Gastrointestinal Motility Disorders, Diagnosis and Treatment (for Indiana Only)

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Instructions for Use

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Related Policies
None

Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

Gastric Electrical Stimulation

For medical necessity clinical coverage criteria for gastric electrical stimulation (GES), refer to the InterQual® CP: Procedures, Gastric Stimulation.

Click here to view the InterQual® criteria.

Gastric electrical stimulation (GES) therapy is proven and medically necessary for treating refractory Gastroparesis that has failed other therapies, or chronic intractable (drug-refractory) nausea and vomiting secondary to Gastroparesis of diabetic or idiopathic etiology.

Refer to the U.S. Food and Drug Administration (FDA) section for information regarding FDA labeling and Humanitarian Device Exemption (HDE) for GES.

Anorectal Manometry

For medical necessity clinical coverage criteria for Anorectal Manometry, refer to the InterQual® Medicare: Procedures, Pelvic Floor Dysfunction: Anorectal Manometry and EMG WPS.

Click here to view the InterQual® criteria.

Other Procedures

Rectal manometry, rectal sensation, tone, and compliance test, and conventional Defecography are proven and medically necessary for evaluation of colorectal function.

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

- Colonic Manometry for evaluating colon motility

- Magnetic Resonance Imaging (MRI) Defecography for evaluating Constipation and Anorectal or pelvic floor disorders
- Cutaneous, mucous, or serosal Electrogastrography, electroenterography, or body surface gastric mapping (e.g., Gastric Alimetry System, G-Tech Gut Tracker wireless patch system) for diagnosing intestinal or gastric disorders including Gastroparesis
- Ingestible vibrating capsule devices (e.g., the Vibrant® System) for the treatment of Constipation

Definitions

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

Colonic Manometry: A functional test for severe constipation where a probe is inserted via antegrade or retrograde in the colon to measure pressure and colonic motor activities (Dinning et al., 2010).

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

Defecography: Fluoroscopic examination with functional, real-time assessment of defecation mechanics; performed for longstanding constipation, unexplained anal or rectal pain, residual sensation after defecation or suspected prolapse (Kim and Rhee, 2011).

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

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

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, 2013, updated 2022).

Magnetic Resonance 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
*43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
*43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
*43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
*43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
*64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array

CPT Code	Description
*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
*74270	Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; single-contrast (e.g., barium) study
*76496	Unlisted fluoroscopic procedure (e.g., diagnostic, interventional)
*91117	Colon motility (manometric) study, minimum 6 hours continuous recording (including provocation tests, e.g., meal, intracolonic balloon distension, pharmacologic agents, if performed), with interpretation and report
*91120	Rectal sensation, tone, and compliance test (i.e., response to graded balloon distention)
*91122	Anorectal manometry
*91132	Electrogastrography, diagnostic, transcutaneous
*91133	Electrogastrography, diagnostic, transcutaneous; with provocative testing

HCPCS Code	Description
*A9286	Hygienic item or device, disposable or nondisposable, any type, each
*A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPCS code
A9999	Miscellaneous DME supply or accessory, not otherwise specified
*E1399	Durable medical equipment, miscellaneous

Note: Codes labeled with an asterisk (*) are not managed for medical necessity review for the state of Indiana at the time this policy became effective. Refer to the most up to date prior authorization list for Indiana at Prior Authorization and Notification: UnitedHealthcare Community Plan of Indiana.

Description of Services

Several gastrointestinal motility disorders, such as Constipation, Fecal Incontinence, and Gastroparesis may require a 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. 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, wireless motility capsule test, scintigraphy, or Colonic Manometry) (Camilleri et al., 2017). While in most cases, Constipation is benign and due to dietary and lifestyle factors, Constipation is sometimes due to disordered colonic and/or pelvic floor/anorectal function.

Fecal Incontinence (FI) is the inability to control bowel movements causing stool to leak unexpectedly from the rectum. Continence requires the rectum, anus, and nervous system to be working normally. FI 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, diabetics 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 patients. Scintigraphy is the reference standard for measurement of gastric emptying. Protocols for standardized meals prior to scintigraphy have been recommended, however for interpretation of test results, it has to be taken into account 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 (EGG) is a non-invasive 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 or upon provocative stimulations or even spontaneously. Abnormal gastric myoelectrical activity includes gastric dysrhythmia, abnormal slow wave propagation and electro-mechanical uncoupling. In the stomach, there is lack of one-to-one correlation between spikes and contractions, and 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, EGG 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 (BGSM) 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 patients 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.

Conventional Defecography (also known as evacuation proctography) involves the x-ray imaging of the defecation process. With the aid of barium, x-rays can follow the movement of fecal matter through the rectum and anus during a bowel movement. It provides useful information about structural changes such as rectoceles, rectal prolapse, and intussusception, and dyssynergic defecation and descending perineum syndrome. Defecography has been proposed as a diagnostic tool to evaluate lower bowel disorders that are not evident by direct visualization.

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

The use of disposable vibrating capsule systems for the treatment of chronic Constipation is being evaluated to determine if the vibrations augment normal peristalsis and help to reset the connection between the gut and the brain’s circadian rhythm. These non-pharmacological systems are intended for home use in adults when conventional laxative therapies do not work (Hayes, 2022).

Clinical Evidence

Gastric Electrical Stimulation (GES) Therapy

In an observational study of two cohorts, Gourcerol et al. (2023) compared the efficacy of GES and gastric-peroral endoscopic myotomy (G-POEM) on nausea and vomiting scores in patients with gastroparesis. The study included 64 patients with medically refractory gastroparesis with predominant nausea and vomiting who had undergone either GES (n = 34) or G-POEM (n = 30) and were followed for 24 months post procedure. The sex ratio, mean age, mean body mass index, and frequency of conditions associated with gastroparesis were not significantly different between groups; however, the median duration of disease at baseline was significantly shorter for GES at 34 months than for the G-POEM cohort at 57 months. Clinical response was defined by the authors as a decrease of ≥ 1 point in nausea and vomiting subscale without premature exclusion due to a switch from one to the other technique before the end of the 24 month follow-up period. The authors reported that the mean score of nausea and vomiting subscale was higher in the GES group (3.0) compared to G-POEM (2.6) while other parameters were comparable. At the 24 month follow-up, clinical response was achieved in 21 of the 34 patients with GES (61.7%) and 21 of the 30 patients who had undergone G-POEM (70%) while the mean scores of nausea and vomiting subscale decreased in both GES (from 3.0 to 1.6) and G-POEM (from 2.6 to 1.2) even though there was no difference between groups. The authors also reported that symptomatic and quality of life scores improved at the end of the follow-up period without difference between the two groups. Limitations of the study include the different patient severity at baseline as the nausea and vomiting subscores were higher while quality of life

was worse at baseline in the group treated with GES compared to the group treated with G-POEM, the lack of randomization and blinding, the small population size, and the use of different symptomatic scales used by the two cohorts. The authors concluded that they did not observe significant difference in efficacy of GES and G-POEM in medically refractory gastroparesis with predominant nausea and vomiting.

Samaan et al. (2022) conducted a single-center, retrospective study of 181 consecutive patients who underwent GES or primary gastrectomy (PG) for medically refractory gastroparesis (MRG) between January 2003 to December 2017 to compare the therapeutic efficacy of GES versus PG for medically refractory gastroparesis. The authors collected data through chart review and a follow-up telephone survey. There were 130 patients (68.5% female, median age 42 years) who underwent GES and 51 (74.5% female, median age 44 years) who underwent PG as their primary intervention. Of the 130 patients that underwent GES placement, 44 (33.8%) underwent GES removal and subsequent secondary gastrectomy (SG) for clinically significant persistence of gastroparesis symptoms. The authors reported that patients who underwent GES were more likely to have diabetic and idiopathic gastroparesis (GES 95% versus PG 39%) while the patients who underwent PG were more likely to have post-surgical gastroparesis (GES 5% versus PG 43%) and that postoperatively, primary PG patients had a higher rate of major inpatient morbidity events (GES 5% versus PG 18%) and longer lengths of stay (GES 3 days versus PG 9 days). Although previous foregut surgery was more common in PG patients (66.7% versus GES 43.1%) The authors noted that, over an average of 37.3 month (range 0.3-176.8) follow-up period, there were no differences between the GES patient population and the PG patient population in the rates of major morbidity, readmissions or mortality and that multivariable regression analysis showed that patients who underwent GES as their primary intervention were less likely to report improvement in symptoms on follow-up when compared to PG patients. The authors also reported that patients who converted to PG from GES were more likely to have post-surgical gastroparesis as the primary etiology. Limitations of the study include the retrospective, single-center design, the potential for recall bias related to the use of the postoperative telephone survey, the heterogeneity of the types of gastroparesis and with the various gastrectomy types that were performed, and the potential for selection bias as the cohort consisted of patients who were willing to comply with the survey and follow-up requirement of the study. The authors concluded that patients who underwent GES as a first-line surgical treatment of MRG had worse outcomes than those who underwent PG. They also concluded that post-surgical etiology was associated with an increased likelihood of GES failure and that for patients who experienced GES failure, upfront gastrectomy may be a superior alternative to GES. The authors recommended further studies to determine patient selection criteria for operative treatment of MRG.

In a systematic review of the therapeutic role of gastric pacemakers in adults with gastroparesis, Rajamanuri et al. (2021) reviewed 12 studies (including the Ducrotte et al. (2020), Chu et al. (2012) and Shada et al. (2018) studies previously included in this section) that included data on adults with medically refractory gastroparesis that required gastric electrical stimulation therapy, and found that the studies showed varying effects of GES on gastroparesis symptoms like nausea, vomiting, and abdominal bloating. They also concluded that there was significant weight gain noted based on the evidence in the studies they reviewed and that, while most of the studies suggested a significant improvement in the quality of life and the Gastroparesis Cardinal Symptom Index (GCSI) scores, the evidence supporting no difference in the quality of life seemed stronger, as shown by the meta-analysis and randomized controlled trials vs. open-label trials that showed positive results for quality of life with gastric pacing. The authors also found other beneficial effects of GES including reductions in inflammatory indicators, improved metabolic hormone levels and improved mucosal electrogram frequencies over baseline that were sustained for over six months. The authors noted that their review was limited due to the inclusion of open-labeled studies. They recommended additional RCTs to analyze the impact of gastric pacemakers in the improvement of symptoms in patients with gastroparesis, studies that evaluate the efficacy for the different causes of gastroparesis, such as diabetes, idiopathic and post-surgical, and future studies that include the pediatric population.

Hayes (2018, updated 2022) published a Health Technology Assessment (HTA) on the safety and efficacy of GES for gastroparesis following their review of 12 studies, including 3 randomized crossover trials (RCTs), six pretreatment/ posttreatment studies, one non-randomized comparative study, one comparative cohort study and one compilation of case series. The Hayes HTA stated that the effectiveness of GES for treating chronic gastroparesis remains uncertain, as findings have not provided consistent evidence. They noted that the available randomized studies provide little confirmation of the apparent benefit that was seen in unblinded studies. The report noted that GES appears safe in most patients but that serious complications can occur, including the movement of the stimulator and/or the electrical leads following implantation. They noted that the device removal rates in the studies they reviewed were between 7% to 12%. The overall quality of the evidence for GES for the treatment of gastroparesis was low due to the individual study limitations and inconsistency in the findings. The HTA concluded that additional randomized and placebo-controlled studies are needed to determine whether GES is a reliable therapy for gastroparesis and whether the benefits of GES treatment outweigh the potential risks.

Levinthal and Bielefeldt (2017) conducted a systematic review and meta-analysis to determine if GES is effective in reducing symptoms in patients with gastroparesis. Five studies randomly allocated patients to periods with or without

GES. Total symptom severity (TSS) scores did not differ between these periods (0.17 [95% confidence interval: -0.06 to 0.4]; p = 0.15). However, sixteen open label studies of GES showed a significant TSS decrease (2.68 [2.04-3.32]; q = 39.0; p < 0.001). Other treatment modalities similarly improved TSS by 1.97 [1.5-2.44] for medical therapy (MED), by 1.52 [0.9-2.15] for placebo arms (PLA), and by 2.32 [1.56-3.06] for botulinum toxin (BTx). There were significant differences in baseline TSS ratings among these studies (GES: 6.28 [6.28-7.42]; MED: 4.76 [4.09-5.42]; PLA: 4.59 [3.77-5.42]; BTx: 6.02 [5.3-6.74]; q = 35.1; p < 0.001). Meta-regression analysis showed these baseline differences to significantly impact TSS ratings during treatment (q = 71.8; p < 0.001). Independent of the treatment modality, baseline symptom severity impacts treatment results in gastroparesis. Considering the skewed population with refractory symptoms, regression to the mean likely contributes to the substantial discrepancies between the reported results of controlled and open label GES studies. [Study by Chu et al. (2012) which was previously cited in this policy, is included in the Levinthal and Bielefeldt (2017) meta-analysis.]

Heckert et al. (2016) assessed the effectiveness of GES with Enterra® for treatment for refractory symptoms of gastroparesis, the improvement in specific symptoms of gastroparesis, and clinical factors impacting on outcome in a cohort of 151 patients with refractory gastroparesis at a single center. Gastroparesis patients (n = 151; (120 females) with refractory gastroparesis (72 diabetic, 73 idiopathic, 6 other) underwent GES with Enterra® (Medtronic). Patients filled out a symptom severity questionnaire (PAGI-SYM) prior to insertion. At each follow-up visit, the patient filled out PAGI-SYM and assessed their therapeutic response using the Clinical Patient Grading Assessment Scale (CPGAS). The investigators concluded that GES improved symptoms in 75% of patients with 43% being at least moderately improved. Response in diabetics was better than in nondiabetic patients. Nausea, loss of appetite, and early satiety responded the best. The unknown length of study follow-up did not allow for assessment of intermediate and long-term outcomes. Furthermore, lack of comparison group limits the conclusions that can be derived from this case series.

Lal et al. (2015) performed a systematic review of GES using the Enterra System. The final review consisted of 21 out of 53 potentially relevant studies published since 2003; eighteen were prospective cohort studies and 3 were crossover studies. The overall risk of bias was considered medium to high in the majority of studies. The main reason was the frequency of non-randomized trials which tend to have a higher risk of bias. There was a variation in the methods used to assess the improvement in symptoms in the patients with GES implants. The most commonly used measures were: Total Symptom Score (TSS), Gastroparesis Cardinal Symptom Index (GCSI), Monthly and Weekly Vomiting Frequency, Monthly and Weekly Nausea Frequency, and Gastrointestinal Symptoms Rating Scale (GSRS). All studies investigating gastric emptying used a 2-hour and 4-hour Gastric Emptying Test (GET) after a low-fat meal. The studies in this systematic review included a variety of outcome measures and variety of preoperative assessments, making it difficult to combine data and offer firm conclusions. The evidence base for the use of GES in gastroparesis is limited with a total of just five months of blinded, randomized study including only 83 patients. However, accepting the limitations of the evidence base, the majority of studies reported an improvement in symptomology and quality of life with GES. An improvement in gastric emptying was seen in most studies, with only two failing to demonstrate an improvement. However, with the exception of one study, improved gastric emptying did not correlate with the improved symptomology. The authors concluded that while current evidence has shown a degree of efficacy in these patients, high-quality, large clinical trials are needed to establish the efficacy of this therapy and to identify the patients for whom this therapy is inappropriate. A consensus view on essential preoperative assessment and postoperative measurement is needed. [Study by McCallum et al. (2010) which was previously cited in this policy, is included in the Lal et al. (2015) systematic review.]

McCallum et al. (2011) assessed the long-term clinical outcomes of GES therapy with Enterra® in a large case series of patients with severe gastroparesis. Patients with gastroparesis (n = 221; 142 diabetic, 48 idiopathic, and 31 postsurgical) treated with Enterra (Medtronic) for 1-11 years were retrospectively assessed; 188 had follow-up visits and data were collected for at least 1 year. Total symptom scores (TSS), hospitalization days, and use of medications were significantly reduced among all patients. More patients with diabetic (58%) and postsurgical gastroparesis (53%) had a greater than 50% reduction in TSS than those with idiopathic disease (48%). Weight significantly increased among all groups, and 89% of J-tubes could be removed. At end of the follow-up period, all etiological groups had similar, abnormal delays in mean gastric retention. Thirteen patients (7%) had their devices removed because of infection at the pulse generator site. The investigators concluded that GES therapy significantly improved subjective and objective parameters in patients with severe gastroparesis; efficacy was sustained for up to 10 years and was accompanied by good safety and tolerance profiles. Patients with diabetic or postsurgical gastroparesis benefited more than those with idiopathic disease. Lack of comparison group however limits the conclusions that can be derived from this case series.

Clinical Practice Guidelines

American College of Gastroenterology (ACG)

The ACG published a clinical guideline for the management of gastroparesis that states that GES may be considered for control of gastroparesis symptoms as a humanitarian use device (HUD), as defined by the Food and Drug Administration (FDA) for medically refractory diabetic gastroparesis or idiopathic gastroparesis. This conditional recommendation was based on a low-quality body of evidence (Camilleri, 2013, updated 2022).

American Gastroenterological Association (AGA)

The AGA published a clinical practice update on the management of medically refractory gastroparesis based on a review of existing literature combined with expert opinion to provide practical advice. Based on this review, the AGA stated that clinicians can consider gastric electrical stimulation for patients with gastroparesis and refractory/intractable nausea and vomiting who have failed standard therapy and are not on opioids. This guidance was based on their review of six published studies that they stated showed that GES improved refractory nausea and vomiting in some patients with gastroparesis and may improve glycemic control, nutritional status, and quality of life, while reducing hospitalizations and medication use. They noted that this document was not based on a systematic review, so no formal rating of the quality of evidence or strength of recommendation was made (Lacy, 2022).

In a white paper on current approaches for the treatment of gastroparesis, the AGA (Pasricha et al., 2017) includes GES therapy (recommendation: conditional; level of evidence: moderate).

The National Institute for Health and Care Excellence (NICE)

The National Institute for Health and Care Excellence (NICE) (2014) interventional procedure guidance on GES for gastroparesis notes that GES is an option for treating chronic, intractable nausea and vomiting secondary to gastroparesis, observing that further publications providing data about the effects of the procedure on symptoms in the long term and on device durability would be useful.

Conventional Defecography

Grossi et al. (2018) conducted a systematic review and meta-analysis to evaluate rates of structural and functional abnormalities diagnosed by barium defecography and/or magnetic resonance imaging defecography (MRID) in patients with symptoms of chronic constipation and in healthy volunteers. From a total of 1760 records identified, 175 full-text articles were assessed for eligibility. Sixty-three studies were included, providing data on outcomes of 7519 barium defecographies and 668 MRIDs in patients with CC, and 225 barium defecographies and 50 MRIDs in healthy volunteers. Pathological high-grade (Oxford III and IV) intussuscepta and large (> 4 cm) rectoceles were diagnosed in 23.7% (95% CI: 16.8-31.4) and 15.9% (10.4-22.2) of patients, respectively. Enterocele and perineal descent were observed in 16.8% (12.7-21.4) and 44.4% (36.2-52.7) of patients, respectively. Barium defecography detected more intussuscepta than MRID (OR: 1.52 [1.12-2.14]; p = 0.009]). Normative data for both barium defecography and MRID structural and functional parameters were limited, particularly for MRID (only one eligible study). The authors concluded that since structural abnormalities cannot be evaluated using non-imaging test modalities (balloon expulsion and anorectal manometry), defecography should be considered the first-line diagnostic test.

Rafiei et al. (2017) evaluated the findings of defecography in 100 patients with severe idiopathic chronic constipation. An analysis of radiographs was performed for the diagnosis of descending perineum syndrome, rectocele, enterocele, rectal ulcer, rectal prolapse, fecal residue of post defecation, or other diagnosis and compared between the two sexes. Normal defecography was only observed in two participants. Descending perineum syndrome was the most common abnormality (73.3%). The results showed that rectocele (80.8%) and descending perineum syndrome (69.2%) were most frequent in women. In males, descending perineum syndrome and rectal prolapse were more prevalent (87% and 43.5%, respectively). Compared with men, rectocele and rectal ulcer were more frequently observed in women ($p < 0.001$, and $p = 0.04$, respectively), while men were more affected by descending perineum syndrome ($p = 0.04$). In total, women had a greater incidence of abnormal defecographic findings compared with men ($p = 0.02$). The authors concluded that defecography can be performed to detect anatomic abnormalities in patients with severe idiopathic chronic constipation, and abnormal balloon expulsion test. This technique can assist physicians in making the most suitable decision for a surgical procedure.

Fabrizio et al. (2017) observed that as obstructed defecation is a complex disorder it requires a multimodal evaluation process. Testing done to elicit a diagnosis can incorporate defecography, proctoscopy, colonic transit time studies, anorectal manometry, a rectal balloon expulsion test, electromyography, and ultrasound. They advise that results from these studies be taken in the context of each patient's clinical situation.

Clinical Practice Guidelines

American Gastroenterological Association (AGA)

An AGA guideline on constipation states that defecography should not be performed before anorectal manometry and a rectal balloon expulsion test (strong recommendation, low-quality evidence). Defecography should be considered when results of anorectal manometry and rectal balloon expulsion are inconclusive for defecatory disorders (strong recommendation, low-quality evidence) (Bharucha et al., 2013a).

According to the AGA's *Technical Review on Constipation*, defecography is particularly useful when the results of anorectal testing are inconsistent with the clinical impression and/or to identify anatomic abnormalities. The most relevant findings in defecatory disorders include inadequate (spastic disorder) or excessive (flaccid perineum, descending perineum syndrome) widening of the anorectal angle and/or perineal descent during defecation. Excessive straining, internal intussusception, solitary rectal ulcers, rectoceles, and rectal prolapse may also be observed. If the vagina and small intestine are opacified, enteroceles as well as bladder and uterovaginal prolapse can also be visualized (Bharucha et al., 2013b).

American Society of Colon and Rectal Surgeons (ASCRS)

In an updated clinical practice guideline on the evaluation and management of constipation, the ASCRS (Paquette et al., 2016) states that if anorectal physiology testing is not diagnostic for defecation dysfunction, other imaging studies, such as defecography, can be useful to identify anatomic abnormalities, such as rectocele, enterocele, internal intussusception, or prolapse that may be associated with constipation. Imaging with cinedefecography, MRI defecography, or transperineal ultrasound echo defecography may be useful in identifying anatomical abnormalities associated with obstructive defecation (Grade of Recommendation: strong recommendation based on low-quality evidence, 1C).

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 physical examination, fluoroscopic defecography, MRI defecography, or balloon expulsion testing 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).

Colonic Motility Testing or Colonic Manometry

Currently there is insufficient evidence regarding the effectiveness of colon manometry or colonic motility testing. Patient selection criteria and the role of colonic manometry in the management of refractory constipation must be better defined in statistically robust, well-designed clinical trials.

Shaukat and Alltaf (2023) completed a retrospective, single-center, observational study with 44 children (2 to 17 years old, 55% female) with chronic idiopathic constipation (CIC) to evaluate the relationship of oro-anal transit time (OTT) with colonic manometry (CM) and to compare the results of OTT and CM with anorectal manometry (ARM). The authors reported that 17 children had normal OTT and 27 had abnormal OTT (slow-transit constipation), 31 children had normal CM results and 13 had abnormal CM test results, and that ARM was normal in 36 children and abnormal in 8 children. Other results reported by the authors included that 30% of children with abnormal OTT studies also had abnormal ARM results, compared to none of the children with normal OTT studies, and that 76% of children with normal OTT studies also had normal CM test results while 24% had abnormal CM test results. Also reported was that children with abnormal OTT studies had normal CM results 67% of the time and abnormal CM results 33% if the time while 30 of the 36 children with normal ARM studies had normal CM studies, and six had abnormal CM studies. The authors stated that the CM test results prompted acceptance of treatment change in 89% of children with 70% of children who underwent CM having improvement in clinical symptoms. The authors also found that more children with abnormal CM testing improved compared to normal CM but the findings did not reach significance. The study is limited by the single-center, retrospective design, the lack of a control or comparison population, and the lack of ability to know if the home-administered pre-procedure protocols were followed correctly. The authors concluded that the OTT results did not predict the presence of colonic dysmotility based on colon motility testing which was contrary to results from previous studies. The authors also concluded that colonic manometry testing resulted in the acceptance of changes in therapy in approximately 90% of children and that more children with colonic dysmotility improved versus those with normal CM studies.

In a systematic review of available published studies, Evans-Barns, et al. (2022), sought to summarize the methodology and outcomes of colonic manometry performed in children with repaired anorectal malformations (ARM). The systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocol, and the quality appraisal of non-randomized study methodology was done according to the Newcastle-Ottawa Scale (NOS). In each of the four studies included in the review, colonic manometry was used to investigate the pathophysiology of post-operative bowel dysfunction and as a tool to predict the outcome of subsequent surgical intervention. There was a total

combined cohort of 151 children, of which, 35 underwent post-operative colonic manometry. ARM type was reported for 25 children in the combined colonic manometry cohort and operative repair type was described in only one of the studies. The quality evaluation completed by the authors identified poor quality of all four studies. Limitations of this systematic review included the variability in the equipment and protocols that were used among the studies, the lack of documentation of the type of ARM, the procedure that was done, and post-operative complications and re-operations, the lack of consensus of terminology and of what "normal" motility is, and the lack of control groups or colonic manometry data from healthy pediatric cohorts. The authors concluded that there are too few studies assessing colonic function in children with ARM that included data specifying how colonic manometry findings may relate to ARM subtypes, operative intervention, and clinical assessments of bowel function.

Singh et al. (2013) investigated whether colonic manometric evaluation is useful for characterizing colonic sensorimotor dysfunction and for guiding therapy in slow transit constipation (STC). Twenty-four-hour ambulatory colonic manometry was performed in 80 patients with STC by placing a six-sensor solid-state probe, along with assessment of colonic sensation with barostat. Anorectal manometry was also performed. Manometrically, patients were categorized as having colonic neuropathy or myopathy based on gastrocolonic response, waking response and high amplitude propagated contractions (HAPC); and based on colonic sensation, as colonic hyposensitivity or hypersensitivity. Clinical response to pharmacological, biofeedback, and surgical treatment was assessed at 1 year and correlated with manometric findings. Forty-seven (59%) patients who had abnormal colonic manometry, with features suggestive of neuropathy (26%), and myopathy (33%); 41% had normal colonic manometry. Seventy-four percent of the patients had abnormal colonic sensation and 61% had overlapping dyssynergic defecation. Patients with neuropathy were more likely to have colonic hyposensitivity. Sixty-four percent of patients with colonic myopathy or normal manometry improved with medical/biofeedback therapy when compared to 15% with colonic neuropathy. Selected patients with colonic neuropathy had excellent response to surgery, but many developed bacterial overgrowth. The authors concluded that colonic manometry demonstrates significant colonic sensorimotor dysfunction in STC patients and reveals considerable pathophysiological heterogeneity. According to the authors, colonic manometry can be useful for characterizing the underlying pathophysiology and for guiding clinical management in STC, especially surgery. The study is limited due to a lack of a controlled comparator group or reference standard diagnostic test.

Giorgio et al. (2013) correlated neuromuscular histological phenotypes in pediatric STC with colonic manometric phenotypes using high-resolution manometry (HRM) and tested the hypothesis that failure of motor quiescence (FQ) between bisacodyl-induced high amplitude propagating sequences (HAPSs) might predict neuromuscular pathology. Eighteen children (10 males, median age: 7.5 years) with refractory STC underwent stationary colonic HRM before segmental colonic resection. Six age-matched constipated children with normal colonic transit served as controls. Conventional manometric parameters and area under the curve (AUC) during a 1-minute period following bisacodyl-induced HAPSs [PBAUC(1)], as measure of FQ, were calculated. In segments with HAPS, PBAUC(1) was predictive of colonic neuropathy (Sensitivity 100%, specificity 86%, PPV92%, NPV100%). Based on the results of the study, the authors concluded that PBAUC(1) is increased in multiple colonic segments in neuropathic pediatric STC and constitutes a sensitive and specific biomarker of neuropathy. The small study population limits the validity of the conclusion of this study.

Sood et al. (2012) evaluated the variability in interpretation of colon manometry in children. Fifty-seven colon motility studies were independently reviewed by five observers. Each observer was required to report on the colonic motility during fasting, after administration of a meal and after bisacodyl stimulation. They were also asked to comment whether colon manometry study was normal or abnormal and if in their opinion the postprandial recording provided clinically useful information. The median (range) agreement regarding the presence of high amplitude propagating contractions (HAPC) was 83% (80% to 92%). The interpretation of gastrocolonic response produced the most inconsistent results with median (range) agreement of 64% (53% to 95%). The post-prandial period was reported to be useful in only 3% to 24% of the studies. The median (range) agreement regarding the overall interpretation of the study being either normal or abnormal was 87% (83% to 90%). According to the authors, the most easily recognizable contraction pattern during colon manometry is the HAPC. Visual interpretation of the gastrocolonic response produces the most inconsistent results and maximum variability. The authors concluded that abbreviated colon manometry studies without the post-prandial period or routine calculation of the motility index to evaluate gastrocolonic response can help make colon manometries more objective and reliable. Further studies to evaluate colon manometry are needed to determine the validity of this test.

Tipnis et al. (2012) compared oro-anal transit time (OTT) measured by radio-opaque markers with colon motility (CM) findings in children with chronic constipation and assessed clinical outcomes in 24 children with chronic constipation evaluated by OTT and CM studies. Patients were studied for a median of 23 months and outcomes reviewed. According to the authors, OTT studies may be helpful to predict which children should be referred for CM studies. Normal OTT studies may predict normal colon manometry; however, abnormal OTT studies may not predict abnormalities in colonic manometry in children with chronic constipation. The authors concluded that patients with slow transit marker studies

should be assessed by colon manometry to evaluate colon neuromuscular integrity. This study did not evaluate the impact of colon manometry for patient management or disease outcomes.

Rao et al. (2010a) evaluated whether colonic manometry is reproducible in a study that included 7 healthy volunteers (three men, four women, mean age = 34 years). Study participants underwent two studies of 24-hour ambulatory colonic manometry, each 2 weeks apart. Paired t-test was used to examine the reproducibility and variability. The number of pressure waves and propagating pressure waves and high-amplitude propagating contractions (HAPC), and area-under-curve (AUC) were similar between the two studies. Diurnal variation, waking, and meal-induced gastrocolonic responses were also reproducible. There was some variability in the incidence of individual colonic motor patterns. The investigators concluded that colonic manometry findings were generally reproducible, particularly for the assessment of key physiologic changes such as meal-induced gastrocolonic, HAPC, and waking responses. Further research is needed to determine the clinical relevance of these findings.

Rao et al. (2004b) studied prolonged colonic motility with colon manometry and assessed its clinical significance in 21 patients with slow-transit constipation and 20 healthy controls by placing a 6-sensor solid-state probe up to the hepatic flexure. The study results indicated that patients with slow-transit constipation exhibited either normal or decreased pressure activity with manometric features suggestive of colonic neuropathy or myopathy. According to the investigators, in refractory patients, colonic manometry may be useful in characterizing the underlying pathophysiology and in guiding therapy. Due to the limitations of this study, these findings and the clinical utility of the test require confirmation.

Pensabene et al. (2003) evaluated the impact of colonic manometry in clarifying pathophysiology of childhood defecatory disorders and evaluated its impact on management in a retrospective review of 145 children. After colonic manometry, treatment changes were recommended in 93% of patients. Changes in medical treatment were suggested for 121 patients (81%). Surgical treatment (cecostomy, subtotal or total colectomy, myectomy) was suggested for 102 (68%), mostly in addition to the changes in medical treatment or recommended in case the medical treatment had failed. Surgery was the only recommendation for 18 children. Follow up was done in 65% of the families. When recommendations were followed (96% of the contacted patients), the symptoms improved in 78%, were unchanged in 18%, and were worse in 4% of patients. Among the parents, 88% believed that the suggestions given after colonic manometry had been helpful in improving their children's health. According to the authors, the study limitations include the shortcomings of a retrospective study. In addition, the duration of follow-up was variable, there was no control group, and only two thirds of the families were contacted for follow up.

Clinical Practice Guidelines

American Gastroenterological Association (AGA)

An AGA guideline on constipation states that colonic intraluminal testing (manometry, barostat) should be considered to document colonic motor dysfunction before colectomy (weak recommendation, moderate-quality evidence). A weak recommendation implies that benefits, risks, and the burden of intervention are more closely balanced, or appreciable uncertainty exists in regard to patient's values and preferences (Bharucha et al., 2013a).

According to the AGA's *Technical Review on Constipation*, colonic manometry or barostat-manometric testing should be considered in patients with medically refractory STC. However, these tests are only available in highly specialized centers with a research interest and their role in management is not well established. Colonic manometry may identify a subset of patients with STC colonic motor dysfunctions that may be explained by a marked reduction in colonic intrinsic nerves and interstitial cells of Cajal. This should prompt consideration of colonic resection in medically refractory patients who do not have pelvic floor dysfunction (Bharucha et al., 2013b).

American Neurogastroenterology and Motility Society (ANMS) and North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN)

In a consensus document on anorectal and colonic manometry in children (based on a systematic review of the evidence), the ANMS and the NASPGHAN state that colon manometry is deemed useful to differentiate children with functional constipation from those with a colonic motor disorder, such as colonic inertia, surgical intervention planning, and to assess the improvement of colonic motility after long-term use of ACE. The authors add that colonic manometry in combination with anorectal manometry (ARM) has emerged as an important tool in understanding the pathophysiology and guiding the management of persistent postoperative symptoms of patients with Hirschsprung's disease and anorectal malformations, such as imperforate anus (Rodriguez et al., 2017).

MRI Defecography

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

In a retrospective single-center test validation study with 46 adults with chronic constipation, Thanaracthanon et al. (2023) evaluated the diagnostic performance of MR defecographic findings in diagnosis of dyssynergic defecation (DD). Study participants were divided into two groups based on the presence of DD in two of three diagnostic tests (anorectal manometry, balloon expulsion test 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 MR defecography according to the institutional standard protocol with both static and dynamic MR defecography images obtained. The study included analysis by two radiologists of nine parameters: anorectal angle (ARA) and M line at rest, defecation, and change between 2 phases; anal canal width; prominent puborectalis muscle; abnormal evacuation. The authors reported that seven of the nine parameters showed statistically significant difference between the DD and the non-DD group with M line at defecation having the highest odds ratio, followed by ARA change, ARA defecation, M line change, 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 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, the small sample size, the lack of a comparison group, the heterogeneity of other diseases in the non-DD group that were not seen in the DD group, and the use of a consensus panel which may incorporate bias. The authors concluded that MR defecography had high diagnostic performance in diagnosis of DD with ARA change of less than 1.5 degrees and prominent puborectalis muscle having good specificity in DD diagnosis. The authors recommend additional prospective studies with normal healthy patients as a control group.

Pääkkö et al. (2022) completed a single-center, retrospective review of both magnetic resonance defecography (MRD) and video defecography (VD) studies that were done on 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 were 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, 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 versus 32.8% for MRD. They reported that 30 enteroceles were observed by VD compared with 7 in 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 versus 29 by MRD with moderate agreement, and dyssynergic defecation was observed in 3 patients by VD and in 11 patients by MRD with slight agreement. Limitations of the study included the variability of which study was done first, the retrospective nature of the study, the small sample size, and the variability of the amount and consistency of the gel used in the studies. The authors concluded that 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 (ODS). The review included 39 studies (including the Foti (2013), Poncelet (2017), van Iersel (2017), Vitton (2011), and Zafar (2017) studies previously included in this section) with 2483 women that evaluated the diagnostic accuracy of evacuation proctography (EP), dynamic magnetic resonance imaging (MRI) and pelvic floor ultrasound for detecting posterior pelvic floor disorders. The meta-analysis was done using Bayesian hierarchical latent class analysis and the overall quality of evidence (QoE) was assessed using the GRADE approach for diagnostic test accuracy. The authors reported that the sensitivity of EP for diagnosis of rectocele was 98%, enterocele 91% and pelvic floor descent 98% while the specificity of enterocele was 96%, intussusception 92% and anismus 97%, all with high QoE. The sensitivity for anismus of 80% and the specificity for rectocele of 78% and pelvic floor descent 83% had a moderate to low QoE. The specificity of MRI defecography for diagnosis of rectocele was 90%, enterocele 99% and intussusception 97% with high QoE. The heterogeneity analysis completed in the study showed that sensitivity of MRI performed with evacuation phase was higher than without for rectocele (94% with and 65% without), and for enterocele (87% with and 62% without), while the sensitivity of MRI without evacuation phase was significantly lower than EP. The study also showed that the specificity of transperineal ultrasound (TPUS) for diagnosis of rectocele was 89%, enterocele was 98% and intussusception 96% while the sensitivity for anismus was 92%. The authors concluded that neither MRI defecography or TPUS met meet the criteria to replace EP as the reference standard for diagnosis of posterior pelvic floor disorders although both met the criteria of a triage test as a positive test confirms the diagnosis of rectocele, enterocele and intussception and a negative test rules out 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 ODS.

Ramage et al. (2018) assessed whether MRI features indicative of pelvic floor dysfunction correlated with patient-reported symptom severity. Univariate and multivariate analyses were performed using pre-treatment questionnaire responses to the Birmingham Bowel, Bladder and Urinary Symptom Questionnaire (BBUSQ), Wexner Incontinence Score (WIS), and modified Obstructed Defecation Symptom (ODS) Score. 302 MRI proctograms were performed (n = 170). Patients with a rectocele > 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 ODS score on multivariate analysis. Lack of rectal evacuation was negatively associated with an abnormal WIS (p = 0.007; OR 0.228). Age > 50 (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. Lack of rectal evacuation (p = 0.027, OR 3.602) was associated with an abnormal BBUSQ constipation score. Age > 50 (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 included lack of a reference standard test and a questionnaire with questions directed at only females.

In a systematic review and meta-analysis of magnetic resonance defecography (MRD) versus clinical examination and fluoroscopy, Ramage et al. (2017) compared detection and miss rates of pelvic floor abnormalities with MRD versus clinical examination and traditional fluoroscopic techniques. Twenty-eight studies were included: 14 studies compared clinical examination to MRD, and 16 compared fluoroscopic techniques to MRD. Detection and miss rates with MRD were not significantly different from clinical examination findings for any outcome except enterocele, where MRD faired significantly better than clinical examination. However, when comparing MRD versus fluoroscopy, MRD have no better detection rate or lower miss rate of a structural abnormality than fluoroscopy. In some studies, fluoroscopy was considered the gold standard, and therefore, a distinct possibility exists that there was a degree of reporting bias with regards to the miss rates of fluoroscopy in particular. Limitations included the large variation in techniques employed during MRD along with numerous fluoroscopic techniques that were utilized 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 advise that clinicians need to be mindful of the risk of under-diagnosis and consideration of the use of additional imaging.

Cappabianca et al. (2011) compared the diagnostic efficacy of dynamic MR defecography (MR-D) with entero-colpo-cysto-defecography (ECCD) in the assessment of midline pelvic floor hernias (MPH) in female pelvic floor disorders. 1,142 participants underwent MR-D with analysis. The results of the study indicated that MR-D shows lower sensitivity than ECCD in the detection of MPH development.

Reiner et al. (2011) evaluated the diagnostic value of MR defecography in 48 patients referred with suspicion of dyssynergic defecation. Patients were divided into patients with dyssynergic defecation (n = 18) and constipated patients without dyssynergic defecation (control group, n = 30). The most frequent finding was impaired evacuation, which was seen in 100% of patients with dyssynergic defecation and in 83% of the control group, yielding a sensitivity for MR defecography for the diagnosis of dyssynergic defecation of 100% but a specificity of only 23%. One major limitation of this study is that no single method of for diagnosis of dyssynergic defecation exists therefore there is no gold standard. Additional limitations of the study included small sample size and that the MR defecography was also part of the consensus panel diagnosis, thus incorporation bias could have occurred.

Clinical Practice Guidelines

American Gastroenterological Association (AGA)

The AGA guideline on constipation states that although anorectal manometry and a rectal balloon expulsion test generally suffice to diagnose or exclude a defecatory disorder, defecography, which is generally performed with barium, or at some centers with magnetic resonance imaging, is useful if results are inconclusive (Bharucha et al. 2013a).

American College of Gastroenterology (ACG)

The ACG clinical guideline for management of benign anorectal disorders notes that barium or magnetic resonance defecography can identify structural causes of outlet obstruction if one is expected. They may also confirm or exclude the diagnosis of defecatory disorders (DD) when the clinical features suggest DD, but the results of anorectal manometry and balloon expulsion test 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 being better resolution of soft tissue surrounding the rectum and anal canal, including the bladder, uterus, and small intestine during dynamic imaging;

improved ability to visualize 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)

In an updated clinical practice guideline on the evaluation and management of constipation, the ASCRS (Paquette et al., 2016) states that if anorectal physiology testing is not diagnostic for defecation dysfunction, other imaging studies, such as defecography, can be useful to identify anatomic abnormalities, such as rectocele, enterocele, internal intussusception, or prolapse that may be associated with constipation. Imaging with cinedefecography, MRI defecography, or transperineal ultrasound echo defecography may be useful in identifying anatomical abnormalities associated with obstructive defecation (Grade of Recommendation: strong recommendation based on low-quality evidence, 1C).

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 physical examination, fluoroscopic defecography, MRI defecography, or balloon expulsion testing 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 (EGG)/Electroenterography/Body Surface Gastric Mapping (BSGM)

Despite a possible use in clinical research, the studies of electrogastrography and body surface gastric mapping fail to provide convincing evidence that this technique is accurate for diagnosis of gastric disorders such as gastric stasis in clinical practice or that it has a positive impact on patient management or disease outcome. 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 diagnosis of gastroparesis with electrogastrography including recording, analysis, and interpretation. No studies were found to indicate electroenterography has a positive impact on patient management or disease outcome.

ECRI (2024) published a Clinical Evidence Assessment on the Gastric Alimetry System and concluded that the published evidence available for review was very low quality. The report assessed one diagnostic cohort study that reported measures of diagnostic accuracy and one retrospective case series that reported test impact on clinical decision making. ECRI did not find any direct clinical utility studies that reported improvements in patient-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 patient-relevant outcomes.

Schamberg et al. (2023) conducted a multi-center, retrospective observational study to compare BGSM and EGG to quantify performance differences. The study included EGG and BSGM data from 178 subjects (43 patients with nausea and vomiting (NVS), 32 patients with type 1 diabetes (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 pre-processing, post-processing, 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 when compared to EGG in the control group and that both tests detected rhythm instability in NVS, but EGG showed opposite frequency effects in T1D. The authors also reported that BSGM showed an 8 times increase in the number of significant correlations with symptoms and that BSGM accuracy for patient-level classification was 0.78 for patients when compared to controls and 0.96 when compared to a blinded consensus panel while EGG accuracy was 0.54 and 0.43. Limitations of the study include the automated EGG analysis methodology, the possibility that proprietary signal processing steps may exist but were not used, the lack of testing with other meal preparations, only using a single electrode configuration for EGG testing, the heterogeneity of EGG processing approaches, and the 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.

Patient-specific phenotyping using BSGM was compared to gastric emptying testing (GET) in an exploratory comparison study by Wang, et al. (2023) that included 75 adults (77% female, median age 43 years) with chronic gastroduodenal symptoms. All patients had undergone a clinical work-up 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-labelled egg meal, and 4-hour postprandial recording. Before motility testing was done, 56 patients met Rome IV Criteria for chronic nausea and vomiting syndromes (CNVS) (75%, with 52/56 also meeting functional dyspepsia (FD) criteria. There were 14 participants who met FD criteria alone, and 5 did not meet either criteria, 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 3 rapid while BSGM spectral analysis was 33.3% with 14 low rhythm stability/low amplitude, 5 high amplitude, and 6 abnormal frequency. The authors also reported that, in patients with normal spectral analysis, BSGM symptom phenotypes included sensorimotor 17% (where 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, the 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 patient phenotyping 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.

In a study to evaluate chronic nausea and vomiting syndrome (NVS) pathologies, Gharibans et al. (2022) performed BSGM in 43 patients with NVS and 43 matched controls. The study participants were adults, primarily female (76.7%) with a median age of 33 years (range 26 to 44). Each participant underwent BSGM that entailed a fasting baseline, ingestion of a 482 kilocalorie meal and a 4-hour postprandial recording, then spectral and spatial biomarker analyses. The authors reported that meal responses were impaired in NVS with multiple BSGM abnormalities compared to the study controls, impaired fed-fasting power ratios, and disorganized slow waves. The authors also reported that most patients (62%) had normal BSGM results with increased psychological comorbidities and anxiety scores while a smaller subgroup (31%) had markedly abnormal BSGM with biomarkers that correlated with symptoms and that patients 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 the use of a consensus panel classification which may introduce subjectivity and limit reproducibility. Limitations of the study included the lack of a control group, the under-representation of patients with diabetes as only 7% of the participants had diabetes, and the inclusion of patients with BMI > 35 as a high BMI may result in overestimating the low rhythm stability phenotype due to declining signal-to-noise ratio. The authors concluded that the study showed that BSGM expanded the phenotyping of patients with chronic gastroduodenal disorders when compared to GET and that the results of BSGM could improve clinical management of these patients 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 electrogastography (EGG) use in adults with gastroesophageal reflex disease (GERD). After the published literature was reviewed, thirteen studies were included in the analysis with a total of 591 participants (427 with GERD; 164 healthy controls) who had completed an EGG procedure. The study found that patients with GERD spent significantly less time with normal gastric slow-wave activity compared to 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 to 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 for the use of EGG in adults with GERD is warranted.

A comparison study by Al Kafee et al. (2021) was performed to assess the stomach's gastric myoelectrical activity using transcutaneous electrogastrography (EGG). This study analyzed 120 subjects with functional dyspepsia (FD) (n = 30), joint hypermobility (JH) (n = 30), diabetic gastroparesis (GP) (n = 30), and control subjects (n = 30). Thirty minutes of EGG recording was performed over the fasting stage (preprandial), and a 10-minute break was provided for eating the test meal. After 60 minutes (postprandial), the recording was done. The electrogastrography parameters included the dominant frequency, dominant power, power ratio, and instability coefficient, which were analyzed pre-prandially and post-prandially. The electrogastrography results showed that pre-prandial dominant frequency (p = .031), dominant power (p = .047), instability coefficient (p = .043), post-prandial dominant frequency (p = .041) and dominant power (p = .035) results were statistically significant among the functional dyspepsia, joint hypermobility, diabetic gastroparesis, and control groups. There was no difference found in terms of power ratio (p = .114) values. However, only glucose (p = .04) and calcium (p = .04) levels showed statistical impact. Several blood tests including hemoglobin (p = .032), creatinine (p= .045), calcium (p = .037), potassium (p= .041), white blood cells (p = .038), and alanine aminotransferase (p = .031) also showed correlation with the dominant frequency, power ratio, and instability coefficient parameters. The authors concluded that EGG is an essential non-invasive test for analyzing abnormal gastric myoelectric activity in FD, JH, and diabetic GP patients, and numerous EGG features have a correlation with blood analysis parameters. Additionally, patients showed satisfactory gastric motility in response to food. Limitations include non-standardization of EGG signal recording, surface electrode location or position, type of food or calories, computed features, and study populations. Further research with randomized controlled trials is needed to validate these findings.

Gharibans et al. (2019) performed a case-control study of cutaneous high resolution electrogastrography (HR-EGG) in 32 subjects to evaluate associations between gastric myoelectric abnormalities, symptoms (based on a validated questionnaire), and gastric emptying. The study consisted of 7 healthy individuals (control), 7 subjects with functional dyspepsia and normal gastric emptying, and 18 subjects with gastroparesis. All subjects were assessed by CT imaging of the abdomen and HR-EGG and completed the PAGI-SYM questionnaire on foregut symptoms, which includes the gastroparesis cardinal symptom index. The authors found abnormal spatial parameters, detected by cutaneous HR-EGG, correlated with severity of upper gastrointestinal symptoms, regardless of gastric emptying. Despite mixed results (slow-wave abnormalities were detected in only 44% of subjects with foregut symptoms), they concluded this noninvasive, repeatable approach might be useful to identify patients for whom gastric myoelectric dysfunction contributes to functional dyspepsia and gastroparesis. Limitations of the study included small sample size, CT imaging not performed at time of electrode placement and the gastric emptying test not performed at time of HR-EGG.

In an evaluation of 54 patients with FD, Russo et al. (2017) utilized the results of EGG to differentiate postprandial distress syndrome (PDS) with epigastric pain syndrome (EPS). Using a symptom questionnaire, 42 patients were classified as PDS and 12 as EPS, although an overlap between the symptom profiles of the 2 subgroups was recorded. The EGG parameters (the postprandial instability coefficient of dominant frequency, the dominant power, and the 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 compared with PDS. Finally, neurotensin polymorphism was shown to be associated with neurotensin levels. The authors concluded that this evidence deserves further studies into FD. This study however does not support the use of EGG in clinical practice or beyond its use for research.

Kayar et al. (2016) utilized transcutaneous EGG to compare patients with functional dyspepsia (FD) (n = 30) to control subjects (n = 30) in terms of motility abnormalities according to the EGG results. A high incidence of gastric motility and myoelectrical activity abnormalities was observed in patients with FD. The authors concluded that although still considered an experimental method, EGG is an effective, dependable, and non-invasive method in differentiating the subgroups and may be an essential and irreplaceable test to diagnose and follow-up patients with FD with motor dysfunction.

Clinical Practice Guidelines

American Gastroenterological Association (AGA)

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 electrogastrography for the diagnosis of gastroparesis.

Ingestible Vibrating Capsule Devices

The limited number of published clinical studies on the use of non-pharmacological, transient, ingestible vibrating capsules for treatment of chronic idiopathic constipation available in the USA fail to provide convincing evidence that this technology is safe and effective for this indication. Additional studies are needed to provide evidence of the benefit of active treatment with this device over sham treatments and to provide long-term follow-up data showing that this technology is safe and effective over time.

Math et al. (2023) conducted a systematic review to synthesize evidence on the role of the vibrating capsule in chronic idiopathic constipation. The review included completed and published original pre-clinical and clinical interventional studies in the English language that evaluated the role of vibrating colon-stimulating capsules in adult patients (≥ 18 years) with chronic idiopathic constipation. Case reports, commentaries, reviews, viewpoints, editorials, or opinions were excluded. There were four human clinical studies (including the Rao (2020) and Zhu (2022) studies below) that were included in the review, One study was a case series and the other three were RCTs, all of which had a moderate risk of bias. The studies had a combined 386 participants (82% female) who were mostly in their mid-40s in age and most of which had various forms of constipation (functional, chronic idiopathic or unspecified) with a few healthy volunteers. Limitations of this systematic review include the small sample sizes of the included studies, the single-center designs of all of the studies, the homogeneity of the participants related to age and sex, the heterogeneity related to the types of constipation, the variability in the treatment protocols, and the lack of long term follow up with all of the studies. The authors concluded that the evidence from the clinical studies suggests that vibrating capsules could increase the number of complete spontaneous bowel movements per week and that vibrating capsules can potentially augment bowel movements, promote defecation, ameliorate symptoms, and improve the quality of life in patients with chronic constipation; however, they recommended more reliable evidence from large RCTs over longer follow-up duration be done to reach definitive conclusions regarding the feasibility of its usage for treating chronic idiopathic constipation.

In a phase III multi-center, randomized, double-blind, sham-controlled trial by Rao et al. (2023) evaluated the safety and efficacy of vibrating capsules in patients with chronic constipation. The study included 312 adult patients 22 years of age or older from 95 centers who were randomized to receive either a vibrating capsule (n = 163) or a placebo capsule (n = 149), once daily, 5 days a week for 8 weeks. The primary study end points were an increase of 1 or more complete spontaneous bowel movements per week (CSBM1 responder) or 2 or more CSBMs per week (CSBM2) from baseline during at least six of the eight weeks. Study participants completed daily eDiaries during a 2-week screening period and for the 8 weeks of the study to capture the number of bowel movements, stool consistency, straining effort, bloating, and use of rescue medication The authors reported that 39.3% of patients who received the vibrating capsule achieved the CSBM1 end point compared to 22.1% of the placebo group and that 22.7% of the treatment group achieved the CSBM2 end point compared to 11/4% of the placebo group. Adverse events reported by the authors were mild, gastrointestinal symptoms that were similar in both groups except for a mild vibrating sensation that was reported by 11% of the patients in the vibrating capsule group. Limitations included the short duration of the study, the low number of males (12.3% in the treatment group and 15.4% in the placebo group), and suboptimal blinding that resulted from the vibration sensations felt in some of the patients in the treatment group. The authors concluded that the vibrating capsule was superior to placebo in improving bowel symptoms and quality of life in patients with chronic constipation.

ECRI (2023) published a Clinical Evidence Assessment on the Vibrant System to identify the most recent literature published on this technology and found three RCTs including the Rao 2023 study above and the Rao 2020 study below) and one single-center case series that reported mixed findings on whether ingestible vibrating capsules improve bowel movement frequency in patients with chronic constipation ECRI reported that one RCT provided good-quality data while the other two RCTs were at significant risk of bias. The studies reported that there were no serious adverse events; however, there was insufficient long-term follow up to assess events that may occur with long-term use of ingestible vibrating capsule devices. ECRI reported that the overall response rates were low and the effects were modest, and that no conclusions can be drawn because the available studies reported inconsistent findings regarding the product's effectiveness. The report recommended large, multicenter RCTs with long-term follow-up to validate the safety and effectiveness of these devices.

In an Emerging Technology Report on the Vibrant System for chronic idiopathic constipation, Hayes (2022, updated 2023) reviewed the same Rao 2020 study that was identified in the ECRI Report above, the results of the pivotal trial (Rao 2023 included above) and a report of post-hoc analyses of data from the phase III trial. They also reviewed an Israeli single-arm study that evaluated the safety of twice-weekly treatment with the Vibrant vibrating capsule and a U.S. sub study that evaluated the effect of the Vibrant capsule versus sham capsule on colonic transit time in patients receiving twice-weekly treatment. According to the Hayes report, this sub-study found no significant difference in colonic transit time between patients treated with the vibrating capsule (n = 12) and those treated with a sham capsule (n = 12). The report stated that additional published evidence is needed to better characterize the efficacy and safety of non-pharmacological vibrating capsules for chronic idiopathic constipation.

To assess the efficacy and safety of another vibrating capsule system (VC, Vibrabot™, ANKON Technologies Co., Ltd) in patients with functional constipation (FC), Zhu, et al. (2022) completed a prospective, multicenter, blinded, placebo-controlled randomized trial with 107 patients aged 18 to 74 in six top general hospitals in China. The patients were randomly assigned 1:1 to receive the vibrating capsule (n = 53) or placebo treatment (n = 54) at a dosage of two capsules per week for six weeks after a two-week washout period of laxatives and other disallowed medications and was followed by a 4-week follow-up period or until the use of laxatives. During the treatment, 53 (100%), 52 (98%), and 50 (94%) patients in the treatment group and 52 (98%), 50 (94%), and 49 (93%) patients in the placebo group completed the two-week, four-week, and six-week visits, respectively. The authors reported that the responder rate in the treatment group (64.2%) was significantly higher than in the placebo group (35.8%) and that more patients in the vibrating capsule group reported at least one complete spontaneous bowel movements (CSBMs) for at least four weeks during the treatment period. They also found that the mean Patient Assessment of Constipation-Symptoms (PAC_SYM) score and Patient Assessment of Constipation-Quality of Life (PAC-QoL) score differed significantly from the baseline in both groups with no significant changes observed in mean PAC-QoL total scores between groups. The authors surmised that the results in their study were more significant because of the slightly larger capsules, higher vibration frequency and longer vibration duration that was used in their study compared to the Rao (2020) study below. While the authors felt their study was superior to previous studies due to the study design, rigorous process and extended follow-up, they identified that there were limitations including the inclusion of mostly female study participants, the strong placebo effect and the change in lifestyle in the study may have interfered with the efficacy analysis, the treatment period of 6 weeks was shorter than the recommended 12 week treatment period, and the lack of long-term follow up data and subgroup analysis in patients based on the Colonic Transit Test. The authors concluded that vibrating capsules can promote defecation as well as ameliorate symptoms and improve the quality of life in patients with functional constipation with sustained efficacy and recommended future studies explore the relationship between the curative effect and course of treatment, combined efficacy with other therapies, and efficacy analysis in special populations such as children, patients with diabetes and

patients with different subtypes. The VibraBot is not currently approved by the Food and Drug Administration for use in the United States.

Rao, et al. (2020) performed a post hoc analyses of two prospective, multi-center, randomized, sham-controlled, double-blind studies that included 250 patients with chronic idiopathic constipation (CIC) who were randomized to receive 5 active or sham non-pharmacological vibrating capsules (Vibrant®, Vibrant Ltd, Hakochav Yokneam, Israel) per week for 8 weeks. In the first study (n = 182), the capsules were programmed for a single vibration session and in the second study (n = 68), the capsules were programed for two vibration sessions with two modes, 8 hours apart. Both studies included a 2-week run-in period to allow for wash out of laxatives and other disallowed medications, and to gather baseline and eligibility information. The participants maintained electronic diaries that assessed their stool habit and percentage of complete spontaneous bowel movements (CSBMs) associated with vibrations. Responders were those patients that experience one or more CSBMs per week over their baseline. The authors reported that there were significantly more CSBMs in the active (50%, n = 133) vs. sham (42%, n = 117) group during and within 3 hours of vibration. They noted that there were two CSBM peaks in the 2nd study that were associated with the vibration sessions. They also noted that, in both studies, the responder rates (primarily a priori specified outcome) did not differ between the active vs. sham groups (study 1, active (21.5%) vs sham (11.5%); study 2, mode 1, 26.9% vs 35.9 and mode 2, 38.1% vs 31.8%). Limitations noted by the authors included the small sample sizes, the high withdrawal rate of 25-30% in both studies, the exploratory nature of the study design, the use of multiple vibration paradigms and the variability of the modes of capsule activation. Furthermore, significant findings were limited in the post hoc data analysis, while no benefit was observed on the a priori specified primary outcome. The authors concluded that vibrating capsules may increase CSBMs by enhancing the normal physiologic effects of waking and meals on bowel movement and that the use of two vibration sessions a day may additionally increase the proportion of CSBMs. The authors recommended additional studies that are better designed, larger with sham or placebo-control for confirmation of their findings.

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 23, 2024)

The only gastric electrical stimulation (GES) device for gastroparesis treatment approved for marketing in the United States is the Enterra™ Therapy System, manufactured by Medtronic, Inc. On March 31, 2000, the FDA approved a Humanitarian Device Exemption (HDE) for the marketing of the Enterra gastric electrical stimulation system for the treatment of chronic, intractable (drug-refractory) nausea and vomiting secondary to paresis of diabetic or idiopathic etiology. Enterra is indicated for the treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years. Based upon the FDA label, the Enterra device should not be used for patients with gastric obstruction or pseudo-obstruction, prior gastric resection, fundoplication, eating disorders, history of seizures, primary swallowing disorders, chemical dependency, or psychogenic vomiting. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=376493. (Accessed January 23, 2024).

Humanitarian use devices may only be used in facilities that have obtained an institutional review board (IRB) approval to oversee the usage of the device in the facility, and after an IRB has approved the use of the device to treat or diagnose the specific rare disease. Additional information may be obtained directly from the U.S. Food and Drug Administration (FDA) [website] - Center for Devices and Radiological Health (CDRH) at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm. (Accessed January 23, 2024)

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 23, 2024)

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 MRI 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 23, 2024)

The Vibrant® System (Vibrant Gastro Inc., Newton, MA) received FDA clearance as a Class II de novo device on August 26, 2022 as an orally ingested transient device that is indicated for the treatment of adults with chronic idiopathic constipation who have not experienced relief of their bowel symptoms by using laxative therapies at the recommended dosage for at least one month. Refer to the following website and search using either the product name or the Product Code of QTN for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm. (Accessed January 23, 2024)

The Vibrabot™ (AnX Robotica Corporation) Digestive Tract Vibrating Capsule System is not currently FDA approved for use in the United States.

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Policy History/Revision Information

Date	Summary of Changes

09/01/2024	**Coverage Rationale**
	• Revised list of unproven and not medically necessary procedures:
	  ○ Removed "Conventional Defecography for evaluating all other conditions not included [in the policy as proven and medically necessary]"
	  ○ Replaced "cutaneous, mucous, or serosal Electrogastrography or electroenterography for diagnosing intestinal or gastric disorders including Gastroparesis" with "cutaneous, mucous, or serosal Electrogastrography, electroenterography, or *body surface gastric mapping (e.g., Gastric Alimetry System, G-Tech Gut Tracker wireless patch system)* for diagnosing intestinal or gastric disorders including Gastroparesis"
	Anorectal Manometry
	• Replaced coverage guidelines with instruction to refer to the InterQual® Medicare: Procedures, Pelvic Floor Dysfunction: Anorectal Manometry and EMG WPS for medical necessity clinical coverage criteria
	Other Procedures
	• Replaced language indicating "conventional Defecography is proven and medically necessary for *evaluating intractable Constipation or Constipation in members who have one or more of the following conditions that are suspected to be the cause of impaired defecation: pelvic floor dyssynergia (inappropriate contraction of the puborectalis muscle), enterocele (e.g., after hysterectomy), or anterior rectocele*" with "conventional Defecography is proven and medically necessary for *evaluation of colorectal function*"
	Definitions
	• Removed definition of "Anorectal Manometry"
	Applicable Codes
	• Added CPT codes 0868T and 74270
	• Added notation to indicate CPT/HCPCS codes 43648, 43881, 43882, 72195, 72196, 72197, 74270, and A9900 are not managed for medical necessity review for the state of Indiana at this time; refer to the most current *Prior Authorization and Notification List* for UnitedHealthcare Community Plan of Indiana
	Supporting Information
	• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
	• Archived previous policy version CS046IN.09

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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