies (2 RCTs and 26 observational studies). Twenty-one studies compared POEM to LHM, eight studies compared POEM to PD, and one study compared all 3 procedures. Average follow up was < 2 years. Most studies included had fewer than 100 patients in total. While POEM had similar efficacy to LHM, POEM treated dysphagia better than PD both in an RCT (treatment "success" RR 1.71, 95% CI 1.34-2.17; 126 patients) and in observational studies (Eckardt score MD - 0.43, 95% CI - 0.71 to - 0.16; 5 studies; I2 21%; 405 patients). Only 1 study had predominantly type 3 achalasia as a baseline; most included studies had predominantly type 2 and/or type 1 achalasia as a baseline. Though 6-12 months patient-reported reflux was worse than PD in 3 observational studies (RR 2.67, 95% CI 1.02-7.00; I2 0%; 164 patients), post-intervention reflux was inconsistently measured and not statistically different in measures ≥ 1 year. POEM had similar safety outcomes to both HM and PD, including treatment-related serious adverse events. POEM required less reintervention than PD or LHM. The authors concluded POEM has similar outcomes to LHM and is more effective than PD.

Facciorusso et al. (2021) conducted a systematic review and network meta-analysis of first-line achalasia therapies. Each of the 3 treatments was evaluated in 6 RCTs that compared the efficacy of PD (n=260), LHM (n=309), and POEM (n=176) in individuals with achalasia. LHM was compared to PD in four studies, POEM was compared to PD in one study, and POEM was compared to LHM in another. Overall, low-quality data, based mostly on direct evidence, supported the use of POEM over PD for one-year treatment success, whereas no meaningful difference between LHM and POEM was seen. POEM, LHM, and PD, respectively, had a 5.3%, 3.7%, and 1.5% incidence of severe esophagitis. Procedure-related major adverse events were 1.4%, 6.7%, and 4.2% after POEM, LHM, and PD, respectively. POEM and LHM are comparable in terms of efficacy and may increase treatment success when compared to PD, according to the authors, albeit with limited confidence in estimates.

Tan et al. (2021) conducted a systematic review and meta-analysis analyzing the efficacy and safety of POEM in achalasia patients with failed previous interventions. Fifteen studies were included, totaling 2,276 achalasia patients. Overall, the pooled technical success, clinical success and adverse events rate of rescue POEM were 98.0% (95% confidence interval [CI], 96.6% to 98.8%), 90.8% (95% CI, 88.8% to 92.4%) and 10.3% (95% CI, 6.6% to 15.8%), respectively. Seven studies compared the clinical outcomes of patients undergoing POEM after previous failed treatment versus patients undergoing POEM as a first line treatment. The risk ratio for technical success, clinical success, and adverse events were 1.00 (95% CI, 0.98 to 1.01), 0.98 (95% CI, 0.92 to 1.04), and 1.17 (95% CI, 0.78 to 1.76), respectively. Overall, there was significant reduction in the pre- and post-Eckardt score (MD, 5.77; $p < 0.001$) and lower esophageal pressure (MD, 18.3 mm Hg; $p < 0.001$) for achalasia patients with failed previous intervention after POEM. The authors concluded that the evidence suggest POEM is both safe and effective in patients with failed previous treatment.

Aiolfi et al. (2020) performed a systematic review and meta-analysis using Bayesian random-effects networks to compare POEM to LHM and PD. There was a total of 19 studies involving 4407 patients. Of these, 10 trials involving 645 patients directly compared POEM to LHM, but none directly compared POEM to PD. POEM was associated with improved dysphasia remission and Eckardt scores but was associated with a higher risk of GERD than LHM. The authors concluded that the results emphasized that the choice of ideal initial management should be left to multidisciplinary team discussion and personalized on each patient basis. The inclusion of arm-based indirect comparisons and the inherent bias associated with its dependence on observational studies are two of the limitations of this network meta-analysis.

Hayes Health Technology Assessment (Hayes 2023) assigned a C rating for POEM as an alternative to both LHM and PD for esophageal achalasia. The assessment analyzed a total of 19 studies and concluded that POEM is comparable to LHM and PD for the treatment of EA. In regard to safety, sixteen studies reported no major complications, leading the assessment to conclude POEM appears to be a safe procedure. It should be noted that there were no eligible randomized controlled trials found in the literature, and many of the findings from nonrandomized studies need to be confirmed through more rigorous study designs and longer follow-up periods. The assessment also noted a lack of discussion of the clinical significance of any differences detected from baseline or between groups in the evaluated studies and recommended that more studies of fair to good quality be conducted to determine the most effective treatment protocols for patients, patient selection criteria, and long-term outcomes.

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National and Specialty Organizations

The **American College of Gastroenterology (ACG)** (Vaezi 2020) published evidence-based clinical guidelines on the diagnosis and treatment of achalasia in 2020. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework was used to rate the quality of the evidence and the strength of the recommendations. The two RCTs comparing POEM to LHM, or pneumatic dilation are included in the evidence review. The ACG issued the following recommendations based on their evaluation:

- POEM or LHM is more effective for type III achalasia when compared to PD
- POEM and PD have comparable symptom improvement in patients with types I or II achalasia
- POEM and LHM have comparable symptom improvement in patients with achalasia
- POEM is a safe option in patients with achalasia who have failed PD or LHM
- POEM is associated with a higher incidence of GERD when compared to LHM with fundoplication or PD

The **American Gastroenterological Association (AGA)** (Kahrilas 2017) published a Clinical Practice Update on POEM use in achalasia stating that POEM appears to be both as effective or better than LHM, and safe and effective in the short term, but long-term durability data is not yet available. The Institute made the following recommendations based on the expert review:

- POEM should be performed in high-volume centers by experienced physicians (an estimated 20 to 40 procedures are required to obtain competence).
- 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 (e.g., proton pump inhibitor therapy and/or surveillance endoscopy) prior to undergoing POEM

The **American Society of Gastrointestinal and Endoscopic Surgeons (ASGE)** (Khashab et al. 2020) published an evidence-based guideline on the treatment of achalasia which was endorsed by both the American Neurogastroenterology and Motility Society and the Society of American Gastrointestinal and Endoscopic Surgeons. The methodological quality of systematic reviews was evaluated using the AMSTAR-2 tool, and the certainty of the body of evidence was rated as very low to high using the GRADE framework. ASGE rated the strength of each recommendation based on the overall quality of the evidence and an evaluation of the anticipated benefits and risks. ASGE utilized "we suggest" for weaker recommendations and "we recommend" for stronger ones. This guideline did not include either of the two RCTs of POEM that were available. ASGE issued the following recommendations in consideration of their analysis:

- "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 LHM), we suggest PD or redo myotomy using either the same or an alternative myotomy technique (POEM or LHM)." (Very low-quality evidence)
- "We suggest that patients undergoing POEM are counseled regarding the increased risk of post-procedure reflux compared with PD and LHM. Based on patient preferences and physician expertise, post-procedure 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 LHM 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)

The **International Society for Diseases of the Esophagus (ISDE)** (Zaninotto 2018) published guidelines for achalasia diagnosis and management. The organization convened 51 experts from 11 countries, including several from the United States, to conduct a systematic review of the evidence, evaluate the recommendations using the GRADE method, and vote on which recommendations should be included in the guidelines (inclusion requires more than 80% approval). The POEM recommendations are summarized in the table below.

Recommendation	Level of Recommendation	Grade of Recommendation
POEM is an effective therapy for achalasia both in short- and medium-term follow-	Conditional	Very Low

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up with results comparable to Heller myotomy.		
POEM is an effective therapy for achalasia both in short- and medium-term follow-up with results comparable to PDs.	Conditional	Low
Pretreatment information on GERD, nonsurgical options (PD), 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	N/A

The **Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)** (Kohn 2021) published evidence-based guidelines for the use of POEM to treat achalasia. The expert panel made the following four recommendations for adults and children with achalasia:

- For adult and pediatric patients with type I and type II achalasia, POEM or LHM may be used for treatment based on a collaborative decision-making process between the surgeon and the patient (conditional recommendation; very low certainty evidence).
- For type III adult or pediatric achalasia, the panel recommends POEM over LHM (expert opinion).
- In patients with achalasia, the panel recommends POEM over PD (strong recommendation, moderate certainty evidence).
- For patients concerned about post-operative proton pump inhibitor use, the panel recommends either POEM or PD, depending on patient and surgeon preferences (conditional recommendation, very low certainty evidence).

SUPPLEMENTAL INFORMATION

Eckardt Symptom Score (ESS) is most frequently used for the evaluation of symptoms, stages, and efficacy of achalasia treatment. The ESS is a 4-item self-report scale measuring weight loss, chest pain, regurgitation, and dysphagia. Each item is graded on a score of 0 to 3 with a maximum score of 12. Score greater than or equal to 3 are considered active achalasia.

Eckardt Score for Symptomatic Evaluation in Achalasia				
Score	Weight loss (kg)	Dysphagia	Retrosternal Pain	Regurgitation
0	None	None	None	None
1	< 5	Occasional	Occasional	Occasional
2	5-10	Daily	Daily	Daily
3	> 10	Each meal	Each meal	Each meal

Subtypes of achalasia defined by the Chicago classification (Kahrilas et al. 2015):

- Type I (classic achalasia): 100% failed peristalsis and normal pan-esophageal pressurization
- Type II (achalasia with esophageal compression): 100% failed peristalsis and increased pan-esophageal pressurization with ≥ 20% of swallows
- Type III (spastic achalasia): abnormal peristalsis and premature contractions with ≥ 20% of swallows

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

Code	Description
43497	Lower esophageal myotomy, transoral (i.e., peroral endoscopic myotomy [POEM])
43499	Unlisted procedure, esophagus

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When

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improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

04/10/2024	Policy reviewed. No changes to coverage criteria.
04/13/2023	Policy reviewed and updated. No changes to coverage criteria.
04/13/2022	Policy revised. Coverage position changed from E/I to medically necessary. Added coverage criteria and updated summary of evidence: systematic review and meta-analyses; Hayes's HTA (updated review in Jan 2022); updated SAGES guidelines. IRO peer reviewed on April 7, 2022, by a practicing physician board certified in Gastroenterology.
12/08/2021	Policy reviewed and updated, no changes in coverage criteria, updated references. Converted to new format. Notable revisions to the summary of evidence include: addition of relevant/updated systematic review and meta-analyses; addition of Hayes's comparative effectiveness review (updated review in April 2021); updated professional society guidelines and inclusion of relevant (ASGE; ISDE; SAGES)
12/09/2020	New policy. IRO Peer Review on 10/8/20 by a practicing physician board certified in Gastroenterology.

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