Gastrointestinal Disorders Diagnostic Procedures

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➲ Instructions for Use

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Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

The following procedures are unproven and not medically necessary due to insufficient evidence of efficacy:

- Magnetic Resonance Imaging Defecography for evaluating Constipation and Anorectal Disorders or pelvic floor disorders
- Cutaneous, mucous, or serosal Electrogastrography, electroenterography, or body surface gastric mapping for diagnosing intestinal or gastric disorders, including Gastroparesis
- Esophageal Mucosal Integrity Testing by electrical impedance for the diagnosis of gastroesophageal reflux disease (GERD), eosinophilic esophagitis, and nonacid reflux disease (non-GERD) or for the monitoring of treatment response in GERD and eosinophilic esophagitis
- Functional Lumen Imaging Probe technology for diagnosing Achalasia

Definitions

Achalasia: A primary esophageal motor disorder of unknown etiology characterized by degeneration of the myenteric plexus, which results in impaired relaxation of the esophagogastric junction, along with the loss of organized peristalsis in the esophageal body (American Society for Gastrointestinal Endoscopy).

Anorectal Disorders: Structural or functional abnormalities of the anorectum or pelvic floor (Patcharatrakul and Rao, 2018).

Constipation: Infrequent or hard-to-pass bowel movements, hard stools, or incomplete bowel movement sensation; infrequent means less than three bowel movements a week (Bharucha et al., 2013a).

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Electrogastrography: A noninvasive method for the measurement of gastric myoelectrical activity using cutaneous electrodes placed on the abdominal skin over the stomach (Yin and Chen, 2013).

Esophageal Mucosal Integrity Testing: An adjunct procedure to routine endoscopy to speed the diagnostic differentiation of gastroesophageal reflux disease from non-gastroesophageal reflux disease and eosinophilic esophagitis that is intended to be an alternative to 24- to 48-hour-long pH monitoring and biopsies (Hayes, 2022; updated 2024).

Fecal Incontinence: The inability to control bowel movements, which causes stool (feces) to leak unexpectedly from the rectum; also called bowel or anal incontinence (Bharucha et al., 2013a).

Functional Lumen Imaging Probe: A catheter-based endoscopic system designed to assess esophageal motility and the Distensibility Index at the esophagogastric junction; the measurement provides insights into the compliance of the lower esophageal sphincter (Alabbas et al., 2025).

Gastroparesis: A digestive disorder in which the motility of the stomach is either abnormal or absent; it is also known as delayed gastric emptying (Camilleri et al., 2022).

Magnetic Resonance Imaging Defecography: A noninvasive test that uses magnetic resonance imaging to obtain images at various stages of defecation to evaluate how well the pelvic muscles are working and provide insight into rectal function (RadiologyInfo.org); it can evaluate pelvic floor anatomy, dynamic motion, and rectal evacuation simultaneously (Rao and Patcharatrakul, 2016).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

CPT Code	Description
0779T	Gastrointestinal myoelectrical activity study, stomach through colon, with interpretation and report
0868T	High-resolution gastric electrophysiology mapping with simultaneous patient-symptom profiling, with interpretation and report
43499	Unlisted procedure, esophagus
72195	Magnetic resonance (e.g., proton) imaging, pelvis; without contrast material(s)
72196	Magnetic resonance (e.g., proton) imaging, pelvis; with contrast material(s)
72197	Magnetic resonance (e.g., proton) imaging, pelvis; without contrast material(s), followed by contrast material(s) and further sequences
76498	Unlisted magnetic resonance procedure (e.g., diagnostic, interventional)
91132	Electrogastrography, diagnostic, transcutaneous
91133	Electrogastrography, diagnostic, transcutaneous; with provocative testing

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Description of Services

Several gastrointestinal disorders, such as Constipation, Fecal Incontinence, and Gastroparesis, may require testing before a diagnosis can be made.

Symptoms of Constipation, one of the most common digestive problems, are extremely common. The prevalence of Constipation is approximately 16% in adults overall and 33% in adults over 60 years of age. If symptoms do not improve, investigations to diagnose rectal evacuation disorders and slow-transit Constipation are sometimes performed, such as digital rectal examination, anorectal structure and function testing (including the balloon expulsion test, anorectal manometry, or defecography), or colonic transit tests (such as the radiopaque marker test or scintigraphy) (Camilleri et al., 2017). In most cases, Constipation is benign and due to dietary and lifestyle factors; however, Constipation is sometimes due to disordered colonic and/or pelvic floor/anorectal function.

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Fecal Incontinence is the inability to control bowel movements, which causes stool to leak unexpectedly from the rectum. Continence requires the rectum, anus, and nervous system to be working normally. Fecal Incontinence is commonly caused by altered stools (generally diarrhea but also Constipation) or conditions that affect the ability of the rectum and anus to hold stool.

Individuals with Gastroparesis may experience symptoms of frequent nausea and vomiting, early satiety, bloating, postprandial fullness, and epigastric pain and burning. Although Gastroparesis can occur with no obvious cause, individuals with diabetes frequently develop this condition. If Gastroparesis causes nausea and persistent vomiting, it can lead to frequent hospitalization for hypoglycemia, hyperglycemia, acidosis, dehydration, pseudo-obstruction, electrolyte dyscrasias, or other complications. The diagnosis of Gastroparesis requires objective evidence of clearly delayed gastric emptying in symptomatic individuals. Scintigraphy is the reference standard for the measurement of gastric emptying. Protocols for standardized meals prior to scintigraphy have been recommended; however, for interpretation of test results, it has to be considered that clinical utility depends on complete consumption of adequate test meals and adequate duration of imaging. For all gastrointestinal function tests, adherence to adequately validated, standardized study protocols is crucial (Keller et al., 2018).

Electrogastrography is a noninvasive technique for recording gastric myoelectrical activity using cutaneous electrodes placed on the abdominal skin over the stomach. The surface recording obtained using electrography is called the electrogastrogram. Gastric myoelectrical activity may be altered or become abnormal in diseased states, on provocative stimulations, or even spontaneously. Abnormal gastric myoelectrical activity includes gastric dysrhythmia, abnormal slow-wave propagation, and electromechanical uncoupling. In the stomach, there is a lack of a one-to-one correlation between spikes and contractions; thus, this abnormality cannot be accurately detected from the in vivo myoelectrical recording. In individuals with gastrointestinal motility disorders or individuals with functional gastrointestinal diseases, Electrogastrography is used to identify the pathophysiology of the diseases associated with gastric slow waves or dysrhythmia (Yin and Chen, 2013). Electroenterography is a similar procedure that records myoelectrical activity from the intestines, and body surface gastric mapping uses high-resolution electrode arrays, along with bioelectronics, automated artifact rejection, and analytics, to measure and map gastric myoelectric activity.

Anorectal Disorders present with a variety of symptoms and result from either structural or functional disorders. Clinical correlation is essential before labeling an abnormal finding as clinically significant. Together with a detailed history, a thorough physical and digital rectal examination, and appropriate testing, in most individuals, the underlying cause and type of Anorectal Disorder can be correctly identified, and treatment can be tailored (Patcharatrakul and Rao, 2018).

Defecatory disorders are primarily characterized by impaired rectal evacuation from inadequate rectal propulsive forces and/or increased resistance to evacuation; the latter may result from high anal resting pressure (anismus) and/or incomplete relaxation or paradoxical contraction of the pelvic floor and external anal sphincters (dyssynergia) during defecation. Structural disturbances (e.g., rectocele, intussusception) and reduced rectal sensation may coexist.

Magnetic Resonance Imaging Defecography is being studied as an imaging tool that may provide an enhanced view of the bowel movement process, including the underlying anatomical and pathophysiological background of pelvic floor disorders. It can evaluate pelvic floor anatomy, dynamic motion, and rectal evacuation simultaneously (Rao and Patcharatrakul, 2016).

Endoluminal Functional Lumen Imaging Probe technology is used for esophageal function testing, such as testing for Achalasia or diffuse esophageal spasm. Functional Lumen Imaging Probe is performed alone or in conjunction with other diagnostic tests; EndoFLIP™ is one such device. A catheter surrounded by a balloon filled with liquid extends from the esophagus into the stomach or from the stomach into the small intestine. The device then applies pressure while providing continuous diameter measurements along its length, giving information about esophageal and/or gastric function (Hayes, 2022).

Clinical Evidence

Functional Lumen Imaging Probe

While functional lumen imaging probe (FLIP) technology is used to enhance current procedures such as endoscopy, the evidence is insufficient for use in assessing esophageal and gastric disorders. The clinical utility, in addition to or instead of standard care, is yet to be defined for the diagnostic workup, procedure guidance, and postprocedure evaluation of clinical outcomes. Additional research, involving larger randomized controlled trials (RCTs) with long-term outcomes, is needed to establish its safety and efficacy.

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Alabbas et al. (2025) conducted a systematic review and meta-analysis of FLIP use in individuals with achalasia, comparing peroral endoscopic myotomy (POEM) and laparoscopic Heller myotomy (LHM) outcomes. Myotomy procedures such as POEM and LHM aim to reduce lower esophageal sphincter pressure and alleviate dysphagia. FLIP measures real-time changes in esophagogastric junction (EGJ) compliance and distensibility during myotomy. Overall, 21 observational studies, with 1,455 individuals, were included in assessing FLIP use during POEM or LHM in the quantitative analysis. The authors concluded that the intraoperative use of FLIP enhances the clinical outcomes in individuals with achalasia undergoing POEM or LHM. Additionally, the authors stated that the meta-analysis emphasizes the importance of FLIP in predicting treatment outcomes following myotomy; however, the FLIP threshold for defining clinical success remains undetermined. Limitations include limited high-quality RCTs and undefined clinical utility of the test on individual outcomes. Further research is necessary that uses standardized FLIP procedure protocols to determine the long-term clinical impact of this technology in individuals with achalasia.

In a systematic review and meta-analysis, Fehervari et al. (2025) evaluated the intraoperative use of FLIPs [Endolumenal Functional Lumen Imaging Probe (EndoFLIP)] during surgical procedures for achalasia, focusing on the Distensibility Index (DI) and treatment outcomes. Overall, 32 studies, with 2,681 individuals, were included in the qualitative synthesis, and 17 studies, with 1,734 individuals, were included in the quantitative synthesis. The authors concluded that the EndoFLIP enhanced achalasia treatment by providing real-time feedback on the DI, which allowed more tailored interventions and improved outcomes. Limitations include the need for a standardization protocol for EndoFLIP usage to further validate its clinical utility and ensure consistent, comparable measurements. Additionally, no RCTs were identified. The study did not address the clinical impact of the technology on patient-centered outcomes.

An Evidence Analysis Research Brief was published by Hayes (2024) to summarize the newly published, peer-reviewed literature and publications on EndoFLIP (Medtronic) for the evaluation of esophageal and gastric disorders. Since 2019, seven new studies were published. None of these studies were case-control studies evaluating EndoFLIP, RCTs comparing treatment guided by EndoFLIP, or systematic reviews with or without meta-analysis. Based on the eight position statements or identified guidelines, all appear to confer no/unclear support for the use of EndoFLIP specifically and impedance planimetry generally to evaluate gastric and esophageal disorders. Limitations include a lack of high-quality RCTs; additionally, this Evidence Analysis Research Brief is based on a review of a study abstract only and is therefore not intended to evaluate the safety or efficacy of the health technology.

An ECRI (2024) revised Executive Summary was published that evaluated the EndoFLIP Impedance Planimetry System (Medtronic) for identifying gastrointestinal motility disorders. Overall, 12 studies, reporting on approximately 2,100 individuals, were reviewed to determine the clinical utility and clinical validity of the device for identifying gastrointestinal disorders and guiding a plan of care. The evidence from the two cohort studies, five case-control studies, and five comparative cohort studies was determined to be limited in quality to permit conclusions on EndoFLIP's clinical utility and validity for the evaluation of gastrointestinal motility disorders using high-resolution manometry or a timed barium esophagram as reference standards. Limitations include small study sample sizes; very low-quality evidence; and the studies being at a high risk of bias due to the retrospective design, lack of blinding, and single-center focus. Four ongoing trials were identified involving EndoFLIP, but none were identified that may address the evidence gaps identified in this summary.

Rafeeqi et al. (2023) analyzed the utility of EndoFLIP in the diagnosis and management of achalasia in pediatric individuals. The authors theorized that the DI may aid in the diagnosis and treatment of pediatric achalasia. Overall, 33 individuals (21 male; 12 female) underwent POEM and EndoFLIP. The authors were able to show that certain measurements, such as Eckardt scores, had a direct correlation to achalasia symptoms. The higher the Eckardt score, the lower the DI. While manometry is the current gold standard test for the diagnosis of achalasia, it is not tolerated well in children, which makes the EndoFLIP a potential alternative for the pediatric population. The authors concluded that EndoFLIP could be beneficial in the pediatric population in the diagnosis and management of achalasia. The DI could be used to guide the extent of myotomy and monitor the results of any lower esophageal sphincter–focused interventions; however, further studies are necessary to better support the use of EndoFLIP as a diagnostic tool. Limitations include the small sample size, lack of manometry data for comparison, and lack of long-term data. Furthermore, the study did not address how the technology improves individuals' outcomes compared with standard of care.

Benitez et al. (2021) conducted a retrospective study in pediatric patients with achalasia, comparing those who underwent FLIP before and immediately after balloon dilations with a nonachalasia cohort. The primary goals of the study were to evaluate EGJ distensibility using FLIP measurements between the two groups and also correlate changes in EGJ distensibility with changes in Eckardt Symptom Score (ESS). The ESS uses a 4-point self-reporting scale assessing the degree of dysphagia, regurgitation, weight loss, and chest pain. The ESS is the most commonly used tool for assessing symptoms in individuals with achalasia. Overall, 30 patients with achalasia (mean age, 15.2 years; 40% female), including 14 treatment-naive patients and 13 controls (mean age, 7.9 years; 61% female), were identified. All patients underwent

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esophageal manometry studies in order to diagnose achalasia prior to intervention. Additionally, 86.7% had an upper gastrointestinal series or esophagram. Balloon dilations were performed under general anesthesia using pneumatic dilator sizes of 30, 35, or 40 mm, based on each pediatric patient's clinical history and the endoscopist's preference for the patients with achalasia. FLIP measurements for the EGJ Distensibility Index (EGJ-DI), diameter, and intraballoon pressures were obtained before and after dilations at 20-, 30-, and 40-ml FLIP balloon inflation volume in all 30 patients with achalasia. This study demonstrates that pediatric individuals diagnosed with achalasia present with (1) a decreased EGJ-DI that is similar to that in adult individuals with achalasia and (2) a significant increase in the EGJ-DI immediately after balloon dilations in treatment-naive and previously treated pediatric individuals with achalasia. Additionally, the authors were able to detect a significant increase in Eckardt score at 1 month following the balloon dilation, indicative of the ability of dilations to improve symptoms. The authors concluded that balloon dilations remain an effective therapeutic method in achalasia, with a significant increase in the EGJ-DI, as assessed by improvement in symptoms and assessed by FLIP. Limitations include the small sample size and a limited quantity of previous high-quality studies assessing pediatric EGJ distensibility data. Larger studies in pediatric individuals with achalasia are needed to further assess the clinical utility of FLIP technology in the pediatric population and evaluate the long-term clinical impact and safety of this technology in pediatric individuals with achalasia.

A Hayes Health Technology Assessment (2019; updated 2022) focused on the use of EndoFLIP as a device for the evaluation, prognosis, and guidance in the management of achalasia, eosinophilic esophagitis (EoE), and gastroparesis. Of the 13 studies evaluated, 11 reviewed the clinical utility of EndoFLIP for detecting and predicting disease course or treatment response. The other two studies evaluated the clinical utility for guidance and the management of gastric disorders, including bariatric surgery. While the body of evidence for EndoFLIP is large for a variety of topics, the quality of evidence is low, with a large range of uses. The evidence is insufficient to support any conclusions for the use of the device for any one gastrointestinal disorder and found no improvement or benefit to health outcomes. Limitations include the lack of comparison groups, lack of systematic evaluation, and lack of long-term outcomes.

In a systematic review, Desprez et al. (2020) summarized the available data in the literature on the use of the EndoFLIP system in the gastrointestinal tract. A search was conducted using MEDLINE/PubMed, Cochrane Library, and Google Scholar databases. Overall, 95 studies were found, and 32 of these reported results in individuals with achalasia. The authors found that the EndoFLIP system demonstrated its relevance in the diagnosis of atypical achalasia and in the prediction of the treatment outcome in achalasia, but the precise EGJ-DI threshold associated with success and prolonged response remains to be determined and therefore warrants additional studies. In addition, a review of 13 studies was completed, which investigated EGJ in individuals with gastroesophageal reflux disease (GERD). Individuals were assessed with upper gastrointestinal endoscopy and esophageal pH monitoring, in addition to symptomatic evaluation. The authors found that the individuals with GERD seemed to have a higher EGJ-DI than the healthy volunteers tested, but the relevance of the EndoFLIP system in the prediction of the efficacy of fundoplication remained unconfirmed. Limitations include the absence of a standard protocol when using EndoFLIP in the esophagus, along with the cost and availability in daily practice. In conclusion, while the authors found that EndoFLIP might have some promise, its use in the body of the esophagus, other esophageal diseases (GERD and EoE), and other sphincter regions (anal canal and pylorus) necessitates the need for additional confirmatory studies.

Yoo et al. (2019) assessed the utility of EndoFLIP in 52 participants with achalasia treated with POEM and hypothesized that improvement in the DI correlated with the postoperative clinical outcome of POEM. EndoFLIP was performed before and after POEM by well-trained endoscopists in an outpatient setting. Esophagogastroduodenoscopy (EGD) was done just before EndoFLIP to measure esophageal length, 4 days following the procedure, and again in the outpatient clinic to evaluate the development of reflux esophagitis. The DI of the EGJ was measured at the point of the narrowest perimeter of the functional lumen image during volumetric distension of the saline bag. After the probe was inserted, the DI and cross-sectional area of the EGJ were measured at the site of the narrowest point. The DI and cross-sectional area were measured twice during volumetric distension of the saline bag, each of them with 30 mL and 40 mL. The authors' conclusion was that EndoFLIP was useful in predicting the treatment response and postprocedure reflux of POEM in participants with achalasia. Limitations include the lack of comparison groups, lack of long-term outcomes, and small sample size.

Clinical Practice Guidelines

American College of Gastroenterology (ACG)

In a 2021 ACG published clinical guideline (Katz et al., 2021) for the diagnosis and management of GERD, the following recommendations are cited:

- Recommend antireflux surgery as an option for long-term treatment of patients with objective evidence of GERD (strong recommendation; moderate level of evidence).

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- Recommend consideration of magnetic sphincter augmentation as an alternative to laparoscopic fundoplication for patients with regurgitation who experience failure of medical management (strong recommendation; moderate level of evidence).
- Consideration of transoral incisionless fundoplication for patients with troublesome regurgitation or heartburn who do not wish to undergo antireflux surgery and who do not have severe reflux esophagitis or hiatal hernias (conditional recommendation; low level of evidence).
- Do not recommend radiofrequency energy (Stretta) as an antireflux procedure due to inconsistent data on the efficacy of the device (conditional recommendation; low level of evidence).

The 2020 ACG published clinical guideline (Vaezi MF et al., 2020) for the diagnosis and management of achalasia indicates that FLIP may be useful in evaluating patients who cannot tolerate or complete a standard manometry, as FLIP is performed during endoscopy while the patient is sedated. The authors note that based on consistent but low-quality data, the role of FLIP in achalasia is evolving, and further studies are required to determine whether FLIP can replace or reduce the number of manometry studies and barium esophagrams in the management of achalasia.

American Gastroenterological Association (AGA)

The AGA published a clinical practice update on FLIP for the management of esophageal disorders, based on an expert review. FLIP is a U.S. Food and Drug Administration–approved measurement tool used to measure simultaneous pressure and diameter to guide the management of various upper gastrointestinal disorders. FLIP has been available since 2009 as EndoFLIP. EndoFLIP has had limited penetrance into clinical settings outside of specialized centers, primarily because of a paucity of data supporting its utility in general practice and a lack of standardized protocols and data analysis methodology. The AGA lists best practices for the management of esophageal disorders regarding FLIP in the following order:

- “Clinicians should not make a diagnosis or treatment decision based on functional lumen imaging probe (FLIP) assessment alone.
- FLIP assessment is a complementary tool to assess EGJ opening dynamics and the stiffness of the esophageal wall.
- Utilization should follow distinct protocols and analysis paradigms based on the disease state of interest.
- Clinicians should not utilize FLIP in routine diagnostic assessments of gastroesophageal reflux disease.
- FLIP should not be used to diagnose eosinophilic esophagitis but may have a role in severity assessment and therapeutic monitoring.”

(Hirano et al., 2017)

Magnetic Resonance Imaging Defecography

There is insufficient evidence regarding the effectiveness and efficacy of magnetic resonance imaging (MRI) defecography. Existing data suggest that this approach is not superior and, in some cases, is inferior to conventional defecography.

An Evidence Analysis Research Brief published by Hayes (2025) evaluated the peer-reviewed literature to evaluate dynamic MRI for evaluation of pelvic floor disorders. The search identified 10 abstracts, including seven studies evaluating test performance (clinical validity), one study evaluating clinical utility, and two systematic reviews/meta-analyses. None of these studies were case-control studies evaluating dynamic MRI for the evaluation of pelvic floor disorders or RCTs comparing treatment guided by dynamic MRI with treatment guided by a reference test. Based on the three position statements and identified guidelines, all appear to confer no/unclear support for the use of dynamic MRI for the evaluation of pelvic floor disorders. Limitations include the lack of high-quality RCTs; additionally, this Evidence Analysis Research Brief is based on a review of study abstracts only and therefore is not intended to evaluate the safety or efficacy of the health technology.

In a retrospective, single-center test development study in 46 adults with chronic constipation, Thanaracthanon et al. (2023) evaluated the diagnostic performance of magnetic resonance defecographic findings in the diagnosis of dyssynergic defecation (DD). Study patients were divided into two groups based on the presence of DD in two of three diagnostic tests [anorectal manometry (ARM), balloon expulsion test (BET), and anal surface electromyography], with 24 in the DD group (37.5% female) and 22 in the non-DD group (81.8% female). All patients underwent magnetic resonance defecography (MRD) according to the institutional standard protocol, with both static and dynamic MRD images obtained. The study included an analysis by two radiologists of nine parameters: anorectal angle (ARA) and M line at rest, defecation, and change between two phases; anal canal width; a prominent puborectalis muscle; and abnormal evacuation. The authors reported that seven of the nine parameters showed a statistically significant difference between the DD and the non-DD groups, with the M line at defecation having the highest odds ratio (OR), followed by ARA change, ARA defecation, M line change, a prominent puborectalis muscle, abnormal evacuation, and anal canal width, respectively. The authors also reported that the ARA change and prominent puborectalis muscle had the highest

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specificity and that multivariate logistic regression revealed two significant findings in differentiating between DD and non-DD, including M line at defecation and ARA at defecation. Limitations include the single-center, retrospective study design; small sample size; lack of a comparison test; heterogeneity of other diseases in the non-DD group that were not seen in the DD group; and use of a consensus panel, which may incorporate bias. The authors concluded that MRD had high diagnostic performance in the diagnosis of DD, with an ARA change of less than 1.5 degrees and the prominent puborectalis muscle having good specificity in DD diagnosis. The authors recommended additional prospective studies that have normal, healthy individuals as a control group. The findings need to be validated in an independent group of individuals, and the clinical utility of the test needs to be defined.

Pääkkö et al. (2022) completed a single-center retrospective review of both MRD and video defecography (VD) studies, which were done in 64 women with defecation disorders who underwent both VD and MRD within a year, to compare the findings of the two methods and to analyze the success rates. In 58 patients, the indication for the first study was symptoms of obstructive defecation, with incontinence as the primary diagnosis for the remaining six patients. The indication for the second study was insufficient information from the first study in 48 patients and for preoperative planning to get more anatomical information in the remaining 16 cases, for which the second imaging was performed before operative treatment to get more anatomical information or to confirm the findings of the first study. Both studies were analyzed in consensus by two radiologists who were blinded to clinical patient data and radiology reports. The authors reported that 96.9% of the VD studies were technically fully diagnostic compared with 45.3% for MRD and that 1.6% of the VD studies were partially diagnostic vs 32.8% for MRD. They reported that 30 enteroceles were observed by VD compared with seven by MRD, with moderate agreement; 53 intussusceptions were observed by VD compared with 27 by MRD, with poor agreement; 47 cases of rectocele were diagnosed by VD vs 29 by MRD, with moderate agreement; and DD was observed in three patients by VD and in 11 patients by MRD, with slight agreement. Limitations of the study include the variability of which study was done first, retrospective nature of the study, small sample size, and variability of the amount and consistency of the gel used in the studies. The authors concluded that the technical success and diagnostic capabilities of VD were better than those of MRD and that VD remains the method of choice in the imaging of defecation disorders.

A Cochrane Database systematic review and meta-analysis by van Gruting et al. (2021) evaluated imaging modalities for the detection of posterior pelvic floor disorders in women with obstructed defecation syndrome. The review included 39 studies [including the Foti et al. (2013), Poncelet et al. (2017), van Iersel et al. (2017), Vitton et al. (2011), and Zafar et al. (2017) studies previously included in this section], with 2,483 women, that evaluated the diagnostic accuracy of evacuation proctography (EP), dynamic MRI, and pelvic floor ultrasound for detecting posterior pelvic floor disorders. The meta-analysis was done using a Bayesian hierarchical latent class analysis, and the overall quality of evidence was assessed using the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach for diagnostic test accuracy. The authors reported that the sensitivity of EP for the diagnosis of rectocele was 98%, enterocele was 91%, and pelvic floor descent was 98%, while the specificity for enterocele was 96%, intussusception was 92%, and anismus was 97%, all with high quality of evidence. The sensitivity for anismus of 80% and the specificity for rectocele of 78% and pelvic floor descent of 83% had a moderate to low quality of evidence. The specificity of MRI defecography for the diagnosis of rectocele was 90%, enterocele was 99%, and intussusception was 97%, with high quality of evidence. The heterogeneity analysis completed in the study showed that the sensitivity of MRI performed with an evacuation phase was higher than that without for rectocele (94% with and 65% without) and for enterocele (87% with and 62% without), while the sensitivity of MRI without an evacuation phase was significantly lower than that of EP. The study also showed that the specificity of transperineal ultrasound for the diagnosis of rectocele was 89%, enterocele was 98%, and intussusception was 96%, while the sensitivity for anismus was 92%. The authors concluded that neither MRI defecography nor transperineal ultrasound meet the criteria to replace EP as the reference standard for the diagnosis of posterior pelvic floor disorders, although both meet the criteria of a triage test, as a positive test confirms the diagnosis of rectocele, enterocele, and intussusception, and a negative test rules out a diagnosis of anismus. The results of the other ultrasound techniques, including endovaginal ultrasound, dynamic anal endosonography, and echodefecography, were of too low a quality of evidence to draw conclusions. The authors recommended more well-designed studies to define the role of MRI defecography in the diagnostic pathway of obstructed defecation syndrome.

Ramage et al. (2018) assessed whether MRI features indicative of pelvic floor dysfunction correlated with participant-reported symptom severity. Univariate and multivariate analyses were performed using pretreatment questionnaire responses to the Birmingham Bowel, Bladder, and Urinary Symptom Questionnaire (BBUSQ), Wexner Incontinence Score, and modified Obstructed Defecation Symptom score. Overall, 302 MRI proctograms were performed (n = 170). Participants with a rectocele larger than 2 cm (p = 0.003; OR, 5.756) or MRD features suggestive of puborectalis syndrome (p = 0.025; OR, 8.602) were more likely to report a higher Obstructed Defecation Symptom score on multivariate analysis. A lack of a rectal evacuation was negatively associated with an abnormal Wexner Incontinence Score (p = 0.007; OR, 0.228). An age of > 50 years (p = 0.027; OR, 2.204) and a history of pelvic floor surgery (p = 0.042; OR, 0.359) were correlated with an abnormal BBUSQ incontinence score. A lack of a rectal evacuation (p = 0.027; OR,

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3.602) was associated with an abnormal BBUSQ constipation score. An age of > 50 years (p = 0.07; OR, 0.156) and the presence of rectoanal intussusception (p = 0.010; OR, 0.138) were associated with an abnormal BBUSQ evacuation score. The authors concluded that while MRD is a useful tool in aiding multidisciplinary decision-making, overall, it is poorly correlated with patient-reported symptom severity, and treatment decisions should not rest solely on results. Limitations of this study include the lack of a reference standard test and a questionnaire with questions directed at only female participants.

In a systematic review and meta-analysis of MRD vs clinical examination and fluoroscopy, Ramage et al. (2017) compared detection and miss rates of pelvic floor abnormalities with MRD vs those of a clinical examination and traditional fluoroscopic techniques. Overall, 28 studies were included: 14 studies compared clinical examination with MRD, and 16 compared fluoroscopic techniques with MRD. Detection and miss rates with MRD were not significantly different from clinical examination findings for any outcome except enterocele, for which MRD faired significantly better than clinical examination. However, when comparing MRD vs fluoroscopy, MRD had no better detection rate or lower miss rate of a structural abnormality than fluoroscopy. In some studies, fluoroscopy was considered the gold standard; therefore, a distinct possibility exists that there was a degree of reporting bias with regard to the miss rates of fluoroscopy in particular. Limitations include the large variation in techniques used during MRD, along with numerous fluoroscopic techniques that were used across the different studies. Based on their analysis, the authors concluded that MRD has a role in the assessment of pelvic floor dysfunction. However, they advised that clinicians need to be mindful of the risk of underdiagnosis and consideration of the use of additional imaging.

Clinical Practice Guidelines

American Gastroenterological Association (AGA)

The AGA guideline on constipation states that although ARM and a rectal BET generally suffice to diagnose or exclude a defecatory disorder, defecography, which is generally performed with barium or, at some centers, with MRI, is useful if results are inconclusive (Bharucha et al., 2013a).

American College of Gastroenterology (ACG)

The ACG clinical guideline for the management of benign anorectal disorders notes that barium or MRD can identify structural causes of outlet obstruction if one is expected. They may also confirm or exclude the diagnosis of defecatory disorders when the clinical features suggest a defecatory disorder but the results of ARM and BET are equivocal (moderate recommendation; moderate quality of evidence) (Wald et al., 2014; updated 2021).

The same ACG 2014 guideline also cites the advantages of MRI over defecography as having better resolution of soft tissue surrounding the rectum and anal canal, including the bladder, uterus, and small intestine, during dynamic imaging; an improved ability to visualize the anal sphincter and levator ani muscles with endoanal MRI; and lack of radiation (Wald et al., 2014; updated 2021).

American Society of Colon and Rectal Surgeons (ASCRS)

The ASCRS clinical practice guideline for the evaluation and management of chronic constipation states that individuals who have no improvement with dietary changes, fiber therapy, and osmotic laxatives should be evaluated for outlet obstruction. Anorectal testing or dynamic imaging by fluoroscopic defecography or MRI defecography may assist in identifying functional or structural causes related to an evacuation disorder. Although MRI performed in the supine position permits excellent assessment of all pelvic floor compartments and the surrounding musculature, fluoroscopic defecography performed in the seated position is considered the evacuation examination with the most construct validity (Alavi et al., 2024). (Grade of recommendation: conditional recommendation based on low-quality evidence.)

In an updated clinical practice guideline on the treatment of rectal prolapse, the ASCRS (Bordeianou et al., 2017) states that if prolapse is suggested but cannot be seen during a physical examination, fluoroscopic defecography, MRI defecography, or BET may reveal the problem. Defecography may also reveal associated anterior pelvic floor support defects, such as cystocele, vaginal vault prolapse, and enterocele. (Grade of recommendation: strong recommendation based on moderate-quality evidence, 1B.)

Electrogastrography/Electroenterography/Body Surface Gastric Mapping

Despite possible use in clinical research, the studies of electrogastrography (EGG) and body surface gastric mapping (BSGM) fail to provide convincing evidence that this technique is accurate for the diagnosis of gastric disorders such as gastric stasis in clinical practice or that it has a positive impact on individuals' management or disease outcomes. Additional studies are needed to determine if EGG is a useful adjunctive test or alternative to radioscintigraphy for the diagnosis of gastric stasis. These studies should involve a standardized procedure for the diagnosis of gastroparesis with

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EGG, including recording, analysis, and interpretation. No studies were found to indicate that electroenterography has a positive impact on individuals' management or disease outcomes.

ECRI (2024; revised 2025) published a Clinical Evidence Assessment on the Gastric Alimetry System and concluded that the published evidence available for review is very low quality. The report assessed one diagnostic cohort study that reported measures of diagnostic accuracy and two small retrospective case series studies that reported test impact on clinical decision-making. ECRI did not find any direct clinical utility studies that reported improvements in individual-relevant outcomes following Alimetry-guided clinical decision-making. The report concluded that additional clinical validity studies, using appropriate reference standards and larger sample sizes, are needed to assess Alimetry's diagnostic accuracy and that clinical utility studies are also needed to determine whether the use of this device to guide treatment and clinical decision-making will result in improvements in individual-relevant outcomes.

Peralta-Palmezano et al. (2025) conducted a systematic review and meta-analysis to determine the prevalence and range of abnormalities in gastric slow waves in children (6-18 years old) with gastroparesis. The systematic review included four articles, with a total of 70 individuals and 15 controls. The authors evaluated percentage outcomes, including normogastria, tachygastria, and bradygastria. The percentage of fasting bradygastria in gastroparetic children was 14.6% (95% CI, 0.6%-41.9%), which was higher than the percentage reported in control children in a single study (3.8% ±2.7%). Additionally, one study reported the percentage of poststimulus bradygastria in gastroparetic children, with 15.9% ±13%, without a control group. The percentage of fasting tachygastria in gastroparetic children was 18.7% (95% CI, 9.8%-29.7%), which was higher than the percentage reported in control children in a single study (8.4% ±6.6%). The authors found that one study reported that the percentage of poststimulus tachygastria in gastroparetic children was 3.1% ±5.1%, without a control group. The authors concluded that fasting gastroparetic children had a lower percentage of normogastria and a higher percentage of tachygastria. Children with gastroparesis had a smaller increase in poststimulus power, reflecting possible alterations in gastric contraction and/or distension. Limitations of this study include the inability to review all studies found due to the lack of full-text access and the small sample size; additionally, the study did not address the clinical utility of the test and whether the test would improve outcomes.

A systematic review and meta-analysis by Peralta-Palmezano et al. (2024) examined the prevalence and range of abnormalities in gastric slow waves in adults with gastroparesis who underwent EGG. The systematic review included 31 prospective studies, with 1,545 individuals with gastroparesis and 340 controls (reported in 14 studies). In the 23 studies that reported the sex of the individuals, 71.1% of the individuals were women. The majority of the studies (67.7%) were conducted in the United States, four were conducted in Germany, and one each was conducted in Taiwan, Turkey, the Netherlands, France, Israel, and Germany. The authors reported that individuals with gastroparesis had less normogastria (fasting: 50.3% vs 65.8%; post stimulus: 54.3% vs 66.5%), more bradygastria (fasting: 37.7% vs 13%; post stimulus: 31.9% vs 16.3%), and more tachygastria (fasting: 16.1% vs 4.6%; post stimulus: 18.3% vs 5.2%). Limitations of this systematic review include the heterogeneity of the included studies' test protocols, concomitant medications used, and total duration of recordings during the EGG procedures. Additionally, the study did not address the clinical utility of the test and whether its use improves individuals' outcomes. The authors concluded that adults with gastroparesis had a significantly lower percentage of normogastria than the controls, while they also had a higher percentage of bradygastria and tachygastria. This systematic review and meta-analysis included the Al Kafee et al. (2022) and Gharibans et al. (2019) studies, which were previously summarized in this policy.

In a comparative study, Sadaka et al. (2025) evaluated the correlation between antroduodenal manometry (ADM), which is considered the gold standard for diagnosing myopathy and neuropathy in individuals with upper gastrointestinal disorders, and BSGM in children (aged 10-19 years). The study included 15 individuals (13 female). ADM was performed using high-resolution water-perfused motility catheters, with simultaneous BSGM. Real-time symptoms were tracked using a validated symptom-logging application in 15-minute intervals, and Nausea Severity Scale scores were recorded. Protocols involved a 2-hour fast, provocative testing, a meal, and over 1 hour of postprandial recordings. ADM tracings were categorized into neuropathy, myopathy, postprandial hypomotility, or normal. BSGM metrics included principal gastric frequency. The authors concluded that dysrhythmic BSGM phenotype reliably identified gastrointestinal neuropathy with identical results to ADM, with significant correlations to nausea and bloating severity; therefore, this supports consideration of BSGM as a feasible biomarker when performing ADM is not practical. Limitations include the small sample size; additionally, the study did not address the clinical utility of the test and whether its use will result in improvements in individual-relevant outcomes.

Xu et al. (2024) conducted a test-validation cohort study to investigate gastric myoelectrical abnormalities and symptoms in individuals after fundoplication using noninvasive BSGM. The study included 16 adults (median age, 34.5 years; 37.5% female) who had undergone a previous fundoplication operation (median time since fundoplication was 5 years) and had ongoing significant gastroduodenal symptoms and 16 adult matched controls [based on age, biological sex, and body mass index (BMI)]. BSGM using the Gastric Alimetry device was performed in each study individual. The authors reported

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that six of the 16 individuals (37.5%) who had previously undergone a fundoplication operation had significant spectral abnormalities, defined by unstable gastric myoelectrical activity (n = 2), abnormally high gastric frequencies (n = 3), or high gastric amplitudes (n = 1), and that these individuals had higher Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity Index scores than the remaining 10 individuals with normal BSGM spectrograms. According to the authors, two of the three individuals with abnormally high gastric frequencies had presumed vagal nerve injury documented in their procedure notes. The authors also reported that seven of 16 individuals had BSGM test results suggestive of gut-brain axis contributions and no myoelectrical dysfunction. The authors concluded that a significant number of individuals with persistent postfundoplication symptoms had abnormal gastric functioning on BSGM testing, which correlated with symptom severity. Limitations of the study include the small cohort size, inclusion of individuals with a single procedure and with multiple revisional procedures, lack of blinding, and consecutive sample individual selection methodology. Also, the study did not address the clinical utility of the test and whether its use improves outcomes in individuals after fundoplication.

Participant-specific phenotyping using BSGM was compared with gastric emptying testing (GET) in an exploratory comparison study by Wang et al. (2024) that included 75 adults (77% female; median age, 43 years) with chronic gastroduodenal symptoms. All participants had undergone a clinical workup by a gastroenterologist, including upper gastrointestinal endoscopy, to exclude alternative pathologies; had withheld any medications affecting gastrointestinal motility for 48 hours; had completed an overnight fast; and were asked to avoid caffeine, nicotine, opiates, and cannabis the morning of to their testing. Each study participant underwent simultaneous GET and BSGM that consisted of a 30-minute baseline reading, consumption of a 99mTC-labeled egg meal, and a 4-hour postprandial recording. Before motility testing was done, 56 participants met Rome IV Criteria for chronic nausea and vomiting syndromes [CNVS; 75%, with 52 of 56 also meeting functional dyspepsia (FD) criteria]. There were 14 participants who met FD criteria alone, and five did not meet either criterion, indicating a high chronic gastroduodenal symptom burden in the study cohort. The authors reported that motility abnormality detection rates were 22.7% for GET, with 14 delayed and three rapid, while BSGM spectral analysis was 33.3%, with 14 low rhythm stability/low amplitude, five high amplitude, and six abnormal frequency. The authors also reported that in participants with normal spectral analysis, BSGM symptom phenotypes included sensorimotor (17%; for which symptoms strongly paired with gastric amplitude), continuous (30%), and other (53%). The authors reported that BSGM phenotypes showed superior correlations with the Gastroparesis Cardinal Symptom Index, Patient Assessment of Upper Gastrointestinal Symptom Severity Index, and anxiety scales, while the Rome IV Criteria did not correlate with psychometric scores. The authors concluded that BSGM improves phenotyping of individuals in chronic gastroduodenal disorders in the presence and absence of motility abnormalities, with increased correlation with symptoms and psychometrics compared with GET and Rome IV Criteria. However, whether the use of BSGM improves individuals' outcomes is not addressed in this study.

Xu et al. (2023) performed a study using BSGM in people with long-standing type 1 diabetes (T1D), with or without symptoms, to define phenotypes of gastric myoelectrical abnormalities. The study included 64 people: 32 who had a medical history of T1D of more than 10 years (mean age of 50 years; 64% female) and 32 controls. Of the 32 participants with T1D, 15 were noted to have a high symptom burden (12 with CNVS and FD and three with FD only) based on their assessment using the Rome IV Criteria for CNVS if they met at least one of the criteria. The 32 participants with T1D were then matched to a database of controls in a 1:1 ratio using the nearest neighbor based on age, sex, and BMI. The authors reported that the participants with T1D with symptoms had more unstable gastric myoelectrical activity and lower average special covariance than controls and that symptomatic participants also had a higher prevalence of peripheral neuropathy, anxiety/depression diagnoses, and mean hemoglobin A_{1c} levels. They also reported that deviation in gastric frequency was positively correlated with symptoms of bloating, upper gut pain, nausea and vomiting (NVS), and fullness. Limitations of the study include the lack of blood glucose monitoring for all the participants (due to device availability); different meals given to the study participants with T1D than those given to the control group; ongoing development of reference values for the emerging spatial metrics; and small sample size. The authors concluded that gastric symptoms in people with long-standing T1D correlated with myoelectrical abnormalities on BSGM testing, in addition to glycemic control, psychological comorbidities, and peripheral neuropathy.

Schamberg et al. (2023) conducted a multicenter, retrospective observational study to compare BGSM and EGG to quantify performance differences. The study included EGG and BSGM data from 178 patients (43 patients with NVS, 32 patients with T1D, and 110 healthy volunteers). The study assessed the use of BSGM and EGG in the following three domains: group-level differences in measures of gastric activity, the relationship between gastric abnormalities and symptoms, and patient-level classifications of gastric health. The comparisons followed standard methodologies for each test, including preprocessing, postprocessing, and analysis. Statistical evaluations were done for group-level differences, symptom correlations, and patient-level classifications. The authors reported that BSGM showed substantially tighter frequency ranges than EGG in the control group and that both tests detected rhythm instability in NVS; however, EGG showed opposite frequency effects in T1D. The authors also reported that BSGM showed an eight-times increase in the number of significant correlations with symptoms and that BSGM accuracy for patient-level classification was 0.78 for

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patients compared with controls and 0.96 compared with a blinded consensus panel; EGG accuracy was 0.54 and 0.43. Limitations of the study include the automated EGG analysis methodology; possibility that proprietary signal processing steps may exist but were not used; lack of testing with other meal preparations; use of only a single electrode configuration for EGG testing; heterogeneity of EGG processing approaches; and focus on only spectral analyses of BSGM and EGG. The authors concluded that EGG detected group-level differences in patients but lacked symptom correlations and showed poor accuracy for patient-level classification, while BSGM demonstrated substantial performance improvements across all three domains.

In a study to evaluate CNVS pathologies, Gharibans et al. (2022) performed BSGM in 43 participants with NVS and 43 matched controls. The study participants were adults and primarily female (76.7%), with a median age of 33 years (range, 26-44 years). Each participant underwent BSGM that entailed a fasting baseline, ingestion of a 482-kcal meal, a 4-hour postprandial recording, and then spectral and spatial biomarker analyses. The authors reported that meal responses were impaired in NVS, with multiple BSGM abnormalities compared with the study controls, impaired fed-fasting power ratios, and disorganized slow waves. The authors also reported that most participants (62%) had normal BSGM results, with increased psychological comorbidities and anxiety scores. A smaller subgroup (31%) had markedly abnormal BSGM, with biomarkers that correlated with symptoms, and participants with NVS shared overlapping symptoms but comprised distinct underlying phenotypes that correlated with symptoms. Limitations of the study include the small sample size that may have affected the subanalyses performed and use of a consensus panel classification, which may introduce subjectivity and limit reproducibility. Other limitations of the study include the lack of a control group; underrepresentation of participants with diabetes, as only 7% of the participants had diabetes; and inclusion of participants with a BMI of > 35 kg/m^2, as a high BMI may result in overestimating the low rhythm stability phenotype due to a declining signal-to-noise ratio. The authors concluded that the study showed that BSGM expands the phenotyping of individuals with chronic gastroduodenal disorders compared with GET and that the results of BSGM could improve the clinical management of these individuals by separating those with gastric dysfunction from those with gut-brain dysregulation or other etiologies.

A systematic review and meta-analysis was completed by Bhat et al. (2021) involving EGG use in adults with gastroesophageal reflex disease (GERD). After the published literature was reviewed, 13 studies were included in the analysis, with a total of 591 individuals (427 with GERD; 164 healthy controls) who had completed an EGG procedure. The study found that individuals with GERD spent significantly less time with normal gastric slow-wave activity than healthy controls. The authors noted that correlations between GERD symptoms and EGG recordings were inconsistently studied; EGG apparatus and techniques also varied across the studies. They also recognized the limitations of the studies available, including the known limitations with low-resolution EGG methodologies (as high-resolution EGG is now available) and the inclusion of studies that relied on subjective symptom-based diagnostic criteria. They concluded that further investigation on the use of EGG in adults with GERD is warranted.

In an evaluation of 54 individuals with FD, Russo et al. (2017) used the results of EGG to differentiate postprandial distress syndrome (PDS) with epigastric pain syndrome (EPS). Using a symptom questionnaire, 42 individuals were classified as PDS and 12 as EPS, although an overlap between the symptom profiles of the two subgroups was recorded. The EGG parameters (the postprandial instability coefficient of dominant frequency, dominant power, and power ratio) were significantly different between the subgroups, whereas the gastric emptying time did not differ significantly. In addition, EPS was characterized by a different gut peptide profile than PDS. Finally, neurotensin polymorphism was shown to be associated with neurotensin levels. The authors concluded that this evidence deserves further studies into FD. However, this study does not support the use of EGG in clinical practice or beyond its use for research.

Clinical Practice Guidelines

American Gastroenterological Association (AGA)

A clinical practice guideline from the AGA on the management of gastroparesis provides recommendations for ensuring an accurate diagnosis and identifying evidence-based, effective treatments among the available pharmacological and procedural interventions for patients with idiopathic gastroparesis or gastroparesis related to diabetes. The following recommendations and treatment implementation considerations are recommended for evaluating and treating patients with suspected gastroparesis:

- In patients with suspected gastroparesis, the use against a 2-hour (or shorter) gastric emptying study compared with a 4-hour gastric emptying study to evaluate for delayed gastric emptying
- The use of metoclopramide when not contraindicated
- The use of erythromycin
- Not using the following medications as a first-line treatment:
  - Domperidone
  - Prucalopride
  - Aprepitant

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    - Nortriptyline
    - Buspirone
- Not using cannabidiol except in the context of a clinical trial

In patients with gastroparesis refractory to medical management, the following are not recommended:
- The use of pyloric botulinum toxin injection
- The routine use of gastric peroral endoscopic pyloromyotomy
- The routine use of gastric electrical stimulation

The AGA makes no recommendation on the use of surgical pyloric interventions (pyloromyotomy or pyloroplasty) (Staller et al., 2025).

A position statement from the AGA (Parkman et al., 2004) on the diagnosis and treatment of refractory gastroparesis does not recommend the use of EGG. In their 2022 clinical practice update (Lacy et al.), the AGA guideline does not focus on the etiology, pathophysiology, or diagnostic testing for refractory gastroparesis, and there is no longer any mention or direction for the use of EGG for the diagnosis of gastroparesis.

Esophageal Mucosal Integrity Testing

The limited number of published clinical studies on the use of esophageal mucosal integrity testing by electrical impedance fails to provide convincing evidence that this technology is safe and effective for diagnosing GERD, EoE, or nonacid reflux disease (non-GERD) or for the monitoring of treatment response in GERD and EoE. Additional studies are needed to provide evidence of the efficacy of this technology.

Hayes (2022; updated 2025) published an Evolving Evidence Review on the safety and efficacy of MiVu™ Mucosal Integrity Testing (Diversatek, Inc.) for the diagnosis of GERD in adults. Following their review of three very poor-quality studies and one systematic review that compared several emerging diagnostic tests, Hayes stated that the system may distinguish previously diagnosed EoE from GERD at least as well as EGD and potentially better than pH testing but that there was a lack of data from individuals who did not yet have a definitive diagnosis. Hayes also stated that insufficient data were published that addressed the clinical utility of the device in terms of impact on clinical management or outcomes to draw conclusions regarding level of support for that use. In their review of medical society guidelines, Hayes assigned a weak level of support to reflect that the guidelines that they identified indicated that there is promise in this device as an adjunctive diagnostic tool; however, the societies did not recommend it as preferable to standard diagnostic methods. Hayes' assessment recommended that the literature continue to be monitored, as mucosal impedance (MI) testing technology is still developing. In their 2024 update, Hayes identified one relevant, newly published, single-center, case-controlled study since this report was published in 2022; however, Hayes stated that this study would not result in a change to their minimal level of support for this device, as there was no new evidence regarding the safety of the device or regarding longer-term follow-up. In the 2025 update, Hayes identified one newly published, relevant case-control clinical study but indicated that the literature identified no new evidence with longer-term follow-up or evidence regarding the clinical validity of the MiVu Mucosal Integrity Testing System for GERD. The level of support remains weak for the use of this device. The Choksi et al. (2018) and Patel et al. (2019) studies, summarized below, are included in this report.

ECRI (2021) published an Evidence Analysis on the efficacy of the MiVu Mucosal Integrity Testing System (Diversatek, Inc.) in diagnosing GERD and its ability to obtain real-time measurements of esophageal epithelial impedance during an endoscopy. The device is not for use as a sole diagnostic screening tool. ECRI's review identified three studies for inclusion. Based on their review of the abstracts, ECRI concluded that the available published evidence is limited and that additional clinical validity studies, with larger sample sizes, are needed to assess the diagnostic accuracy of this device. ECRI also stated that clinical utility studies are needed to determine whether the use of this device to guide treatment and clinical decision-making will result in improvements in individual-relevant outcomes. The ECRI review included the Patel et al. (2019) and Choksi et al. (2018) studies summarized below.

Patel et al. (2019) conducted a prospective, multicenter test-validation study to evaluate the ability of a balloon MI catheter system to detect and evaluate esophageal disorders such as GERD and EoE. The study included 69 adult participants (91.7% Caucasian) who underwent EGD then balloon MI testing during endoscopy and prior to wireless pH monitoring or esophageal biopsies for suspected GERD. The participants were classified, based on endoscopic pH monitoring and pathology findings, as having GERD (n = 24; median age, 48 years; 54% female), EoE (n = 21; median age, 33 years; 33% female), or non-GERD (n = 24; median age, 62 years; 71% female). The authors reported that the MI pattern along the esophageal axis differed significantly among participants with GERD, EoE, or non-GERD, as the MI pattern for GERD was easily distinguished from that for EoE, with low MI values in the distal esophagus and normalized values along the proximal esophagus in those participants with GERD; the measurements were low in all segments of the esophagus in

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participants with EoE. The authors also reported that those with non-GERD had higher baseline MI values in the distal esophagus, and MI values remained elevated along the esophagus. One adverse event was reported by the authors in a participant with EoE who had a small distal esophageal mucosal tear similar to that seen during endoscopic dilation. The authors concluded that the balloon MI catheter system instantly detected changes in esophageal mucosal integrity during endoscopy, which could potentially obviate the need for 24- to 48-hour ambulatory wireless pH monitoring or esophageal biopsies for histopathology. The authors also concluded that the MI was safe and effective in identifying participants with GERD, EoE, or non-GERD. Limitations of the study include the small sample size, lack of blinding, homogeneity of the study population, and assumption that the participants must belong to one of the three diagnosis groups with an equal baseline prevalence of GERD, non-GERD, and EoE. Furthermore, the findings of this study need to be validated in an independent population of individuals, and the clinical utility of the test in improving the participants' outcomes was not addressed.

Choksi et al. (2018) conducted a retrospective analysis in 91 adult patients (80.32% Caucasian) with upper gastrointestinal symptoms (non-GERD, n = 30) who were referred for GERD (n = 38) and EoE (n = 23) diagnostic testing to quantify MI testing that measured epithelial integrity during EGD and to identify patterns that differentiated patients with or without GERD from those with EoE. Additionally, the authors sought to determine whether MI values and patterns were sufficient in identifying patients with EoE, using histological findings as a reference. The patients underwent an initial endoscopy, with MI measurements obtained. The authors used statistical modeling to identify MI patterns in the esophagus that were associated with GERD vs EoE. The authors reported that there were no statistically significant differences in the groups regarding race. MI parameters were determined for distinguishing EoE from non-EoE conditions (GERD or normal). The authors reported that the data showed significant improvement in sensitivity (100% vs 86%) and specificity (96% vs 59%) when predicting a diagnosis of EoE using an MI pattern. Findings were validated by the authors in a prospective cohort of 49 participants who were symptomatic for dysphagia, with no prior diagnosis, and who had undergone EGD for dysphagia to test the ability of MI patterns to identify participants with vs without EoE. The authors reported that participants with EoE had a unique MI pattern and low values along the esophageal axis and that MI measurements differentiated the individual populations. The authors reported, per the validation cohort, that the assessment of mucosal integrity by MI values and pattern alone, without endoscopic or clinical presentation, was sufficient, with a high level of accuracy in providing the correct diagnosis. Limitations of the study include the use of only two impedance rings, forming a single MI sensing channel, and a catheter that was manually repositioned to various sites of the esophagus, which may have resulted in some variability. Additional limitations include the small sample size as well as the homogeneity of the study population.

Clinical Practice Guidelines

American College of Gastroenterology (ACG)

The ACG's clinical guideline addressing the diagnosis and management of GERD states that the ACG expects new diagnostic tools and treatments to be developed and refined. The statement goes on to state that mucosal integrity testing is available commercially but that it is not developed sufficiently to warrant discussion in this guideline (Katz et al., 2022).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Instruments to perform cutaneous electrogastrography, electroenterography, and body surface gastric mapping are regulated by the FDA as Class II devices. Refer to the following website for more information (use product code MYE or FFX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 5, 2026)

Several radiopaque markers have been approved by the FDA for colonic transit testing. Refer to the following website for more information (use product code FFX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 5, 2026)

Defecography is a procedure and therefore is not subject to FDA regulation. However, any medical equipment, drugs, or tests used as part of this procedure may be subject to FDA regulation. A general list of cleared magnetic resonance imaging systems for magnetic resonance imaging defecography can be found by entering the code LNH into the Product Code window in the form at the following FDA 510(k) database website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 5, 2026)

The MiVu Mucosal Integrity Testing System (MiVu; Diversatek Healthcare, Highlands Ranch, CO) received FDA clearance as a Class II de novo device on December 23, 2019, as a new approach to assessing esophageal mucosal integrity. FDA 510(k) premarket notification was received on April 25, 2023, under 510(k) Number K230056. Refer to the

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following website, and search using either the product name or the product code of QIS for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 5, 2026)

The EndoFLIP System is indicated for use in a clinical setting to measure pressure and dimensions in the esophagus, pylorus, and anal sphincters and received 510(k) approval on April 17, 2017. It is intended to be used as an adjunct procedure to other diagnostic methods as part of a comprehensive evaluation of patients with symptoms consistent with gastrointestinal motility disorders. Refer to the following website for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K170833. (Accessed January 5, 2026)

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Policy History/Revision Information

Date	Summary of Changes
06/01/2026	**Definitions** • Updated definition of "Magnetic Resonance Imaging Defecography" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version 2026T0415HH

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